Hard Empty Capsules from Brazil, China, India, and Vietnam

Investigation Nos. 701-TA-742-745 and 731-TA-1720-1723 (Preliminary)

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Note.—Information that would reveal confidential operations of individual concerns may not be published. Such information is identified by brackets in confidential reports and is deleted and replaced with asterisks (***) in public reports.

UNITED STATES INTERNATIONAL TRADE COMMISSION

Investigation Nos. 701-TA-742-745 and 731-TA-1720-1723 (Preliminary)

Hard Empty Capsules from Brazil, China, India, and Vietnam

DETERMINATIONS

On the basis of the record¹ developed in the subject investigations, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930 ("the Act"), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of hard empty capsules from China, India and Vietnam, and that there is a reasonable indication that an industry in the United States is threatened with material injury by reason of imports of hard empty capsules from Brazil provided for in subheadings 9602.00.10 and 9602.00.50 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value ("LTFV") and imports of the subject merchandise from Brazil, China, India, and Vietnam that are alleged to be subsidized by the governments of Brazil, China, India, and Vietnam.²

COMMENCEMENT OF FINAL PHASE INVESTIGATIONS

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the *Federal Register* as provided in § 207.21 of the Commission's rules, upon notice from the U.S. Department of Commerce ("Commerce") of affirmative preliminary determinations in the investigations under §§ 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under §§ 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Any other party may file an entry of appearance for the final phase of the investigations after publication of the final

¹ The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

² 88 FR 91684 and 81 FR 91680, November 20, 2024.

phase notice of scheduling. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations. As provided in section 207.20 of the Commission's rules, the Director of the Office of Investigations will circulate draft questionnaires for the final phase of the investigations to parties to the investigations, placing copies on the Commission's Electronic Document Information System (EDIS, https://edis.usitc.gov), for comment.

BACKGROUND

On October 24, 2024, Lonza Greenwood LLC, Greenwood, South Carolina filed petitions with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized imports of hard empty capsules from Brazil, China, India, and Vietnam and LTFV imports of hard empty capsules from Brazil, China, India, and Vietnam. Accordingly, effective October 24, 2024, the Commission instituted countervailing duty investigation Nos. 701-TA-742-745 and antidumping duty investigation Nos. 731-TA-1720-1723 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the *Federal Register* of October 30, 2024 (89 FR 86370). The Commission conducted its conference on November 14, 2024. All persons who requested the opportunity were permitted to participate.

Views of the Commission

Based on the record in the preliminary phase of these investigations, we determine that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of hard empty capsules ("HECs") from China, India, and Vietnam that are allegedly sold in the United States at less than fair value and subsidized by the governments of China, India, and Vietnam. We also determine that there is a reasonable indication that an industry in the United States is threatened with material injury by reason of imports of HECs from Brazil that are allegedly sold at less than fair value and subsidized by the government of Brazil.

I. The Legal Standard for Preliminary Determinations

The legal standard for preliminary antidumping and countervailing duty determinations requires the Commission to determine, based upon the information available at the time of the preliminary determinations, whether there is a reasonable indication that a domestic industry is materially injured or threatened with material injury, or that the establishment of an industry is materially retarded, by reason of the allegedly unfairly traded imports. In applying this standard, the Commission weighs the evidence before it and determines whether "(1) the record as a whole contains clear and convincing evidence that there is no material injury or threat of such injury; and (2) no likelihood exists that contrary evidence will arise in a final investigation."

II. Background

Lonza Greenwood LLC ("Lonza," or "Petitioner"), a domestic producer of HECs, filed the petitions in these investigations on October 24, 2024. Lonza appeared at the staff conference accompanied by counsel and submitted a postconference brief.

Several respondent entities participated in these investigations. The Associated Capsules Group ("ACG"), a corporate group comprising producers and exporters of HECs in

¹ 19 U.S.C. §§ 1671b(a), 1673b(a) (2000); see also American Lamb Co. v. United States, 785 F.2d 994, 1001-04 (Fed. Cir. 1986); Aristech Chem. Corp. v. United States, 20 CIT 353, 354-55 (1996). No party argues that the establishment of an industry in the United States is materially retarded by the allegedly unfairly traded imports.

² American Lamb Co., 785 F.2d at 1001; see also Texas Crushed Stone Co. v. United States, 35 F.3d 1535, 1543 (Fed. Cir. 1994).

India³ and Brazil⁴ and their U.S. importer,⁵ appeared at the staff conference accompanied by counsel. Indian producer/exporter Custom Capsules Private Limited ("Custom Capsules") and its U.S. importer, Torpac, Inc. ("Torpac"), also appeared at the staff conference accompanied by counsel. ACG, Custom Capsules, and Torpac (collectively, the "ACG Respondents") submitted a joint postconference brief.⁶ Huangshan Capsule Inc. ("Huangshan"), an importer of HECs from China, also appeared at the staff conference, unaccompanied by counsel, and submitted a preconference statement. Finally, Suheung Vietnam Co., Ltd. and Suheung America Corp. (collectively, "Suheung"), a producer and exporter of HECs in Vietnam and a U.S. importer of HECs from Vietnam, respectively, submitted a joint postconference brief.

Data Coverage. U.S. industry data are based on the questionnaire responses of two domestic producers that accounted for all known U.S. HEC production in 2023. U.S. import data are based on the questionnaire responses of 18 firms that accounted for *** percent of U.S. imports from Brazil in 2023, *** percent of U.S. imports from China in 2023, *** percent of U.S. imports from Vietnam in 2023, and *** percent of U.S. imports from Vietnam in 2023, and *** percent of U.S. imports from nonsubject sources in 2023. The Commission received usable responses to its questionnaire from 14 foreign producers of subject merchandise: two producers/exporters in Brazil, accounting for approximately *** percent of production of

³ The ACG affiliates in India are: ACG Associated Capsules Private Limited and ACG Universal Capsules Private Limited (collectively, "ACG India").

⁴ The ACG affiliate in Brazil is: ACG do Brasil S.A. ("ACG Brazil").

⁵ The ACG affiliate in the United States is: ACG North America, LLC ("ACG USA").

⁶ While ACG is unaffiliated with Custom Capsules and Torpac, we refer to them collectively for concision.

⁷ Confidential Staff Report, INV-WW-150 (December 2, 2024) ("CR"); *Hard Empty Capsules from Brazil, China, India, and Vietnam*: Inv. Nos. 701-TA-742-745 and 731-TA-1720-1723 (Prelim.), USITC Pub. 5572 (December 2024) ("PR") at I-4.

⁸ CR/PR at IV-1. Coverage estimates were calculated using Harmonized Tariff Schedule of the United States ("HTSUS") statistical reporting numbers 9602.00.1040 and 9602.00.5010 adjusted to include imports classified under the secondary HTSUS statistical reporting numbers as reported in importer questionnaire responses. *Id.* at IV-1 n.2. The imports reported by firms importing from China, India, Vietnam, and nonsubject sources ***. This is possible because we calculated import coverage by dividing the volume of HEC imports from a given source that firms reported in their questionnaire responses by the volume of HEC imports from that source as reported in adjusted official Commerce import statistics. CR/PR at IV-1, n.2. As the numerator and denominator in this calculation are drawn from different data sources, it is possible for import coverage *** as reported in the official adjusted statistics. Additionally, there may be some differences in time-period and unit of quantity between these data sources that contribute to ***.

subject merchandise in Brazil in 2023; six producers/exporters in China, accounting for approximately *** percent of production of subject merchandise in China in 2023; five producers/exporters in India, accounting for approximately *** percent of production of subject merchandise in India in 2023; and one producer/exporter in Vietnam, accounting for approximately *** percent of production of subject merchandise in Vietnam in 2023.⁹

III. Domestic Like Product

In determining whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury by reason of imports of the subject merchandise, the Commission first defines the "domestic like product" and the "industry." ¹⁰ Section 771(4)(A) of the Tariff Act of 1930, as amended ("the Tariff Act"), defines the relevant domestic industry as the "producers as a whole of a domestic like product, or those producers whose collective output of a domestic like product constitutes a major proportion of the total domestic production of the product." ¹¹ In turn, the Tariff Act defines "domestic like product" as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation." ¹²

By statute, the Commission's "domestic like product" analysis begins with the "article subject to an investigation," *i.e.*, the subject merchandise as determined by the U.S. Department of Commerce ("Commerce").¹³ Therefore, Commerce's determination as to the scope of the imported merchandise that is subsidized and/or sold at less than fair value is "necessarily the starting point of the Commission's like product analysis." ¹⁴ The Commission then defines the domestic like product in light of the imported articles Commerce has

⁹ CR/PR at Table VII-1.

¹⁰ 19 U.S.C. § 1677(4)(A).

¹¹ 19 U.S.C. § 1677(4)(A).

¹² 19 U.S.C. § 1677(10).

¹³ 19 U.S.C. § 1677(10). The Commission must accept Commerce's determination as to the scope of the imported merchandise that is subsidized and/or sold at less than fair value. *See*, *e.g.*, *USEC*, *Inc. v. United States*, 34 Fed. App'x 725, 730 (Fed. Cir. 2002) ("The ITC may not modify the class or kind of imported merchandise examined by Commerce."); *Algoma Steel Corp. v. United States*, 688 F. Supp. 639, 644 (Ct. Int'l Trade 1988), *aff'd*, 865 F.3d 240 (Fed. Cir.), *cert. denied*, 492 U.S. 919 (1989).

¹⁴ Cleo Inc. v. United States, 501 F.3d 1291, 1298 (Fed. Cir. 2007); see also Hitachi Metals, Ltd. v. United States, Case No. 19-1289, slip op. at 8-9 (Fed. Cir. Feb. 7, 2020) (the statute requires the Commission to start with Commerce's subject merchandise in reaching its own like product determination).

identified.¹⁵ The decision regarding the appropriate domestic like product(s) in an investigation is a factual determination, and the Commission has applied the statutory standard of "like" or "most similar in characteristics and uses" on a case-by-case basis.¹⁶ No single factor is dispositive, and the Commission may consider other factors it deems relevant based on the facts of a particular investigation.¹⁷ The Commission looks for clear dividing lines among possible like products and disregards minor variations.¹⁸ It may, where appropriate, include domestic articles in the domestic like product in addition to those described in the scope.¹⁹

In its notices of initiation, Commerce defined the imported merchandise within the scope of these investigations as follows:

The merchandise subject to the scope of these investigations is hard empty capsules, which are comprised of two prefabricated, hollowed cylindrical sections (cap and body). The cap and body pieces each have one closed and rounded end and one open end, and are constructed with different or equal diameters at their open ends.

¹⁵ Cleo, 501 F.3d at 1298 n.1 ("Commerce's {scope} finding does not control the Commission's {like product} determination."); Hosiden Corp. v. Advanced Display Mfrs., 85 F.3d 1561, 1568 (Fed. Cir. 1996) (the Commission may find a single like product corresponding to several different classes or kinds defined by Commerce); Torrington Co. v. United States, 747 F. Supp. 744, 748–52 (Ct. Int'l Trade 1990), aff'd, 938 F.2d 1278 (Fed. Cir. 1991) (affirming the Commission's determination defining six like products in investigations where Commerce found five classes or kinds).

¹⁶ See, e.g., Cleo, 501 F.3d at 1299; NEC Corp. v. Dep't of Commerce, 36 F. Supp. 2d 380, 383 (Ct. Int'l Trade 1998); Nippon Steel Corp. v. United States, 19 CIT 450, 455 (1995); Torrington, 747 F. Supp. 744, 749 n.3 (Ct. Int'l Trade 1990), aff'd, 938 F.2d 1278 (Fed. Cir. 1991) ("every like product determination 'must be made on the particular record at issue' and the 'unique facts of each case'"). The Commission generally considers a number of factors including the following: (1) physical characteristics and uses; (2) interchangeability; (3) channels of distribution; (4) customer and producer perceptions of the products; (5) common manufacturing facilities, production processes, and production employees; and, where appropriate, (6) price. See Nippon, 19 CIT at 455 n.4; Timken Co. v. United States, 913 F. Supp. 580, 584 (Ct. Int'l Trade 1996).

¹⁷ See, e.g., S. Rep. No. 96-249 at 90–91 (1979).

¹⁸ See, e.g., Nippon, 19 CIT at 455; Torrington, 747 F. Supp. at 748–49; see also S. Rep. No. 96-249 at 90–91 (Congress has indicated that the like product standard should not be interpreted in "such a narrow fashion as to permit minor differences in physical characteristics or uses to lead to the conclusion that the product and article are not 'like' each other, nor should the definition of 'like product' be interpreted in such a fashion as to prevent consideration of an industry adversely affected by the imports under consideration.").

¹⁹ See, e.g., Pure Magnesium from China and Israel, Inv. Nos. 701-TA-403 and 731-TA-895-96 (Final), USITC Pub. 3467 at 8 n.34 (Nov. 2001); *Torrington,* 747 F. Supp. at 748-49 (holding that the Commission is not legally required to limit the domestic like product to the product advocated by the petitioner, coextensive with the scope).

Hard empty capsules are unfilled cylindrical shells composed of at least 80 percent by weight of a water soluble polymer that is considered nontoxic and appropriate for human or animal consumption by the United States Pharmacopeia—National Formulary (USP–NF), Food Chemical Codex (FCC), or equivalent standards. The most common polymer materials in HECs are gelatin derived from animal collagen (including, but not limited to, pig, cow, or fish collagen), hydroxypropyl methylcellulose (HPMC), and pullulan.

Hard empty capsules may also contain water and additives, such as opacifiers, colorants, processing aids, controlled release agents, plasticizers, and preservatives. Hard empty capsules may also be imprinted or otherwise decorated with markings.

Hard empty capsules are covered by the scope of these investigations regardless of polymer material, additives, transparency, opacity, color, imprinting, or other markings.

Hard empty capsules are also covered by the scope of these investigations regardless of their size, weight, length, diameter, thickness, and filling capacity.

Cap and body pieces of hard empty capsules are covered by the scope of these investigations regardless of whether they are imported together or separately, and regardless of whether they are imported in attached or detached form.

Hard empty capsules covered by the scope of these investigations are those that disintegrate in water within 2 hours under tests specified in Chapter 701 of the USP–NF, or equivalent disintegration tests.

Hard empty capsules are classifiable under subheadings 9602.00.1040 and 9602.00.5010 of the Harmonized Tariff Schedule of the United States (HTSUS). In addition, hard empty capsules may be imported under HTSUS subheading 1905.90.9090; gelatin hard empty capsules may be imported

under HTSUS subheading 3503.00.5510; HPMC hard empty capsules may be imported under HTSUS subheading 3923.90.0080; and pullulan hard empty capsules may be imported under HTSUS subheading 2106.90.9998. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by these investigations is dispositive.²⁰

HECs are hard, cylindrical shells used to deliver medications and supplements. They are composed of a shorter cap and a longer body. Both the cap and the body have one closed end and one open end. The open end of the cap and the open end of the body have rings or indentations allowing them to interlock. HEC manufacturers supply finished caps and bodies to pharmaceutical and nutraceutical companies, which fill them with medications or supplements and then interlock them for distribution. Once interlocked, the caps and bodies form hermetically sealed chambers.²¹

HECs are made from either gelatin- or plant-based polymers. Gelatin-based polymers are derived from animal collagen, including pig, cow, and fish collagen. Plant-based polymers are derived from fibrous plant materials and include hydroxypropyl methylcellulose ("HPMC") and pullulan.²² The scope of these investigations covers HECs regardless of polymer type.

HECs are produced in a variety of standardized sizes and are typically available between size five (approximately 11 millimeters closed length) and size 000 (approximately 26 millimeters closed length). ²³ The scope of these investigations covers HECs regardless of size.

All HECs must meet industry standards. HECs for pharmaceuticals must additionally meet Food and Drug Administration ("FDA") requirements when sold in the U.S. market.²⁴

²⁰ Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigations, 89 FR 91684, 91690 (Nov. 13, 2024); Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Initiation of Countervailing Duty Investigations, 89 Fed. Reg. 91680, 91684 (Nov. 13, 2024). The scope is the same in the antidumping and countervailing duty investigations.

²¹ CR/PR at I-6-8.

²² CR/PR at I-6-7 and II-1.

²³ CR/PR at I-7.

²⁴ CR/PR at I-7. n.19 and I-9.

A. Parties' Arguments

1. Petitioner's Arguments

Lonza argues that the Commission should define a single domestic like product coextensive with the scope of these investigations. ²⁵ It contends that there are no clear dividing lines between gelatin- and plant-based HECs. Regardless of polymer type, Petitioner maintains, all HECs have the same physical characteristics and uses, ²⁶ are produced at the same facilities using similar processes by the same employees, ²⁷ and are primarily sold to end users. ²⁸ It further contends that, regardless of polymer type, all HECs are broadly interchangeable, ²⁹ are perceived by producers and customers as being within the same product category, ³⁰ and are similarly priced. ³¹

2. Respondents' Arguments

Gelatin-Based HECs and Plant-Based HECs. The ACG Respondents argue that the Commission should define gelatin- and plant-based HECs as separate domestic like products.³² They contend that gelatin- and plant-based HECs have distinct physical characteristics,³³ are generally produced on different equipment,³⁴ possess limited interchangeability,³⁵ and are perceived differently by producers and customers.³⁶

²⁵ Petitioner's Postconf. Br. at 4-12.

²⁶ Petitioner's Postconf. Br. at 6-7.

²⁷ Petitioner's Postconf. Br. at 10-11.

²⁸ Petitioner's Postconf. Br. at 8-9.

²⁹ Petitioner's Postconf. Br. at 7-8.

³⁰ Petitioner's Postconf. Br. at 7-8.

³¹ Petitioner's Postconf. Br. at 12.

³² ACG/Custom Capsules/Torpac Postconf. Br. at 11-17.

³³ ACG/Custom Capsules/Torpac Postconf. Br. at 11-12. They maintain, for example, that gelatin-based HECs dissolve immediately in gastric fluid, whereas plant-based HECs only do so after ***. *Id*.

³⁴ ACG/Custom Capsules/Torpac Postconf. Br. at 15-16. They further maintain that a domestic HEC producer with Halal certification would not produce gelatin-based (and specifically pig-gelatin-based) HECs in the same facility as plant-based HECs, as doing so would risk the certification. *Id*.

³⁵ ACG/Custom Capsules/Torpac Postconf. Br. at 13.

³⁶ ACG/Custom Capsules/Torpac Postconf. Br. at 17.

HECs Above 1.45 mL. The ACG Respondents acknowledge that HECs with a fill size of greater than 1.45 milliliters ("HECs above 1.45 mL") are not produced domestically.³⁷

Nonetheless, they argue that the Commission should define HECs above 1.45 mL as a separate domestic like product than HECs with a fill size of less than 1.45 milliliters ("HECs below 1.45 mL") based on an analysis of the six traditional like product factors.³⁸ HECs above and below 1.45 mL, they contend, are physically distinct and used for different purposes, with the former being suitable for veterinary use and the latter for human use.³⁹ The ACG Respondents further argue that HECs above and below 1.45 mL are sold in different channels of distribution,⁴⁰ are produced on different equipment,⁴¹ and are not interchangeable.⁴² Finally, they argue that HECs above and below 1.45 mL are viewed differently by producers and customers,⁴³ and are disparately priced.⁴⁴

B. Analysis and Conclusion

Based on the record, we define a single domestic like product consisting of HECs, coextensive with Commerce's scope.

1. Whether Gelatin- and Plant-Based HECs Should Be Defined as Separate Domestic Like Products

Physical Characteristics and Uses. While gelatin- and plant-based HECs differ in terms of raw materials, they overlap in terms of many other physical characteristics. They share the same design, an interlocking cap and body.⁴⁵ They are identical in appearance.⁴⁶ They come in

³⁷ ACG/Custom Capsules/Torpac Postconf. Br. at 18 ("... there is no U.S. producer of capsules with a filling capacity greater than 1.45 mL").

³⁸ ACG/Custom Capsules/Torpac Postconf. Br. at 17-23.

³⁹ ACG/Custom Capsules/Torpac Postconf. Br. at 17-19.

⁴⁰ ACG/Custom Capsules/Torpac Postconf. Br. at 20-21.

⁴¹ ACG/Custom Capsules/Torpac Postconf. Br. at 21-22.

⁴² ACG/Custom Capsules/Torpac Postconf. Br. at 19-20.

⁴³ ACG/Custom Capsules/Torpac Postconf. Br. at 22-23.

 $^{^{44}}$ ACG/Custom Capsules/Torpac Postconf. Br. at 23-24. No other Respondent addressed the definition of the domestic like product.

⁴⁵ CR/PR at I-6 and I-9 (all HECs, regardless of polymer type, comprise a cap and body with rings or indentations for interlocking).

⁴⁶ Conference Transcript ("Conf. Tr.") at 91 (Singh) (ACG representative stating that gelatin- and plant-based HECs "look identical.").

the same sizes, ⁴⁷ can disintegrate at the same rate, ⁴⁸ and have the same taste and smell. ⁴⁹ They are produced to the same standards. ⁵⁰

Gelatin- and plant-based HECs also have the same use, which is the delivery of medicines and supplements.⁵¹ Moreover, because they are compatible with the same fill materials, gelatin- and plant-based HECs can be used to deliver medications and supplements in the same preparations (*e.g.*, in liquid, viscous, or granular preparations).⁵²

Manufacturing Facilities, Production Processes, and Employees. All HECs, regardless of polymer type, are produced using the same general process.⁵³ The polymer is first mixed with water and additives, creating a solution. The polymer solution is then coated onto metal pins. The solution-coated pins are then kiln-dried, stiffening their coatings into hardened shells. The

⁴⁷ CR/PR at I-7 (All HECs, regardless of polymer type, are available in the same size range). *See also* Conf. Tr. at 25 (Goetter) (stating that either "gelatin or HPMC HECs" are available in "standard-size{s}.")

⁴⁸ CR/PR at I-7. Contrary to the ACG Respondents' argument that gelatin-based HECs always dissolve *** in gastric fluid than do plant-based HECs, the record indicates that plant-based HECs can disintegrate *** as gelatin-based HECs. Indeed, the ACG Respondents themselves have provided a technical industry reference document reflecting that several plant-based capsules are capable of "immediate release." *See* Attachment 4 to Exhibit 4 of ACG/Custom Capsules/Torpac Postconf. Br. at 6. Moreover, at the staff conference, a Lonza representative testified that HECs of both polymer types can be "designed to have specific disintegration properties," as either "immediate release" or "delayed release." Conf. Tr. at 19 (McCutcheon). This testimony thus indicates that both gelatin- and plant-based HECs can have the same disintegration rate (*i.e.*, immediate or delayed), depending on how they are engineered.

⁴⁹ CR/PR at I-7 (all HECs, regardless of polymer type, are tasteless and odorless).

⁵⁰ CR/PR at I-7, n.19 and I-9. Further corroborating that they are produced to the same standards, a technical industry reference document provided by the ACG Respondents states that domestically manufactured gelatin- and plant-based HECs are produced to the same "specification parameters." *See* Attachment 4 to Exhibit 4 of ACG/Custom Capsules/Torpac Postconference Br. at 22 (technical industry reference document stating that domestically produced gelatin- and plant-based HECs share the following "specification parameters": disintegration time; loss on drying; sulphated ash; heavy metals; residual solvents; microbial count; mold count; and bile-tolerant, Gram-negative bacteria).

⁵¹ CR/PR at I-7.

⁵² CR/PR at I-6 (all HECs, regardless of polymer type, can be used with liquid, viscous, or granular materials). *See also* Attachment 4 to Exhibit 4 of ACG/Custom Capsules/Torpac Postconf. Br. at 30 (technical reference document stating that both gelatin- and plant-based HECs are compatible with dry powder, liquid, and hydrophobic fill materials).

⁵³ CR/PR at I-8-9. *See also* Conf. Tr. at 22 (McCutcheon) ("there are no significant differences between the production process for HECs made from different polymers.").

hardened shells are then stripped from the pins and trimmed to specific lengths, forming completed caps and bodies.⁵⁴

All HECs, regardless of polymer type, are produced in the same manufacturing facilities.⁵⁵ While the record supports the ACG Respondents' contention that domestic producers generally manufacture gelatin- and plant-based HECs on different equipment,⁵⁶ it also indicates that they sometimes manufacture them on the same equipment.⁵⁷

Finally, all HECs, regardless of polymer type, are produced by the same employees.⁵⁸ While an ACG representative asserted at the staff conference that "the chemistries {of gelatinand plant-based HECs} are completely different," necessitating different employees with different trainings to produce each,⁵⁹ the record indicates that the same employees are trained to produce, and actually produce, both types of HECs.⁶⁰

Channels of Distribution. During the January 2021 - June 2024 period of investigation ("POI"), domestically produced HECs of all types were overwhelmingly sold to ***, with the

⁵⁴ CR/PR at I-8-9. *See also* Conf. Tr. at 20-22 (McCutcheon).

⁵⁵ See Petition, Volume I at Exhibit I-21 (Affidavit of Gabriel McCutcheon) at para. 18 (stating that Lonza produces HECs of all polymer types at its Greenwood, North Carolina facility). As Lonza is Halal certified – see Exhibit 1 to Petitioners' Postconf. Br. at 14 – and does in fact manufacture gelatinand plant-based HECs in the same facility, the ACG Respondents' argument that domestic producers with such certifications would not do so is unavailing. Their Halal certification argument is additionally unavailing because, even if it were true that concerns over maintaining such certifications would lead domestic producers to manufacture gelatin-based HECs in different facilities than plant-based HECs, this would extend only to pig-gelatin-based HECs (and not, e.g., cow- or fish-gelatin-based HECs). Consequently, even hypothetically, the alleged concerns over losing Halal certification that the ACG Respondents posit would not prevent domestic producers from manufacturing most types of gelatin-based HECs in the same facilities as plant-based HECs.

⁵⁶ See, e.g., Conf. Tr. at 79 (McCutcheon). The Commission normally does not consider the manufacture of products on different equipment within a common facility sufficient to establish a clear dividing line between such products. See, e.g., Cleo Inc. v. United States, 30 C.I.T. 1380 (2006), aff'd, 501 F.3d 1291 (Fed. Cir. 2007) (upholding the Commission's definition of bulk and consumer tissue paper within a single domestic like product, notwithstanding that domestic producers manufactured them on different production lines within the same facilities). See also Brake Drums from China and Turkey, Inv. Nos. 701-TA-729-730 and 731-TA-1698-1699 (Preliminary), USITC Pub. 5532 (Aug. 2024) at 9 (finding a single domestic like product notwithstanding that brake drum castings were "produced on different input lines for different machines based on SKU").

⁵⁷ See Exhibit 4 to Petitioner's Postconf. Br. (Affidavit of Gabriel McCutcheon) at para. 7 (stating that Lonza does occasionally produce HECs of different polymer types on the same equipment, but acknowledging that it requires *** to convert a machine used to make gelatin-based HECs into one capable of making plant-based HECs (and vice versa)).

⁵⁸ See Exhibit 4 to Petitioner's Postconf. Br. (Affidavit of Gabriel McCutcheon) at para. 8.

⁵⁹ See Conf. Tr. at 124 (Singh).

⁶⁰ See Exhibit 4 to Petitioner's Postconf. Br. (Affidavit of Gabriel McCutcheon) at para. 8.

remainder sold to ***.⁶¹ Within the *** channel, domestically produced HECs of all types were primarily sold to ***, with a lesser share of sales going to ***.⁶²

Interchangeability. There is limited information on the record concerning the degree of interchangeability between gelatin- and plant-based HECs, but as noted above they are used in the same end uses and capable of delivering medications and supplements in the same preparations (e.g., in liquid, viscous, or granular). Petitioner contends that, despite some consumers preferring plant-based HECs over gelatin-based HECs for dietary or religious reasons, they remain broadly interchangeable.⁶³ The ACG Respondents contend that they have only limited interchangeability.⁶⁴

Producer and Customer Perceptions. There is limited information on the record concerning producer and customer perceptions. Petitioner contends that producers and customers perceive all HECs as a single product category, 65 while the ACG Respondents contend that they distinguish between HECs based on polymer type. 66

Price. Lonza states, and the ACG Respondents do not dispute, that HECs of all polymer types are similarly priced.⁶⁷

Conclusion. While gelatin- and plant-based HECs differ in terms of raw materials, they overlap in terms of many other physical characteristics – including design, appearance, size, disintegration rate, taste, smell, and industry- and regulatory-mandated specifications – and have the same end use. They are also produced at the same facilities using the same general process by the same employees and are sold through identical channels of distribution. Lonza states that both types of HECs are similarly priced, which no party disputes. Although Petitioner and the ACG Respondents disagree as to their interchangeability and customer and producer perceptions, the preponderance of similarities between gelatin- and plant-based HECs in terms of the other factors indicates that there is no clear dividing line separating the two.

⁶¹ CR/PR at Table II-1.

⁶² CR/PR at Table II-1.

⁶³ Petitioner's Postconf. Br. at 7-8.

⁶⁴ ACG/Custom Capsules/Torpac Postconf. Br. at 13.

⁶⁵ Petitioner's Postconf. Br. at 9-10.

⁶⁶ ACG/Custom Capsules/Torpac Postconf. Br. at 17. While the ACG Respondents cite to the questionnaire responses of certain importers, *id.*, importer responses are not necessarily probative as to the perceptions of producers and customers.

⁶⁷ Petitioner's Postconf. Br. at 12. The ACG Respondents do not address price in their gelatin-based/plant-based HEC separate domestic like product argument.

We therefore define a single domestic like product encompassing both gelatin- and plant-based HECs. ⁶⁸

2. Whether HECs Above 1.45 mL Should Be Defined as a Separate Domestic Like Product

We do not define a separate domestic like product corresponding to HECs above 1.45 mL, as advocated by the ACG Respondents. Only those articles domestically produced may be defined as a separate domestic like product, ⁶⁹ and HECs above 1.45 mL are not domestically produced. ⁷⁰ In the absence of domestic production of HECs above 1.45 mL, they are not capable of examination under the Commission's traditional domestic like product analysis, which entails comparison of products that are in fact produced domestically. ⁷¹ Instead, the Commission must define a domestic like product to include the domestically produced article "most similar" to the imported HECs above 1.45 mL within the scope of the investigations. ⁷² The domestically produced article most similar to imported HECs above 1.45 mL would be inscope HECs below 1.45 mL, which possess characteristics and uses most similar to those of imported HECs above 1.45 mL. ⁷³ In light of the analysis above showing that all domestically produced articles described within the scope constitute a single domestic like product, we do not define a separate domestic like product corresponding to imported HECs above 1.45 mL.

⁶⁸ In any final phase of these investigations, we intend to further investigate the extent to which gelatin- and plant-based HECs compete in the U.S. market.

⁶⁹ See Mattresses from Bosnia and Herzegovina, Bulgaria, Burma, India, Indonesia, Italy, Kosovo, Mexico, Philippines, Poland, Slovenia, Spain, and Taiwan, Inv. Nos. 701-TA-693 and 731-TA-1629-1640 (Preliminary), USITC Pub. 5460 (Sept. 2023) at 15.

⁷⁰ As discussed, the ACG Respondents acknowledge that "there is no U.S. producer of capsules with a filling capacity greater than 1.45 mL." ACG/Custom Capsules/Torpac Postconference Br. at 18; *See also* Conf. Tr. at 100 (Tahil) (stating that no U.S. producer has made HECs above 1.45 mL for over 25 years); CR/PR at I-10.

⁷¹ See Large Residential Washers from China, Inv. No. 731-TA-1306 (Preliminary), USITC Pub. 4591 (Feb. 2016) at 10 ("Absent evidence of domestic production of such washers, we have no basis for determining whether a clear dividing line separates domestically produced out-of-scope low-tech and front load extra-wide washers from in-scope LRWs in terms of our like product factors"); 19 U.S.C. § 1677(4).

⁷² 19 U.S.C. § 1677(10).

⁷³ All HECs, regardless of fill size, have the same physical characteristics, *i.e.*, an interlocking cap and body, and the same overarching use, *i.e.*, the delivery of medicines and supplements. Moreover, while the ACG Respondents have attempted to distinguish HECs above 1.45 mL from those below 1.45 mL under the six like product factors, they have not identified a domestically produced article that is more similar to HECs above 1.45 mL than HECs below 1.45 mL are.

In sum, based on the record of the preliminary phase of these investigations, we define a single domestic like product consisting of HECs, coextensive with Commerce's scope.⁷⁴

IV. Domestic Industry

The domestic industry is defined as the domestic "producers as a whole of a domestic like product, or those producers whose collective output of a domestic like product constitutes a major proportion of the total domestic production of the product." In defining the domestic industry, the Commission's general practice has been to include in the industry producers of all domestic production of the like product, whether toll-produced, captively consumed, or sold in the domestic merchant market.

A. Related Parties

These investigations raise the issue of whether appropriate circumstances exist to exclude any domestic producers from the domestic industry pursuant to Section 771(4)(B) of the Tariff Act. This provision allows the Commission, if appropriate circumstances exist, to exclude from the domestic industry producers that are related to an exporter or importer of subject merchandise or which are themselves importers.⁷⁶ Exclusion of such a producer is within the Commission's discretion based upon the facts presented in each investigation.⁷⁷

⁷⁴ Should any party wish to argue for a different definition of the domestic like product in any final phase of these investigations, it must request the collection of pertinent information in its comments on the final phase questionnaires. 19 C.F.R. § 207.20(b).

⁷⁵ 19 U.S.C. § 1677(4)(A).

⁷⁶ See Torrington Co. v. United States, 790 F. Supp. 1161, 1168 (Ct. Int'l Trade 1992), aff'd mem., 991 F.2d 809 (Fed. Cir. 1993); Sandvik AB v. United States, 721 F. Supp. 1322, 1331-32 (Ct. Int'l Trade 1989), aff'd mem., 904 F.2d 46 (Fed. Cir. 1990); Empire Plow Co. v. United States, 675 F. Supp. 1348, 1352 (Ct. Int'l Trade 1987).

⁷⁷ 19 U.S.C. § 1677(4)(B). The primary factors the Commission has examined in deciding whether appropriate circumstances exist to exclude a related party include the following:

⁽¹⁾ the percentage of domestic production attributable to the importing producer;

⁽²⁾ the reason the U.S. producer has decided to import the product subject to investigation (whether the firm benefits from the LTFV sales or subsidies or whether the firm must import in order to enable it to continue production and compete in the U.S. market);

⁽³⁾ whether inclusion or exclusion of the related party will skew the data for the rest of the industry;

⁽⁴⁾ the ratio of import shipments to U.S. production for the imported product; and

*** are subject to possible exclusion from the domestic industry under the related parties provision because they imported subject merchandise during the POI.⁷⁸ *** also qualify as related parties by virtue of their relationships to exporters of subject merchandise.⁷⁹ No party has argued for *** exclusion.

B. Analysis and Conclusion

Based on the following analysis, we find that appropriate circumstances do not exist to exclude *** from the domestic industry under the related parties provision.

***. *** accounted for *** percent of U.S. production in 2023, making it *** domestic HEC producers that year.⁸⁰ It *** these investigations.⁸¹ *** imported subject merchandise from *** only in 2022 and January – June 2024 ("interim 2024"),⁸² when the ratio of its subject imports to its domestic production was *** percent.⁸³ *** indicates that ***.⁸⁴

Given that *** only imported subject merchandise in 2022 and interim 2024, when its ratio of subject imports to domestic production was *** low, as well as its status as the *** U.S. producer and ***, its primary interest appears to be in domestic production. Moreover, there is no information on the record that its subject imports from *** or affiliation with *** shielded it from subject import competition or otherwise benefitted its domestic operations to the extent that its inclusion in the domestic industry would mask injury. ⁸⁵ In light of these considerations, and in the absence of any contrary argument, we find that appropriate circumstances do not exist to exclude *** from the domestic industry.

⁽⁵⁾ whether the primary interest of the importing producer lies in domestic production or importation. *Changzhou Trina Solar Energy Co. v. USITC*, 100 F. Supp.3d 1314, 1326-31 (Ct. Int'l. Trade 2015), *aff'd*, 839 F.3d 1377 (Fed. Cir. 2018); *see also Torrington Co.*, 790 F. Supp. at 1168.

⁷⁸ CR/PR at III-6; 19 U.S.C. § 1677(4)(B)(i).

⁷⁹ ***. See CR/PR at Table III-2; *** importer questionnaire, EDIS Doc. ***, at I-4 (reporting that ***). Thus, *** qualifies as a related party under 19 U.S.C. § 1677(4)(B)(ii)(III). ***. See CR/PR at Table III-2; *** U.S. producer questionnaire, EDIS Doc. ***, at I-4 (reporting that ***). Thus, *** qualifies as a related party under 19 U.S.C. § 1677(4)(B)(ii)(III).

⁸⁰ CR/PR at Table III-1.

⁸¹ CR/PR at Table III-1.

⁸² CR/PR at Table III-11.

⁸³ CR/PR at Table III-11.

⁸⁴ CR/PR at Table III-13.

⁸⁵ Indeed, the fact that its ratio of subject imports from *** to domestic production was *** low indicates that any benefit these imports had to its domestic operations was minor, and the fact that it *** indicates that its affiliation with *** did not shield it from the effects of competition from subject imported HECs from ***.

***. *** accounted for *** percent of U.S. production in 2023, making it *** domestic HEC producers that year. ** It ***. ** imported subject merchandise from *** only in 2021, ** in an amount equivalent to *** percent of its domestic production that year. ** indicates that ***. ** indicates that ***. **

Given that *** only imported subject merchandise in 2021, when its ratio of subject imports to domestic production was *** low, its primary interest appears to be in domestic production. Moreover, there is no information on the record that *** subject imports or affiliation with *** shielded it from subject import competition or otherwise benefitted its domestic operations to the extent that its inclusion in the domestic industry would mask injury. In light of these considerations, and in the absence of any contrary argument, we find that appropriate circumstances do not exist to exclude *** from the domestic industry.

Accordingly, consistent with our definition of the domestic like product, we define the domestic industry to include all domestic producers of HECs.

V. Negligible Imports

Pursuant to Section 771(24) of the Tariff Act, imports from a subject country of merchandise corresponding to a domestic like product that account for less than 3 percent of all such merchandise imported into the United States during the most recent 12 months for which data are available preceding the filing of the petition shall be deemed negligible. 91 92

⁸⁶ CR/PR at Table III-1.

⁸⁷ CR/PR at Table III-1; *** U.S. Producer Questionnaire at I-4.

⁸⁸ CR/PR at Table III-12.

⁸⁹ CR/PR at Table III-11.

⁹⁰ CR/PR at Table III-13.

⁹¹ 19 U.S.C. § 1677(24)(A)(i). The statute further provides that subject imports from a single country which comprise less than 3 percent of total such imports of the product may not be considered negligible if there are several countries subject to investigation with negligible imports and the sum of such imports from all those countries collectively accounts for more than 7 percent of the volume of all such merchandise imported into the United States. 19 U.S.C. § 1677(24)(A)(ii). This exception does not apply here. Although there are four subject countries in these investigations, imports from three of these four countries – China, India, and Vietnam – are each well above the negligibility threshold, as shown below.

⁹² In the case of countervailing duty investigations involving developing countries (as designated by the United States Trade Representative ("USTR")), the statute indicates that the negligibility limits are 4 percent and 9 percent, rather than 3 percent and 7 percent. 19 U.S.C. § 1677(24)(B). USTR has not designated Brazil, China, India, or Vietnam, the sources of imports subject to these countervailing duty

Additionally, even if subject imports are found to be negligible for purposes of present material injury, they shall not be treated as negligible for purposes of a threat analysis should the Commission determine that there is a potential that subject imports from the country concerned will imminently account for more than three percent of all such merchandise imported into the United States.⁹³

A. Parties' Arguments

Petitioner's Arguments. Lonza argues that imports from each subject source exceed the negligibility threshold. While it concedes that subject imports from Brazil accounted for only *** percent of total HEC imports during the negligibility period, it maintains that the Commission should subtract out *** from the volume of total HEC imports it uses for purposes of its negligibility analysis. After this adjustment, it maintains, subject imports from Brazil accounted for *** percent of total HEC imports during the negligibility period. 94

Lonza further argues that even if the Commission finds that subject imports from Brazil are negligible for purposes of its present injury analysis, it should not treat them as such for purpose of any threat analysis because they are likely to imminently exceed the three percent threshold. In support, it emphasizes that the Brazilian industry has significant unused capacity with which to increase its exports and considers the United States an attractive export market.⁹⁵

Respondents' Arguments. The ACG Respondents argue that subject imports from Brazil are negligible and will not imminently exceed the three percent negligibility threshold. They contend that projected exports from Brazil to the United States are below three percent of total projected exports from subject countries to the United States in both 2024 and 2025, and are declining. The ACG Respondents further maintain that the Brazilian industry's capacity, capacity

investigations, as developing countries. *See Designations of Developing Countries and Least Developed Countries Under the Countervailing Duty Law, 85 Fed. Reg. 7613 (USTR Feb. 10, 2020).*

⁹³ 19 U.S.C. § 1677(24)(A)(iv). For a USTR-designated developing country in a countervailing duty investigation, imports shall not be treated as negligible for purposes of a threat analysis should the Commission determine that there is a potential that subject imports from the country concerned will imminently account for more than 4 percent (rather than 3 percent) of all such merchandise imported into the United States. 19 U.S.C. § 1677(24)(B). Below, we perform a negligibility for threat analysis in the countervailing duty investigation concerning HECs from Brazil. Because USTR has not designated Brazil a developing country, the applicable threshold for this analysis is three percent.

⁹⁴ Petitioner's Postconf. Br. at 14-15.

⁹⁵ Petitioner's Postconf. Br. at 16-18.

utilization, and home market orientation demonstrate "no potential" for subject imports from Brazil to imminently exceed the negligibility threshold.⁹⁶

B. Analysis and Conclusion

As an initial matter, we disagree with Petitioner that the Commission should downwardly adjust the total volume of HECs imported during the 12-month period preceding the petitions by subtracting out from this total ***.⁹⁷ The negligibility statute refers to the total volume of "all" in-scope merchandise imported during the negligibility period and does not specify that re-exports are to be excluded.⁹⁸ The natural reading of this is that the total volume of "all" HECs imported during the negligibility period of these investigations, inclusive of ***, should be considered by the Commission in conducting its negligibility analysis.⁹⁹

During the most recent 12-month period preceding the filing of the petitions in these investigations (October 2023 through September 2024), based on questionnaire responses, subject imports from Brazil accounted for *** percent of total imports of HECs, subject imports from China for *** percent of total imports, subject imports from India for *** percent of total imports, and subject imports from Vietnam for *** percent of total imports. Decause imports from China, India, and Vietnam respectively exceed the three percent negligibility threshold, we find that the imports from each of these countries subject to the antidumping and countervailing duty investigations are not negligible. Because imports from Brazil fall below this threshold, we find that imports from Brazil subject to the antidumping and countervailing duty investigations are negligible for purposes of the Commission's present material injury analysis. Decause in the second countervailing duty investigations are negligible for purposes of the Commission's present material injury analysis.

⁹⁶ ACG/Custom Capsules/Torpac Postconf. Br. at 3-9. No other Respondent addressed negligibility.

⁹⁷ Petitioner's Postconf. Br. at 15.

⁹⁸ 19 U.S.C. § 1677(24)(A)(i).

⁹⁹ Petitioner does not identify any caselaw or prior Commission determinations supporting its proposed adjustment. ***.

¹⁰⁰ CR/PR at Table IV-5. Subject import volumes from Brazil, China, India, and Vietnam are the same with respect to the antidumping and countervailing duty investigations. *Id.* Based on adjusted official import statistics, subject imports from Brazil accounted for *** percent of total imports, subject imports from China for *** percent, subject imports from India for *** percent, and subject imports from Vietnam for *** percent. *Id.*

¹⁰¹ Irrespective of whether questionnaire data or adjusted official import statistics are used, imports from China, India, and Vietnam each exceed three percent of total imports, while imports from Brazil do not. CR/PR at Table IV-5. Consequently, our negligibility findings remain the same regardless of data source.

We next consider whether imports from Brazil have the potential to imminently exceed the three percent threshold for purposes of determining threat of material injury. ¹⁰³ The record in the preliminary phase of these investigations indicates that there is the potential for imports from Brazil to imminently exceed the negligibility threshold. First, as noted above, subject imports from Brazil accounted for *** percent of total imports of HECs during the October 2023 through September 2024 period, which approaches the three percent negligibility threshold. Moreover, subject imports from Brazil met or exceeded the negligibility threshold in the prior 12-month periods ending in July and August 2024, immediately preceding the end of the negligibility period in September 2024. ¹⁰⁴ That subject imports from Brazil accounted for nearly three percent of all HECs imported during the negligibility period, and in fact accounted for three percent or more of the HECs imported during the 12-month periods immediately preceding the end of the negligibility period, indicate that they have the potential to imminently exceed the three percent negligibility threshold.

Other record evidence also indicates that the volume of imports from Brazil could imminently increase to exceed the negligibility threshold. ¹⁰⁵ In particular, the Brazilian industry

¹⁰² Because we have found that imports from Brazil subject to the antidumping and countervailing duty investigations are negligible for purposes of the Commission's present material injury analysis, they are ineligible for cumulation with subject imports from China, India, and Vietnam for present material injury purposes. 19 U.S.C. § 1677 (24)(a)(iv).

¹⁰³ See 19 U.S.C. § 1677(24)(A)(iv).

¹⁰⁴ CR/PR at Table IV-6 (subject imports from Brazil accounted for *** percent of total imports in the 12-month period ending in July 2024 and *** percent of total imports in the 12-month period ending in August 2024). To assess the potential for imports imminently to surpass the negligibility threshold, the Commission has typically examined the share of total imports, especially toward the latter portion of the negligibility period. *See Certain Steel Concrete Reinforcing Bars from Belarus, China, Korea, Latvia, and Moldova*, Inv. Nos. 731-873-874 and 877-879 (Final), USITC Pub. 3440 (July 2001); *Certain Stainless Steel Butt-Weld Pipe Fittings from Germany*, Inv. No. 731-TA-864 (Final), USITC Pub. 3372 (November 2000); *Cold-Rolled Steel Flat Products from Brazil, India, Korea, Russia, and the United Kingdom*, Inv. Nos. 701-TA-540 and 542-544 and 731-TA-1283, 1285, 1287, 1289-1290 (Final), USITC Pub. 4637 (Sept. 2016).

¹⁰⁵ CR/PR at Table VII-19. We acknowledge that the volume of arranged imports of HECs from Brazil was below three percent of all arranged imports in the three quarters following the end of the negligibility period in September 2024. CR/PR at Table VII-19. However, these arranged imports likely do not account for the total volume of future imports, particularly given that longer-term demand can be hard to predict and the fact that importers, including those importing from Brazil, make a significant number of their sales on the spot market for immediate delivery. *See* CR/PR at Table V-2 (32.4 percent of U.S. importers' sales in 2023 were spot sales). Moreover, while we recognize that the volume of arranged imports from Brazil progressively declined over the three quarters after the end of the negligibility period, CR/PR at Table VII-19, that does not necessarily reflect the actual trend in such imports that will occur over these quarters as it can be difficult for importers to accurately predict their

increased its exports to the United States during the POI and has the ability to continue increasing its exports to the United States in the imminent future. The Brazilian industry's exports to the United States increased irregularly by *** percent from 2021 to 2023 and were *** percent higher in interim 2024 compared to interim 2023. 106 At the same time, the Brazilian industry's exports to the United States as a share of its total shipments increased irregularly from *** percent in 2021 to *** percent in 2023, and were *** percent in interim 2024, compared to *** percent in interim 2023. 107

The record indicates that the Brazilian industry is capable of continuing its pattern of increased exports to the United States in the imminent future. The Brazilian industry's capacity increased *** percent from 2021 to 2023 and was *** percent higher in interim 2024 compared to interim 2023. ¹⁰⁸ In 2023, the Brazilian industry possessed excess capacity of *** units, equivalent to *** percent of apparent U.S. consumption that year, and end-of-period inventories of *** units, equivalent to *** percent of apparent U.S. consumption that year. ¹⁰⁹ ACG Brazil has previously emphasized the importance of the United States among its export markets. ¹¹⁰ The Brazilian industry's increasing reliance on the U.S. market during the POI, as well as its substantial excess capacity and inventories, further indicate that there is the potential for subject imports from Brazil to imminently exceed the negligibility threshold. ¹¹¹

For the above reasons, based on the record of the preliminary phase of the investigations, we find that there is a potential that imports of HECs from Brazil subject to the antidumping and countervailing duty investigations will imminently account for more than three percent of total imports and that such imports are therefore not negligible for purposes of our threat analysis in the preliminary phase of these investigations.

needs for a given product in increasingly distant future quarters. For these reasons, and in light of the other record evidence discussed below, we do not consider that the volume of, and trend in, arranged imports of HECs from Brazil after the end of the negligibility period demonstrate that there is "no potential" that such imports will imminently exceed the three percent negligibility threshold. *See* ACG/Custom Capsules/Torpac Postconf. Br. at 4-5.

- ¹⁰⁶ CR/PR at Table VII-15.
- ¹⁰⁷ CR/PR at Table VII-15.
- ¹⁰⁸ CR/PR at Table VII-14.

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¹⁰⁹ Derived from CR/PR Tables IV-10, VII-14, and VII-16. The Brazilian industry's excess capacity and inventories in 2023 were sufficient to *** the share of apparent U.S. consumption held by subject imports from Brazil that year. *Id.*

¹¹⁰ See Petition, Volume I at Exhibit I-86 (article from <www.pfarma.com.br> quoting ACG Brazil's General Sales Manager as stating that its exports to the United States, Mexico, and other Latin American countries "contributed significantly" to its strong performance).

¹¹¹ CR/PR at Table VII-14.

VI. Cumulation

For purposes of evaluating the volume and effects for a determination of reasonable indication of material injury by reason of subject imports, section 771(7)(G)(i) of the Tariff Act requires the Commission to cumulate subject imports from all countries as to which petitions were filed and/or investigations self-initiated by Commerce on the same day, if such imports compete with each other and with the domestic like product in the U.S. market. In assessing whether subject imports compete with each other and with the domestic like product, the Commission generally has considered four factors:

- (1) the degree of fungibility between subject imports from different countries and between subject imports and the domestic like product, including consideration of specific customer requirements and other quality related questions;
- (2) the presence of sales or offers to sell in the same geographic markets of subject imports from different countries and the domestic like product;
- (3) the existence of common or similar channels of distribution for subject imports from different countries and the domestic like product; and
- (4) whether the subject imports are simultaneously present in the market. 112

While no single factor is necessarily determinative, and the list of factors is not exclusive, these factors are intended to provide the Commission with a framework for determining whether the subject imports compete with each other and with the domestic like product. Only a "reasonable overlap" of competition is required.

¹¹² See Certain Cast-Iron Pipe Fittings from Brazil, the Republic of Korea, and Taiwan, Inv. Nos. 731-TA-278-80 (Final), USITC Pub. 1845 (May 1986), aff'd, Fundicao Tupy, S.A. v. United States, 678 F. Supp. 898 (Ct. Int'l Trade), aff'd, 859 F.2d 915 (Fed. Cir. 1988).

¹¹³ See, e.g., Wieland Werke, AG v. United States, 718 F. Supp. 50 (Ct. Int'l Trade 1989).

¹¹⁴ The Statement of Administrative Action (SAA) to the Uruguay Round Agreements Act (URAA), expressly states that "the new section will not affect current Commission practice under which the statutory requirement is satisfied if there is a reasonable overlap of competition." H.R. Rep. No. 103-316, Vol. I at 848 (1994) (*citing Fundicao Tupy*, 678 F. Supp. at 902); *see Goss Graphic Sys., Inc. v. United States*, 33 F. Supp. 2d 1082, 1087 (Ct. Int'l Trade 1998) ("cumulation does not require two products to be highly fungible"); *Wieland Werke, AG*, 718 F. Supp. at 52 ("Completely overlapping markets are not required.").

A. Parties' Arguments

Petitioner's Arguments. Lonza argues that the Commission should cumulate subject imports, including those from Brazil, because the petitions were filed on the same day and there is a reasonable overlap of competition between and among subject imports from each source and the domestic like product.¹¹⁵

Lonza argues that subject imports from each source are fungible with both each other and the domestic like product. It contends that market analysts, industry participants, and consumers all consider HECs, regardless of source, to be a commodity product. Lonza maintains that both itself and producers in each of the subject countries manufacture both gelatin- and plant-based HECs. ¹¹⁶

Lonza argues that subject imports from each source and the domestic like product are sold in the same channels of distribution. Specifically, it argues that they are all primarily sold to end users.¹¹⁷

Lonza argues that subject imports from each source and the domestic like product overlap geographically, as HECs from all sources are sold throughout the United States. ¹¹⁸ Finally, it argues that subject imports from each source were simultaneously present with both each other and the domestic like product in the U.S. market throughout most of the POI. ¹¹⁹

Respondents' Arguments. At the staff conference, the ACG Respondents stated that they are not contesting cumulation for purposes of the preliminary phase of these investigations. Suheung argues that subject imports from Vietnam should not be cumulated with imports from other subject sources because they are purchased by customers that the domestic industry is allegedly incapable of supplying and thus do not compete with the domestic like product. 121

¹¹⁵ Petitioner's Postconf. Br. at 18 (resting on its cumulation arguments in the Petition, Vol. I at 67-73).

¹¹⁶ Petition, Vol. I at 69-70.

¹¹⁷ Petition, Vol. I at 72-73.

¹¹⁸ Petition, Vol. I at 71.

¹¹⁹ Petition, Vol. I at 73.

¹²⁰ See Conf. Tr. at 106 (Levinson).

¹²¹ Suheung Postconf. Br. at 9.

B. Analysis and Conclusion

As discussed above, we have found that subject imports from Brazil are negligible for purposes of present material injury and thus ineligible for cumulation. With respect to subject imports from China, India, and Vietnam, we consider these imports on a cumulated basis because the statutory criteria for cumulation are satisfied. As an initial matter, Petitioner filed the antidumping and countervailing duty petitions with respect to all subject countries on the same day, October 24, 2024. There also appears to be a reasonable overlap of competition between subject imports from China, India, and Vietnam, and among subject imports from each of these sources and the domestic like product, as discussed below.

Fungibility. All U.S. producers and a majority of U.S. importers reported that subject imports from China, India, and Vietnam are always or frequently interchangeable with both each other and the domestic like product. Additionally, imports from each of these sources as well as the domestic like product consisted of both gelatin- and non-gelatin HECs in 2023. Furthermore, HECs for sale in the U.S. market, regardless of source, are produced to the same standards.

Moreover, the Commission's pricing data also indicate that subject imports from China, India, and Vietnam are fungible with both each other and the domestic like product. Specifically, domestic producers and importers reported sales of overlapping products; domestic producers reported sales of domestically produced products 2 and 4, and U.S. importers reported sales of products 2 and 4 imported from China, India, and Vietnam, throughout the POI. Finally, purchasers responding to the Commission's Lost Sales/Lost Revenue survey reported choosing subject imports from China, India, and Vietnam instead of domestic HECs, with some reporting price as a main deciding factor, further indicating

¹²² None of the statutory exceptions to cumulation applies.

¹²³ CR/PR at Tables II-6-7. The sole exception to this is that U.S. importers were evenly split with respect subject imports from India and the domestic like product, with the same number of importers (3) reporting them sometimes or never interchangeable as reporting them always or frequently interchangeable. *Id*.

¹²⁴ CR/PR at IV-7.

¹²⁵ CR/PR at I-7, n.19 and I-9.

¹²⁶ CR/PR at Table V-4 (showing that domestically produced pricing product two (HEC: gelatin, non-imprinted) was sold throughout the period, as was subject imported pricing product two from China, India and Vietnam); and at Table V-6 (showing that domestically produced pricing product four (HEC: HPMC, non-imprinted) was sold throughout the period, as was subject imported pricing product four from China, India and Vietnam).

fungibility between the domestic like product and subject imports from each of these sources. 127

Channels of Distribution. Domestically produced HECs and subject imports from China, India, and Vietnam were sold in overlapping channels of distribution, *** to end users, with the balance sold to distributors, throughout the POI. 128

Geographic Overlap. Domestically produced HECs and subject imports from China, India, and Vietnam were sold in overlapping geographic markets, with the domestic like product and subject imports from China and India being sold in all regions of the United States and subject imports from Vietnam being sold in all regions except "other." Moreover, HECs from all subject sources overlapped with respect to borders of entry, with HECs from China and India entering the United States through all borders in 2023, and HECs from Vietnam entering through all but the Northern border that year. 130

Simultaneous Presence in Market. Domestically produced HECs and subject imports from China, India, and Vietnam were simultaneously present in the U.S. market throughout the POI. 131

We are unpersuaded by Suheung's argument that the Commission should not cumulate subject imports from Vietnam because these imports allegedly do not compete with the domestic like product. As discussed above, the record indicates that there is a reasonable overlap of competition between these imports and the domestic like product. Additionally,

¹²⁷ CR/PR at Table V-15.

¹²⁸ CR/PR at Table II-1. Nearly all U.S. shipments of subject imports from China, and Vietnam were made to nutraceutical end users during the POI, as were a majority of U.S. shipments of subject imports from India, and a substantial minority of the domestic industry's U.S. shipments. *Id.* A majority of the domestic industry's U.S. shipments, and a substantial minority of U.S. shipments of subject imports from India, were made to pharmaceutical end users during the POI, as were small shares of U.S. shipments of subject imports from China and Vietnam. *Id.*

¹²⁹ CR/PR at Table II-2. The "other" region of the United States refers to Alaska, Hawaii, Puerto Rico, and the U.S. Virgin Islands. *Id*.

¹³⁰ CR/PR at Table IV-8.

¹³¹ CR/PR at Table IV-9 (showing subject imports from China, India, and Vietnam present in every month of the POI) and Tables V-3-6 (showing domestically produced HECs present in every quarter of the POI).

¹³² Suheung Postconf. Br. at 9.

¹³³ As discussed, the record indicates that: all U.S. producers and a majority of U.S. importers reported that the domestic like product and subject imports from Vietnam are always or frequently interchangeable (CR/PR at Tables II-6-7); the domestic like product and subject imports from Vietnam were both sold *** to end users throughout the POI (CR/PR at Table II-1); the domestic like product was sold in all regions of the United States that subject imports from Vietnam were sold in (CR/PR at Table II-

the record does not support Suheung's assertion that subject imports from Vietnam are sold to purchasers that the domestic industry is unable to supply. A respondent to the Commission's Lost Sales/Lost Revenue survey reported purchasing subject imports from Vietnam in lieu of domestically produced HECs, reflecting head-to-head competition between the domestic industry and such imports for sales to this purchaser. Moreover, Lonza submitted multiple cotemporaneous "intelligence summaries" concerning various customer accounts, prepared by its salespeople, indicating that it competes with subject imports from Vietnam for sales to the same U.S. customers. Sales

Conclusion. The record of the preliminary phase of these investigations indicates that subject imports from China, India, and Vietnam are fungible with the domestic like product and each other. The record also indicates that imports from each of these subject countries and the domestic like product were sold in overlapping channels of distribution and geographic markets and were simultaneously present in the U.S. market throughout the POI. Because there appears to be a reasonable overlap of competition between and among the domestic like product and subject imports from China, India, and Vietnam, we cumulate subject imports from these sources for purposes of our present material injury analysis.

VII. Reasonable Indication of Material Injury by Reason of Subject Imports

A. Legal Standard

In the preliminary phase of antidumping and countervailing duty investigations, the Commission determines whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury by reason of the imports under investigation. ¹³⁷ In making this determination, the Commission must consider the volume of subject imports, their effect on prices for the domestic like product, and their impact on domestic producers of the domestic like product, but only in the context of U.S. production

^{2);} and the domestic like product and subject imports from Vietnam were simultaneously present throughout the POI (CR/PR at Table IV-9 and Tables V-3-6).

¹³⁴ Suheung Postconf. Br. at 9.

¹³⁵ CR/PR at Table V-15.

¹³⁶ See Attachment 2 to Exhibit 2 to Lonza's Postconference Br. (containing, among other things, intelligence summaries concerning: (1) the *** account, stating that ***; (2) the *** account, stating that this customer confirmed to the salesperson that ***; and (3) the *** account, stating that this customer confirmed to the salesperson that ***, and noting that this customer ***.").

¹³⁷ 19 U.S.C. §§ 1671b(a), 1673b(a).

operations.¹³⁸ The statute defines "material injury" as "harm which is not inconsequential, immaterial, or unimportant."¹³⁹ In assessing whether there is a reasonable indication that the domestic industry is materially injured by reason of subject imports, we consider all relevant economic factors that bear on the state of the industry in the United States.¹⁴⁰ No single factor is dispositive, and all relevant factors are considered "within the context of the business cycle and conditions of competition that are distinctive to the affected industry."¹⁴¹

Although the statute requires the Commission to determine whether there is a reasonable indication that the domestic industry is "materially injured or threatened with material injury by reason of" unfairly traded imports, 142 it does not define the phrase "by reason of," indicating that this aspect of the injury analysis is left to the Commission's reasonable exercise of its discretion. 143 In identifying a causal link, if any, between subject imports and material injury to the domestic industry, the Commission examines the facts of record that relate to the significance of the volume and price effects of the subject imports and any impact of those imports on the condition of the domestic industry. This evaluation under the "by reason of" standard must ensure that subject imports are more than a minimal or tangential cause of injury and that there is a sufficient causal, not merely a temporal, nexus between subject imports and material injury. 144

In many investigations, there are other economic factors at work, some or all of which may also be having adverse effects on the domestic industry. Such economic factors might include nonsubject imports; changes in technology, demand, or consumer tastes; competition

¹³⁸ 19 U.S.C. § 1677(7)(B). The Commission "may consider such other economic factors as are relevant to the determination" but shall "identify each {such} factor ... and explain in full its relevance to the determination." 19 U.S.C. § 1677(7)(B).

¹³⁹ 19 U.S.C. § 1677(7)(A).

¹⁴⁰ 19 U.S.C. § 1677(7)(C)(iii).

¹⁴¹ 19 U.S.C. § 1677(7)(C)(iii).

¹⁴² 19 U.S.C. §§ 1671b(a), 1673b(a).

¹⁴³ Angus Chemical Co. v. United States, 140 F.3d 1478, 1484-85 (Fed. Cir. 1998) ("{T}he statute does not 'compel the commissioners' to employ {a particular methodology}."), aff'd, 944 F. Supp. 943, 951 (Ct. Int'l Trade 1996).

¹⁴⁴ The Federal Circuit, in addressing the causation standard of the statute, observed that "{a}s long as its effects are not merely incidental, tangential, or trivial, the foreign product sold at less than fair value meets the causation requirement." *Nippon Steel Corp. v. USITC*, 345 F.3d 1379, 1384 (Fed. Cir. 2003). This was further ratified in *Mittal Steel Point Lisas Ltd. v. United States*, 542 F.3d 867, 873 (Fed. Cir. 2008), where the Federal Circuit, quoting *Gerald Metals, Inc. v. United States*, 132 F.3d 716, 722 (Fed. Cir. 1997), stated that "this court requires evidence in the record 'to show that the harm occurred "by reason of" the LTFV imports, not by reason of a minimal or tangential contribution to material harm caused by LTFV goods." *See also Nippon Steel Corp. v. United States*, 458 F.3d 1345, 1357 (Fed. Cir. 2006); *Taiwan Semiconductor Industry Ass'n v. USITC*, 266 F.3d 1339, 1345 (Fed. Cir. 2001).

among domestic producers; or management decisions by domestic producers. The legislative history explains that the Commission must examine factors other than subject imports to ensure that it is not attributing injury from other factors to the subject imports, thereby inflating an otherwise tangential cause of injury into one that satisfies the statutory material injury threshold. In performing its examination, however, the Commission need not isolate the injury caused by other factors from injury caused by unfairly traded imports. Nor does the "by reason of" standard require that unfairly traded imports be the "principal" cause of injury or contemplate that injury from unfairly traded imports be weighed against other factors, such as nonsubject imports, which may be contributing to overall injury to an industry. It is clear that the existence of injury caused by other factors does not compel a negative determination.

Assessment of whether material injury to the domestic industry is "by reason of" subject

¹⁴⁵ SAA at 851-52 ("{T}he Commission must examine other factors to ensure that it is not attributing injury from other sources to the subject imports."); S. Rep. 96-249 at 75 (1979) (the Commission "will consider information which indicates that harm is caused by factors other than less-than-fair-value imports."); H.R. Rep. 96-317 at 47 (1979) ("in examining the overall injury being experienced by a domestic industry, the ITC will take into account evidence presented to it which demonstrates that the harm attributed by the petitioner to the subsidized or dumped imports is attributable to such other factors;" those factors include "the volume and prices of nonsubsidized imports or imports sold at fair value, contraction in demand or changes in patterns of consumption, trade restrictive practices of and competition between the foreign and domestic producers, developments in technology and the export performance and productivity of the domestic industry"); accord Mittal Steel, 542 F.3d at 877.

¹⁴⁶ SAA at 851-52 ("{T}he Commission need not isolate the injury caused by other factors from injury caused by unfair imports."); *Taiwan Semiconductor Industry Ass'n*, 266 F.3d at 1345 ("{T}he Commission need not isolate the injury caused by other factors from injury caused by unfair imports ... Rather, the Commission must examine other factors to ensure that it is not attributing injury from other sources to the subject imports." (emphasis in original)); *Asociacion de Productores de Salmon y Trucha de Chile AG v. United States*, 180 F. Supp. 2d 1360, 1375 (Ct. Int'l Trade 2002) ("{t}he Commission is not required to isolate the effects of subject imports from other factors contributing to injury" or make "bright-line distinctions" between the effects of subject imports and other causes.); *see also Softwood Lumber from Canada*, Inv. Nos. 701-TA-414 and 731-TA-928 (Remand), USITC Pub. 3658 at 100-01 (Dec. 2003) (Commission recognized that "{i}f an alleged other factor is found not to have or threaten to have injurious effects to the domestic industry, *i.e.*, it is not an 'other causal factor,' then there is nothing to further examine regarding attribution to injury"), *citing Gerald Metals*, 132 F.3d at 722 (the statute "does not suggest that an importer of LTFV goods can escape countervailing duties by finding some tangential or minor cause unrelated to the LTFV goods that contributed to the harmful effects on domestic market prices.").

¹⁴⁷ S. Rep. 96-249 at 74-75; H.R. Rep. 96-317 at 47.

¹⁴⁸ See Nippon Steel Corp., 345 F.3d at 1381 ("an affirmative material-injury determination under the statute requires no more than a substantial-factor showing. That is, the 'dumping' need not be the sole or principal cause of injury.").

imports "does not require the Commission to address the causation issue in any particular way" as long as "the injury to the domestic industry can reasonably be attributed to the subject imports." The Commission ensures that it has "evidence in the record" to "show that the harm occurred 'by reason of' the LTFV imports," and that it is "not attributing injury from other sources to the subject imports." The Federal Circuit has examined and affirmed various Commission methodologies and has disavowed "rigid adherence to a specific formula." 151

The question of whether the material injury threshold for subject imports is satisfied notwithstanding any injury from other factors is factual, subject to review under the substantial evidence standard. Congress has delegated this factual finding to the Commission because of the agency's institutional expertise in resolving injury issues. 153

B. Conditions of Competition and the Business Cycle

The following conditions of competition inform our analysis of whether there is a reasonable indication of material injury by reason of subject imports.

1. Demand Conditions

HECs are used by the pharmaceutical and nutraceutical industries to encapsulate

¹⁴⁹ Mittal Steel, 542 F.3d at 876 & 78; see also id. at 873 ("While the Commission may not enter an affirmative determination unless it finds that a domestic industry is materially injured 'by reason of' subject imports, the Commission is not required to follow a single methodology for making that determination ... {and has} broad discretion with respect to its choice of methodology."), citing United States Steel Group v. United States, 96 F.3d 1352, 1362 (Fed. Cir. 1996) and S. Rep. 96-249 at 75. In its decision in Swiff-Train v. United States, 793 F.3d 1355 (Fed. Cir. 2015), the Federal Circuit affirmed the Commission's causation analysis as comporting with the Court's guidance in Mittal.

¹⁵⁰ Mittal Steel, 542 F.3d at 873 (quoting from Gerald Metals, 132 F.3d at 722), 877-79. We note that one relevant "other factor" may involve the presence of significant volumes of price-competitive nonsubject imports in the U.S. market, particularly when a commodity product is at issue. In appropriate cases, the Commission collects information regarding nonsubject imports and producers in nonsubject countries in order to conduct its analysis.

¹⁵¹ Nucor Corp. v. United States, 414 F.3d 1331, 1336, 1341 (Fed. Cir. 2005); see also Mittal Steel, 542 F.3d at 879 ("Bratsk did not read into the antidumping statute a Procrustean formula for determining whether a domestic injury was 'by reason' of subject imports.").

¹⁵² We provide in our discussion below a full analysis of other factors alleged to have caused any material injury experienced by the domestic industry.

¹⁵³ Mittal Steel, 542 F.3d at 873; Nippon Steel Corp., 458 F.3d at 1350, citing U.S. Steel Group, 96 F.3d at 1357; S. Rep. 96-249 at 75 ("The determination of the ITC with respect to causation is ... complex and difficult, and is a matter for the judgment of the ITC.").

pharmaceuticals and supplements.¹⁵⁴ Thus, demand for HECs is driven by demand for pharmaceuticals and supplements.¹⁵⁵ Demand for pharmaceuticals is driven by a number of factors, including U.S. health trends (including the prevalence of contagious diseases), the willingness of U.S. patients to seek medical care, drug prices, and government policies promoting or disincentivizing pharmaceutical use.¹⁵⁶ Overall demand for supplements is driven by demand for the various classes of supplements, including dietary supplements, mineral supplements, and probiotics. Demand for each of these supplement classes has been growing over the long term, as the U.S. population ages and consumers increasingly focus on weight management and immune, gut, and digestive health.¹⁵⁷

*** U.S. producers and *** importers reported seasonality in demand for HECs. Market participants reported that HEC demand increases in the fall, in advance of cold and flu season. 158

*** U.S. producers reported that U.S. demand has fluctuated upwards since January 1, 2021, while *** reported that it has fluctuated downwards. Most U.S. importers reported that demand has fluctuated upwards.¹⁵⁹

Lonza and the ACG Respondents agree that demand rose in 2021, as pharmaceutical and nutraceutical manufacturers stocked up on HECs to hedge against possible pandemic-related supply disruptions, and fell between 2021 and 2023, as these manufacturers destocked in lieu of buying new HECs. ¹⁶⁰ Lonza and the ACG respondents also agree that demand normalized starting in 2023, reverting to its typical, pre-pandemic trend of single-digit annual growth. ¹⁶¹

Apparent U.S. consumption of HECs declined from *** units in 2021 to *** units in 2022, then increased to *** units in 2023, a level *** percent lower than in 2021. It was ***

¹⁵⁴ CR/PR at II-1; II-9.

¹⁵⁵ CR/PR at II-9.

¹⁵⁶ CR/PR at II-9.

¹⁵⁷ CR/PR at II-9.

¹⁵⁸ CR/PR at II-10.

¹⁵⁹ CR/PR at Table II-4.

¹⁶⁰ Petitioners' Postconf. Br. at 19-20; ACG/Custom Capsules/Torpac Postconf. Br. at 28-29. The ACG Respondents additionally argue that increasing consumer demand for supplements and pharmaceuticals as the pandemic intensified contributed to the growth in HEC demand in 2021, and that decreasing consumer demand for these products as the pandemic subsided contributed to the contraction in HEC demand between 2021 and 2023. *See* ACG/Custom Capsules/Torpac Postconf. Br. at 28-29.

¹⁶¹ Petitioners' Postconf. Br. at 20; ACG/Custom Capsules/Torpac Postconf. Br. at 28-29; Conf. Tr. at 129 (Singh) (stating that demand "normalized" from January 2023).

percent higher in interim 2024, at *** units, than in January – June 2023 ("interim 2023"), at *** units. 162

2. Supply Conditions

The domestic industry was the smallest source of supply to the U.S. market throughout the POI. Its share of apparent U.S. consumption decreased by *** percentage points from 2021 to 2023, from *** percent in 2021 to *** percent in 2022 and *** percent in 2023. Its market share was *** percentage points lower in interim 2024, at *** percent, than in interim 2023, at *** percent. While the domestic industry supplies both gelatin- and plant-based HECs to the U.S. market, it focuses on gelatin-based HECs. The domestic industry does not currently produce HECs above 1.45 mL, 165 although Lonza states that it is capable of doing so. 166

While *** U.S. producers reported prolonged shutdowns and curtailments during the POI, ¹⁶⁷ *** also reported an acquisition and *** an expansion, ¹⁶⁸ and the domestic industry maintained sizeable excess capacity throughout the period. ¹⁶⁹ Although *** extended its lead times to *** during the height of the COVID-19 pandemic, it reports that its lead times subsequently returned to normal. ¹⁷⁰ The domestic industry's lead times for its produced-to-order HECs, which account for the majority of its production, averaged 133 days (*i.e.*, 19 weeks). ¹⁷¹

Cumulated subject imports were the second largest source of supply in 2021 and the largest source of supply during the rest of the POI. Their share of apparent U.S. consumption increased by *** percentage points from 2021 to 2023, from *** percent in 2021 to *** percent in 2022 and *** percent in 2023. Their market share was *** percentage points greater in interim 2024, at *** percent, than in interim 2023, at *** percent. Importers reported

¹⁶² CR/PR at Tables IV-10 and C-1.

¹⁶³ CR/PR at Tables IV-10 and C-1.

¹⁶⁴ CR/PR at Tables V-3-6; Table IV-7.

¹⁶⁵ Conf. Tr. at 98 (Tahil) ("Domestic producers make HEC capsules with a filling capacity of under 1.4 ml.").

¹⁶⁶ Exhibit 3 to Petitioners' Postconf. Br. (affidavit of Michael Goetter) at paras. 4-5.

¹⁶⁷ CR/PR at Table III-4.

¹⁶⁸ CR/PR at Table III-3.

¹⁶⁹ CR/PR at Tables III-7 and C-1. The domestic industry's excess capacity ranged between *** percent and *** percent of its total practical production capacity during the POI. *Id*.

¹⁷⁰ Exhibit 3 to Petitioners' Postconf. Br. (affidavit of Michael Goetter) at para. 16.

¹⁷¹ CR/PR at II-14.

¹⁷² CR/PR at Table C-1.

importing both gelatin- and plant-based HECs from China, India, and Vietnam during the POI. Their U.S. shipments were *** gelatin- and plant-based HECs in 2023, with gelatin-based HECs comprising *** percent of their U.S. shipments and plant-based HECs *** percent. One importer, Torpac, reported supplying subject imported HECs above 1.45 mL to the U.S. market.

Nine of 15 importers reported that they had experienced supply constraints during the POI resulting from COVID-19-related supply chain disruptions. Producers/exporters in China and India reported production bottlenecks, and a producer/exporter in Vietnam reported "other constraints." 178

Nonsubject imports were the largest source of supply in 2021, and the second largest source of supply during the rest of the POI. Their share of apparent U.S. consumption decreased by *** percentage points from 2021 to 2023, from *** percent in 2021 to *** percent in 2022 and *** percent in 2023. Their market share was *** percentage points higher in interim 2024, at *** percent, than in interim 2023, at *** percent. The largest sources of nonsubject imports were Canada, Mexico, and South Korea. 180

3. Substitutability and Other Conditions

We find that there is at least a moderate degree of substitutability between the domestic like product and cumulated subject imports. As discussed in Section VI.B. above, all U.S. producers and a majority of U.S. importers reported that subject imports from China, India, and Vietnam are always or frequently interchangeable with the domestic like product. Moreover, while the domestic industry largely produces gelatin-based HECs, the record indicates that cumulated subject imports also significantly comprise gelatin-based HECs. Indeed, gelatin-based HECs accounted for *** percent of importers' U.S. shipments of

¹⁷³ CR/PR at Tables V-3-6 and Table IV-7.

¹⁷⁴ Derived from CR/PR Table IV-7.

¹⁷⁵ Conf. Tr. at 97 (Tahil); ***.

¹⁷⁶ CR/PR at II-8.

¹⁷⁷ CR/PR at Table VII-10.

¹⁷⁸ CR/PR at Table VII-10.

¹⁷⁹ CR/PR at Tables IV-10 and C-1.

¹⁸⁰ CR/PR at II-8.

¹⁸¹ CR/PR at Tables II-6-7. As also previously discussed, the sole exception to this is that U.S. importers were evenly split with respect subject imports from India and the domestic like product, with the same number of importers (3) reporting them sometimes or never interchangeable as reporting them always or frequently interchangeable. *Id*.

cumulated subject imports in 2023.¹⁸² Further, as discussed in Section III.B.1. above, the record indicates that all HECs, regardless of polymer type, share many physical characteristics and are produced to the same standards, suggesting that subject imported HECs of both polymer types are largely substitutable with domestically produced HECs of both polymer types. Even to the extent that there may be some limitations on the substitutability of gelatin- and plant-based HECs, the domestic industry produces appreciable volumes of plant-based HECs, accounting for *** percent of its U.S. shipments in 2023, that would compete directly with subject imported plant-based HECs.¹⁸³

The record also indicates, however, that that certain purchasers may be limited in their ability to switch between HEC suppliers. Pharmaceutical companies in particular may face barriers in switching between domestic and subject HECs, resulting from the time and expense attendant in satisfying FDA requirements for doing so.¹⁸⁴ Although such barriers may limit the substitutability between domestically produced and subject imported HECs for pharmaceutical purchasers to some extent, they would not limit the substitutability between domestic and subject HECs for nutraceutical purchasers, which do not have to satisfy these FDA requirements.¹⁸⁵ Moreover, even for a pharmaceutical company, in some situations, such as when switching to a supplier of HECs with the same composition and appearance as those produced by the company's current supplier, the available evidence indicates that the regulatory burden appears to be relatively light, entailing notification of the change in the company's next annual report to the FDA.¹⁸⁶ Further, a Lonza representative testified that there

¹⁸² Derived from CR/PR at Table IV-7.

¹⁸³ CR/PR at Table IV-7. While cumulated subject imports include HECs above 1.45 mL, which the domestic industry does not currently produce, nothing on the current record indicates that this meaningfully limits the substitutability between cumulated subject imports and the domestic like product, given the *** size of the market for such HECs. Only one subject importer, Torpac, reported importing HECs above 1.45 mL, and its imports were equivalent to only *** percent of total cumulated subject imports in 2023. *Derived from* Table IV-2 and ***. Moreover, Torpac's industry witness at the staff conference testified that the total annual U.S. market for HECs above 1.45 mL is \$5 million, which would be equivalent to only *** percent of apparent U.S. consumption, by value, in 2023. *See* Conf. Tr. at 98 (Tahil); CR/PR at Table C-1. Consistent with the above information, Lonza submitted an affidavit stating that the "vast majority" of all HECs sold in the U.S. market are below 1.45 mL. *See* Exhibit 3 to Petitioners' Postconf. Br. (affidavit of Michael Goetter) at para. 15. Thus, even to the extent that HECs above 1.45 mL are not substitutable with HECs below 1.45 mL, nothing on the current record indicates that this would significantly limit the substitutability of the domestic like product with cumulated subject imports.

¹⁸⁴ CR/PR at II-12; Conf. Tr. at 61-62 (Romanski); Huangshan Preconf. Statement at 3.

¹⁸⁵ CR/PR at II-12; Conf. Tr. at 61-62 (Romanski).

¹⁸⁶ Exhibit 4 to Petitioners' Postconf. Br. (affidavit of Gabriel McCutcheon) at para. 11.

are other situations in which pharmaceutical purchasers can "freely switch" between HEC suppliers without any FDA involvement. Accordingly, notwithstanding the regulatory requirements that may complicate a pharmaceutical company's switch from one HEC supplier to another, the available evidence does not indicate that such requirements preclude such switching and is consistent with the conclusion that there is at least a moderate degree of substitutability between subject and domestic HECs.

In addition, lead times for domestic producers and subject imports differ to some degree which may affect substitutability. U.S. producers reported that they produced *** percent of their commercial shipments to order, with lead times averaging 133 days. The remaining *** percent of their commercial shipments were from inventories, with lead times averaging three days. Responding importers reported that *** percent of their commercial shipments were from U.S. inventories, with lead times averaging four days. The remaining *** percent of their commercial shipments were made to order, with lead time averaging 90 days. ¹⁸⁸

We also find that price is an important factor in HEC purchasing decisions, particularly when importers of subject merchandise and domestic producers are both qualified to supply the same HECs to a purchaser. More purchasers ranked price as among the top three factors they consider in their purchasing decisions than any other factor. All U.S. producers and majorities or pluralities of importers reported that factors other than price are only sometimes or never significant in purchasing decisions.

Raw material costs accounted for the second largest share of the domestic industry's cost of goods sold ("COGS") throughout the POI, after other factory costs. The major raw materials for HECs are gelatin- and plant-based polymers. The industry's raw material costs as a share of its COGS decreased by *** percentage points from 2021 to 2023, from *** percent in 2021 to *** percent in 2022 and *** percent in 2023, and was ***

¹⁸⁷ Conf. Tr. at 63 (Romanski) ("Once a dual source is qualified, then you can freely switch without any notification. So it's essentially instantaneous.").

¹⁸⁸ CR/PR at II-14.

¹⁸⁹ Conf. Tr. at 63 (Romanski) (indicating that once domestic and subject suppliers are dual-qualified, considerations other than price in choosing between them diminish).

¹⁹⁰ CR/PR at Table II-5.

¹⁹¹ CR/PR at Table II-8. The sole exception to this is that, in decisions between domestically produced HECs and subject imports from India, four importers reported factors other than price always or frequently significant, while two reported them only sometimes or never significant. *Id*.

¹⁹² CR/PR at Table VI-1.

¹⁹³ CR/PR at V-1; Table VI-4.

¹⁹⁴ CR/PR at VI-12, n.7.

¹⁹⁵ CR/PR at VI-12. n.7.

percentage points lower in interim 2024, at *** percent, than in interim 2023, at *** percent. 196

U.S. producers sold most of their HECs in 2023 on the spot market, with most of the balance sold under annual contracts and a relatively small amount sold under long-term contracts. ¹⁹⁷ Subject importers sold most of their HECs in 2023 under short-term contracts or on the spot market, with most of the balance sold under annual contracts and a relatively small amount sold under long-term contracts. ¹⁹⁸

Inventories of HECs are held domestically by U.S. producers¹⁹⁹ and subject importers,²⁰⁰ and in each subject country by the subject foreign industries.²⁰¹ Inventories held by U.S. producers rose by *** percent from 2021 to 2023, from *** units to *** units, and were *** percent lower in interim 2024, at *** units, than in interim 2023, at *** units.²⁰² Inventories held domestically by subject importers rose by *** percent from 2021 to 2023, from *** units to *** units, and were *** percent greater in interim 2024, at *** units, than in interim 2023, at *** units.²⁰³

Subject imports from China entering the United States under HTSUS subheadings 9602.00.10 and 9602.00.50 (the primary HTSUS subheadings for the subject merchandise) became subject to additional *ad valorem* duties of 7.5 percent under Section 301 of the Trade Act of 1974 ("section 301 tariffs"), effective February 14, 2020.²⁰⁴ *** reported that the section 301 tariffs have had any impact on the U.S. market, while seven of 17 importers reported that they have had an impact, including decreased overall demand for HECs.²⁰⁵

C. Volume of Cumulated Subject Imports

Section 771(7)(C)(i) of the Tariff Act provides that the "Commission shall consider whether the volume of imports of the merchandise, or any increase in that volume, either in absolute terms or relative to production or consumption in the United States, is significant." ²⁰⁶

¹⁹⁶ Derived from CR/PR at Table VI-I.

¹⁹⁷ CR/PR at Table V-2.

¹⁹⁸ CR/PR at Table V-2.

¹⁹⁹ CR/PR at Table III-10.

²⁰⁰ CR/PR at Table VII-18.

²⁰¹ CR/PR at Tables VII-16.

²⁰² CR/PR at Table C-1.

²⁰³ CR/PR at Table VII-18.

²⁰⁴ CR/PR at I-6.

²⁰⁵ CR/PR at II-2.

²⁰⁶ 19 U.S.C. § 1677(7)(C)(i).

Cumulated subject import volume increased irregularly by *** percent from 2021 to 2023, increasing from *** units in 2021 to *** units in 2022, then decreasing to *** units in 2023; cumulated subject import volume was *** percent greater in interim 2024, at *** units, than in interim 2023, at *** units. 207

Cumulated subject imports as a share of apparent U.S. consumption increased by *** percentage points from 2021 to 2023, from *** percent in 2021 to *** percent in 2023 and *** percent in 2023. Their share was *** percentage points greater in interim 2024, at *** percent, than in interim 2023, at *** percent.²⁰⁸

The volume of cumulated subject imports relative to U.S. production increased overall by *** percentage points from 2021 to 2023, increasing from *** percent in 2021 to *** percent in 2022, then decreasing to *** percent in 2023. The volume of cumulated subject imports relative to U.S. production was *** percentage points greater in interim 2024, at *** percent, than in interim 2023, at *** percent.²⁰⁹

Based on the foregoing, we find that both the volume and the increase in volume of cumulated subject imports were significant in absolute terms and relative to consumption and production in the United States during the POI.

D. Price Effects of the Cumulated Subject Imports

Section 771(7)(C)(ii) of the Tariff Act provides that, in evaluating the price effects of subject imports, the Commission shall consider whether –

- (I) there has been significant price underselling by the imported merchandise as compared with the price of domestic like products of the United States, and
- (II) the effect of imports of such merchandise otherwise depresses prices to a significant degree or prevents price increases, which otherwise would have occurred, to a significant degree.²¹⁰

²⁰⁷ Derived from CR/PR Table IV-2.

²⁰⁸ CR/PR at Table C-1. Apparent U.S. consumption is based on importers' U.S. shipments of imports. Such shipments of cumulated subject imports increased from *** units in 2021 to *** units in 2022 and *** units in 2023, for an overall increase of *** percent; importers' U.S. shipments of cumulated subject imports were *** percent greater in interim 2024, at *** units, than in interim 2023, at *** units. *Id*

²⁰⁹ Derived from CR/PR Table IV-2

²¹⁰ 19 U.S.C. § 1677(7)(C)(ii).

As addressed in Section VII.B.3. above, we have found that there is at least a moderate degree of substitutability between the domestic like product and cumulated subject imports and that price is an important factor in HEC purchasing decisions.

The Commission collected quarterly pricing data for the total quantity and f.o.b. value of four products shipped by U.S. producers and importers to unrelated customers. Two domestic producers and 12 importers provided usable pricing data for sales of the requested products, although not all firms reported pricing for all products for all quarters. Pricing data reported by these firms accounted for approximately *** percent of U.S. producers' U.S. shipments, *** percent of U.S. shipments of HECs from China, *** percent of U.S. shipments of HECs from India, and *** percent of U.S. shipments of HECs from Vietnam in 2023.

The pricing data show that cumulated subject imports undersold the domestic like product in 126 of 127 quarterly comparisons, or in 99.2 percent of the comparisons, at margins ranging between *** and *** percent and averaging *** percent. In contrast, cumulated subject imports oversold the domestic like product in 1 of 127 quarterly comparisons, or in 0.8 percent of the comparisons, at a margin of *** percent. The cumulated subject import volume that undersold the domestic like product accounted for 99.97 percent of the reported volume of cumulated subject import sales (*** units), and the cumulated subject import volume that oversold the domestic like product accounted for 0.03 percent of the reported volume of cumulated subject import sales (*** units). ²¹⁴

We have also considered lost sales information. Five of eight responding purchasers reported that they had purchased subject imports in lieu of the domestic like product during

²¹¹ CR/PR at V-3. The four pricing products are:

Product 1.-- Hard empty gelatin capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), imprinted, and sold in per 1,000 unit increments.

Product 2.-- Hard empty gelatin capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), not imprinted, and sold in per 1,000 unit increments.

Product 3.-- Hard empty HPMC capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), imprinted, and sold in per 1,000 unit increments.

Product 4.-- Hard empty HPMC capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), not imprinted, and sold in per 1,000 unit increments.

²¹² CR/PR at V-4.

²¹³ CR/PR at V-4.

²¹⁴ CR/PR at Table V-8.

the POI.²¹⁵ Four of those five reported that subject imports were priced lower than the domestic like product.²¹⁶ Two of those four reported that price was a primary reason for purchasing *** units of subject HECs in lieu of the domestic like product, equivalent to *** percent of all reported purchases, and *** percent of reported subject import purchases.²¹⁷

Consistent with the preceding evidence, Petitioner provided internal communications and contemporaneous "intelligence summaries" prepared by its salespeople indicating that subject imports from China, India, and Vietnam were lower-priced than domestically produced HECs during the POI.²¹⁸

Given the at least moderate degree of substitutability between cumulated subject imports and the domestic like product, the importance of price in purchasing decisions, the pricing data showing near-universal underselling on both a quarterly and volume basis, the lost sales information, and the contemporaneous documentation indicating that subject imports were lower-priced than the domestic like product, we find that subject import underselling was significant during the POI. The subject import underselling caused a shift in market share from the domestic industry to cumulated subject imports during the period. Cumulated subject imports captured *** percentage points of market share from the domestic industry from 2021 to 2023, and *** percentage points of market share from the industry in interim 2024 compared to interim 2023.²¹⁹

We have also considered price trends during the POI. Pricing data for the domestic industry show mixed trends, with prices fluctuating somewhat throughout the POI and the prices for two products increasing overall from the first quarter of 2021 to the second quarter of 2024 while the prices for the two other products declined overall. Prices for domestically produced pricing product one fluctuated within a narrow band from the first quarter of 2021 through the second quarter of 2024 to a price *** percent higher than in the first quarter of 2021. Prices for domestically produced pricing product two increased irregularly from the

²¹⁵ CR/PR at Table V-14.

²¹⁶ CR/PR at Table V-14.

²¹⁷ Derived from CR/PR Tables V-12 and V-14.

²¹⁸ See Attachment 2 to Exhibit 2 to Lonza's Postconference Br. (containing, among other things: (1) an internal Lonza email communication stating that purchaser ***; (2) an intelligence summary concerning the *** account, stating that this purchaser confirmed to the salesperson that ***; (3) an intelligence summary concerning the *** account, stating that this purchaser informed the salesperson of ***; (4) an intelligence summary concerning the *** account, stating that this purchaser confirmed to the salesperson that ***; and (5) an intelligence summary concerning the *** account, stating that this purchaser informed the salesperson that ***.

²¹⁹ CR/PR at Table C-1.

²²⁰ CR/PR at Table V-3; Figure V-1.

first quarter of 2021 through the second quarter of 2023, then declined irregularly through the second quarter of 2024 to a price *** percent lower than in the first quarter of 2021.²²¹ After remaining relatively stable from the first through the fourth quarter of 2021, prices for domestically produced pricing product three then fluctuated upward through the second quarter of 2024 to a price *** percent higher than in the first quarter of 2021.²²² Prices for domestically produced pricing product four sharply declined from the first through the third quarter of 2021, fluctuated through the fourth quarter of 2023, then sharply declined though the second quarter of 2024 to a price *** percent lower than in the first quarter of 2021.²²³ Prices for most of the subject imported pricing products for which data are available decreased over the POI, from *** to *** percent depending on the product.²²⁴ Only prices for subject imported pricing product one from India and subject imported pricing product two from China increased over the period.²²⁵

We have also considered whether subject imports prevented price increases that otherwise would have occurred to a significant degree. The domestic industry's ratio of COGS to net sales increased from *** percent in 2021 to *** percent in 2022 and then decreased to *** percent in 2023, a level *** percentage points higher than in 2021; it was *** percentage points higher in interim 2024, at *** percent, than in interim 2023, at *** percent. The domestic industry's unit raw material costs increased from \$*** in 2021 to \$*** in 2022 and \$*** in 2023; they were \$*** in interim 2024, down from \$*** in interim 2023. The industry's total unit COGS increased from \$*** in 2021 to \$*** in 2022 and \$*** in 2023; they were \$*** in interim 2024, up from \$*** in interim 2023. At the same time, the average unit value ("AUV") of the domestic industry's net sales increased from \$*** in 2021 to \$*** in 2021 to \$*** in 2021.

²²¹ CR/PR at Table V-4; Figure V-2.

²²² Derived from CR/PR Table V-5; Figure V-3.

²²³ Derived from CR/PR Tables V-6; Figure V-4.

From the first quarter of 2021 to the second quarter of 2024, prices for pricing product one from Vietnam declined by *** percent, prices for pricing product two from India and Vietnam declined by *** percent and *** percent, respectively, prices for pricing product three from India declined by *** percent, and prices for pricing product four from China, India, and Vietnam declined by *** percent, *** percent, and *** percent, respectively. CR/PR at Table V-7.

²²⁵ From the first quarter of 2021 to the second quarter of 2024, prices for pricing product one from India increased by *** percent and prices for pricing product two from China increased by *** percent. CR/PR at Table V-7.

²²⁶ CR/PR at Tables VI-1 and C-1.

²²⁷ CR/PR at Table VI-1. Unit costs are calculated in dollars per 1,000 units. *Id*.

²²⁸ CR/PR at Table VI-1.

and \$*** in 2023; it was \$*** in interim 2024, down from \$*** in interim 2023. 229 Apparent U.S. consumption declined overall by *** percent from 2021 to 2023, but was *** percent higher in interim 2024 than in interim 2023. Although the irregular increase in the domestic industry's ratio of COGS to net sales from 2021 to 2023 was driven partly by increasing unit raw material costs, the only increase in the ratio during this time occurred between 2021 and 2022. The increase from 2021 to 2022 coincided with a *** percent decline in apparent U.S. consumption, and a decline of the domestic industry's operating income to net sales ratio from *** to ***. 231 The industry's higher ratio of COGS to net sales in interim 2024 compared to interim 2023 resulted from lower net sales AUVs and higher unit labor and other factory costs, while unit raw material costs declined slightly and apparent U.S consumption increased. 232

In sum, we find that cumulated subject imports significantly undersold the domestic like product, causing the domestic industry to lose sales and market share to these imports. Consequently, we find that cumulated subject imports had significant price effects.

E. Impact of the Cumulated Subject Imports²³³

Section 771(7)(C)(iii) of the Tariff Act provides that the Commission, in examining the impact of the subject imports on the domestic industry, "shall evaluate all relevant economic factors which have a bearing on the state of the industry." These factors include output, sales, inventories, capacity utilization, market share, employment, wages, productivity, gross profits, net profits, operating profits, cash flow, return on investment, return on capital, ability to raise capital, ability to service debt, research and development ("R&D"), and factors affecting domestic prices. No single factor is dispositive and all relevant factors are considered "within the context of the business cycle and conditions of competition that are distinctive to the

²²⁹ CR/PR at Tables VI-1 and C-1.

²³⁰ CR/PR at Tables VI-1 and C-1.

²³¹ CR/PR at Tables VI-1 and C-1. As discussed in section VII.B.1., Lonza and the ACG Respondents agree that demand rose in 2021, as pharmaceutical and nutraceutical manufacturers stocked up on HECs to hedge against possible pandemic-related supply disruptions, and fell between 2021 and 2023, as these manufacturers destocked in lieu of buying new HECs.

²³² CR/PR at Tables VI-1 and C-1. We intend to further investigate the effect of cumulated subject imports on domestic prices in any final phase of these investigations.

²³³ Commerce initiated these investigations based on estimated dumping margins of 128.01 to 158.04 percent for imports from China, 54.81 to 82.95 percent for imports from India, and 63.53 percent to 86.04 percent for imports from Vietnam. *Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigations*, 89 FR 91684, 91690 (Nov. 13, 2024); CR/PR at I-4.

affected industry."234

The domestic industry's performance declined by most measures as it lost *** percentage points of market share to cumulated subject imports and apparent U.S. consumption declined irregularly from 2021 to 2023. Although apparent U.S. consumption was *** percent higher in interim 2024 than in interim 2023, the domestic industry's performance continued to worsen as it lost another *** percentage points of market share to cumulated subject imports.

Measures of the domestic industry's output generally declined from 2021 to 2023 and were lower in interim 2024 than in interim 2023. The industry's capacity decreased by *** percent from 2021 to 2023, from *** units in 2021 to *** units in 2022 and *** units in 2023; it was *** percent lower in interim 2024, at *** units, than in interim 2023, at *** units. ²³⁵ The domestic industry's production decreased by *** percent from 2021 to 2023, from *** units in 2021 to *** units in 2022 and *** units in 2023; it was *** percent lower in interim 2024, at *** units, than in interim 2023, at *** units. ²³⁶ The industry's capacity utilization rate increased overall by *** percentage points from 2021 to 2023, declining from *** percent in 2021 to *** percent in 2022, then increasing to *** percent in 2023; it was *** percentage points lower, however, in interim 2024, at *** percent, than in interim 2023, at *** percent. ²³⁷

The domestic industry's employment indicia generally increased from 2021 to 2023 but were lower in interim 2024 than in interim 2023, including its employment, ²³⁸ hours worked, ²³⁹ and wages paid. ²⁴⁰ Productivity, as measured in 1,000 units per hour, decreased by *** percent from 2021 to 2023, from *** in 2021 to *** in 2022 and *** in 2023; it was *** percent lower in interim 2024, at ***, than in interim 2023, at ***. ²⁴¹

²³⁴ 19 U.S.C. § 1677(7)(C)(iii). This provision was amended by the Trade Preferences Extension Act ("TPEA") of 2015, Pub. L. 114-27.

²³⁵ CR/PR at Tables III-5 and C-1.

²³⁶ CR/PR at Tables III-5 and C-1.

²³⁷ CR/PR at Tables III-5 and C-1.

²³⁸ Employment increased by *** percent from 2021 to 2023, from *** production and related workers ("PRWs") in 2021 to *** PRWs in 2022 and *** PRWs in 2023; it was *** percent lower in interim 2024, at *** PRWs, than in interim 2023, at *** PRWs. CR/PR at Tables III-14 and C-1.

²³⁹ Total hours worked increased by *** percent from 2021 to 2023, from *** hours in 2021 to *** hours in 2022 and *** hours in 2023. They were *** percent lower in interim 2024, at *** hours, than in interim 2023, at *** hours. CR/PR at Tables III-14 and C-1.

 $^{^{240}}$ Wages paid increased by *** percent from 2021 to 2023, from \$*** in 2021 to \$*** in 2022 and \$*** in 2023. They were *** percent lower in interim 2024, at \$***, than in interim 2023, at \$***. CR/PR at Tables III-14 and C-1.

²⁴¹ CR/PR at Tables III-14 and C-1.

The industry's U.S. shipments decreased by *** percent from 2021 to 2023, from *** units in 2021 to *** units in 2022 and *** units in 2023; they were *** percent lower in interim 2024, at *** units, than in interim 2023, at *** units. 242 The domestic industry's share of apparent U.S. consumption decreased by *** percentage points from 2021 to 2023, from *** percent in 2021 to *** percent in 2022 and *** percent in 2023; its share of apparent U.S. consumption was *** percentage points lower in interim 2024, at *** percent, than in interim 2023, at *** percent. 243

The industry's end-of-period inventories increased by *** percent from 2021 to 2023, from *** units in 2021 to *** units in 2022 and *** units in 2023; they were *** lower in interim 2024, at *** units, than in interim 2023, at *** units. 244 As a ratio of total shipments, the industry's end-of-period inventories increased from *** percent in 2021 to *** percent in 2022 and *** percent in 2023, and were higher in interim 2024, at *** percent, than in interim 2023, at *** percent. 245

Along with decreased shipments and share of apparent U.S. consumption, most of the domestic industry's financial performance indicators declined overall from 2021 to 2023 and were dramatically lower in interim 2024 than in interim 2023. The industry's net sales revenue increased overall by *** percent from 2021 to 2023, decreasing from \$*** in 2021 to \$*** in 2022, then increasing to \$*** in 2023; its net sales revenue was *** percent lower in interim 2024, at \$***, than in interim 2023, at \$***. ²⁴⁶ The industry's gross profits decreased overall by *** percent from 2021 to 2023, decreasing from \$*** in 2021 to \$*** in 2022, then increasing to \$*** in 2023; its gross profits were *** percent lower in interim 2024, at \$***, than in interim 2023, \$***. ²⁴⁷ The domestic industry's operating income decreased overall by *** percent from 2021 to 2023, declining from \$*** in 2021 to \$*** in 2022, then increasing to \$*** in 2023; its operating income was *** percent lower in interim 2024, at \$***, than in interim 2023, at \$***. ²⁴⁸ As a ratio to net sales, the domestic industry's operating income margin declined overall by *** percentage points from 2021 to 2023, decreasing from *** percent in 2021 to *** percent in 2022, then increasing to *** percent in 2023; the industry's operating margin was *** percent in 2022, then increasing to *** percent in 2023; the industry's operating margin was *** percent in 2022, then increasing to *** percent in 2023; the industry's operating margin was *** percent in 2022, then increasing to *** percent, than in

²⁴² CR/PR at Tables III-8 and C-1.

²⁴³ CR/PR at Tables IV-10 and C-2.

²⁴⁴ CR/PR at Tables III-10 and C-1.

²⁴⁵ CR/PR at Tables III-10 and C-1.

²⁴⁶ CR/PR at Tables VI-1 and C-1.

²⁴⁷ CR/PR at Tables VI-1 and C-1.

²⁴⁸ CR/PR at Tables VI-1 and C-1.

interim 2023, at *** percent.²⁴⁹ The industry's net income declined overall by *** percent from 2021 to 2023, decreasing from \$*** in 2021 to \$*** in 2022, then increasing to \$*** in 2023; its net income was \$*** in interim 2024 compared to \$*** in interim 2023.²⁵⁰ The industry's net income margin decreased overall by *** percentage points from 2021 to 2023, declining from *** percent in 2021 to *** percent in 2022, then increasing to *** percent in 2023; its net income margin was *** percentage points lower in interim 2024, at *** percent, than in interim 2023, at *** percent.²⁵¹ The domestic industry's return on assets declined from *** percent in 2021 to *** percent in 2022, then increased to *** percent in 2023.²⁵²

The industry's capital expenditures decreased overall by *** percent from 2021 to 2023, declining from \$*** in 2021 to \$*** in 2022, then increasing to \$*** in 2023. Its capital expenditures were *** percent lower in interim 2024, at \$***, than in interim 2023, at \$***. The domestic industry ***. The domestic industry reported negative effects on investment, growth, and development due to subject imports. 255

The record shows that as cumulated subject imports increased significantly during the period, driven by significant underselling, they took sales and captured *** percentage points of market share from the domestic industry from 2021 to 2023, and *** percentage points of market share from the industry in interim 2024 compared to interim 2023.²⁵⁶ Consequently, the industry's production, employment, and financial performance declined during the POI.²⁵⁷ Notably, in interim 2024 compared to interim 2023, the domestic industry was unable to capitalize on the *** percent increase in apparent U.S. consumption because low-priced cumulated subject imports increased by *** percent and captured *** percentage points of market share from the industry. This occurred while the industry's operating income dropped by *** percent, its operating income margin fell to a POI-low of *** percent, its gross profits fell by *** percent, its production declined by *** percent, and both its net income and net margin *** for the first time during the POI.²⁵⁸

We have also considered whether there are other factors that may have had an adverse

²⁴⁹ CR/PR at Table C-1.

²⁵⁰ CR/PR at Tables VI-1 and C-1.

²⁵¹ CR/PR at Tables VI-1 and C-1.

²⁵² CR/PR at Table VI-9.

²⁵³ CR/PR at Tables VI-6 and C-1.

²⁵⁴ CR/PR at Table C-1.

²⁵⁵ CR/PR at Tables VI-11-12.

²⁵⁶ CR/PR at Tables IV-10 and C-1.

²⁵⁷ CR/PR at Table C-1.

²⁵⁸ CR/PR at Tables IV-10, VI-1, and C-1.

impact on the domestic industry during the POI to ensure that we are not attributing injury from such other factors to subject imports. Nonsubject imports had a significant presence in the U.S. market during the POI, accounting for *** percent of apparent U.S. consumption in 2023.²⁵⁹ Nevertheless, nonsubject imports lost *** percentage points of market share from 2021 to 2023, while subject imports gained *** percentage points of market share at the domestic industry's expense. Although nonsubject imports also took market share from the domestic industry in interim 2024 relative to interim 2023, subject imports captured an additional *** percentage points of market share from the domestic industry between the interim periods.²⁶⁰ Nonsubject imports cannot explain the injury we have attributed to cumulated subject imports as a result of cumulated subject imports capturing sales and market share from the domestic industry during the POI.²⁶¹

Although apparent U.S. consumption declined overall by *** percent between 2021 and 2023, the domestic industry's capacity, U.S. shipments, and net sales all declined by a greater proportion over this time, as the industry lost *** percentage points of market share to cumulated subject imports. Considering the decline in the industry's performance and lost sales information during 2021 through 2023, the decline in apparent U.S. consumption during that period cannot explain the loss in market share experienced by the domestic industry. The industry's performance continued to decline over the interim periods, despite the *** percent increase in apparent U.S. consumption in interim 2024 compared to interim 2023, as the industry lost an additional *** percentage points of market share to cumulated subject imports.

We are unpersuaded by the ACG Respondents' argument that Brazilian antidumping duties on HECs from the United States, rather than subject imports, account for any injury experienced by the domestic industry. We recognize that the domestic industry's exports accounted for around half of the industry's net shipments during the POI. Contrary to the ACG Respondents' argument, however, the industry's exports increased irregularly by ***

²⁵⁹ CR/PR at Table C-1.

 $^{^{260}}$ Nonsubject imports took *** percentage points of market share from the domestic industry in interim 2024 relative to interim 2023. CR/PR at Table C-1

²⁶¹ As we have explained why nonsubject imports cannot account for the injury we have attributed to subject imports, we reject the ACG Respondents' argument that nonsubject imports from Mexico account for this injury, and Suheung's argument that nonsubject imports made with raw materials produced using forced labor do so. ACG/Custom Capsules/Torpac Postconf. Br. at 37; Suheung Postconf. Br. at 9-10.

²⁶² ACG/Custom Capsules/Torpac Postconf. Br. at 36-37.

²⁶³ CR/PR at Table III-8.

percent from 2021 to 2023, despite Brazil's imposition of antidumping duties on imports for HECs from the United States in May 2023.²⁶⁴ Although the domestic industry's exports were *** percent lower in interim 2024 than in interim 2023, reduced exports cannot explain declines in the industry's performance over the period caused by the loss of *** percentage points of market share to cumulated subject imports in the U.S. market.²⁶⁵

We are also unpersuaded by the ACG Respondents' argument that the domestic industry's own alleged failings – in particular, its long lead times during the pandemic, its failure to supply plant-based HECs, and its poor customer service – explain the market share shift to cumulated subject imports and the industry's consequent injury.²⁶⁶ While we intend to further examine these issues in any final phase of these investigations, the available evidence in the preliminary phase of these investigations appears to indicate that lead times during the pandemic were similar as between domestic producers and subject importers. Specifically, Lonza submitted an affidavit from Michael Goetter, Vice President and Regional Unit Head for the Americas, as well as supporting contemporaneous business documentation, indicating that its lead times during the pandemic were similar to those offered by subject producers.²⁶⁷ An ACG representative also testified at the staff conference that ACG's lead times were similar to those reported by Lonza during the pandemic.²⁶⁸ Lonza has further indicated, and no party has disputed, that the domestic industry's lead times returned to normal in 2023.²⁶⁹ Accordingly, the domestic industry's extended lead times during the COVID-19 pandemic do not appear to explain its loss of market share to cumulated subject imports during the POI.

Regarding the domestic industry's alleged failure to supply plant-based HECs, we note as an initial matter that the industry did supply appreciable volumes of plant-based capsules during the POI, with such capsules accounting for *** percent of the industry's U.S. shipments

²⁶⁴ CR/PR at VII-28 and Table III-8.

²⁶⁵ CR/PR at II-6 and Table III-8. The industry's U.S. shipments accounted for *** percent of the industry's total shipments in interim 2024. *Id.* at Table III-8.

²⁶⁶ ACG/Custom Capsules/Torpac Postconf. Br. at 35.

²⁶⁷ See Exhibit 3 to Petitioner's Postconf. Br. (affidavit of Michael Goetter) at paras. 3-5.

²⁶⁸ See Tr. at 115 (Singh) (stating ACG's pandemic-era lead times were 48 weeks). This is in line with Lonza's *** lead times during the pandemic. See Exhibit 3 to Petitioner's Postconf. Br. (affidavit of Michael Goetter) at paras. 3-5. The ACG Respondents assert that Mr. Singh "misstated" ACG's lead times at the conference. ACG/Custom Capsules/Torpac Postconf. Br. at 31. As indicated, we intend to further examine lead time issues in any final phase of these investigations.

²⁶⁹ See Exhibit 3 to Petitioner's Postconf. Br. (affidavit of Michael Goetter) at paras. 3-5 and attachment 1 (results of Lonza's Net Promoter Score customer satisfaction survey concerning lead times, among other topics).

in 2023.²⁷⁰ Additionally, the record indicates that gelatin-based HECs, not plant-based HECs, "are the most popular type of HEC."²⁷¹ Consequently, the record of the preliminary phase of these investigations does not appear to support the ACG Respondents' contention that plant-based HECs have grown in popularity such that the domestic industry's alleged failure to supply sufficient volumes of them could explain the market share shift from the domestic industry to cumulated subject imports during the POI.

Regarding the domestic industry's allegedly poor customer service, Lonza has provided multiple customer survey responses indicating that Lonza provided good customer service. ²⁷² In any event, purchasers did not identify any factors pertaining to customer service, such as customer support and technical services, as among the top factors influencing their purchasing decisions. ²⁷³ Thus, the record of the preliminary phase of these investigations does not appear to indicate that differences in customer service account for the shift in market share from the domestic industry to cumulated subject imports.

Finally, we are unpersuaded by the ACG Respondents' argument that cumulated subject imports could not have injured the domestic industry because they consisted largely of plant-based HECs, while the domestic industry focuses on gelatin-based HECs, and included HECs above 1.45 mL that the industry does not produce.²⁷⁴ As discussed in Sections III.B.1. and VII.B.3. above, the record indicates that plant- and gelatin-based HECs share many of the same physical characteristics, being produced to the same standards, and may be used in the same applications. Additionally, contrary to the ACG Respondents' assertion, *** percent of cumulated subject import shipments in 2023 consisted of gelatin-based HECs that would have competed directly with gelatin-based HECs produced by the domestic industry.²⁷⁵ For these reasons, among others, we have found that there is at least a moderate degree of substitutability between subject imports and the domestic like product. Furthermore, as discussed in Section VII.B.3. above, the record indicates that HECs above 1.45 mL account for a very small portion of the U.S. market.

In sum, based on the record in the preliminary phase of these investigations, we determine that there is a reasonable indication that an industry in the United States is materially injured by reason of cumulated subject imports.

²⁷⁰ CR/PR at Table IV-7.

²⁷¹ CR/PR at I-6.

²⁷² See Attachment 1 to Exhibit 3 to Petitioner's Postconf. Br. (affidavit of Michael Goetter).

²⁷³ CR/PR at Table II-5.

²⁷⁴ ACG/Custom Capsules/Torpac Postconf. Br. at 38-39.

²⁷⁵ CR/PR at Table IV-7.

VIII. Threat of Material Injury by Reason of Subject Imports from Brazil

C. Legal Standard

Section 771(7)(F) of the Tariff Act directs the Commission to determine whether the U.S. industry is threatened with material injury by reason of the subject imports by analyzing whether "further dumped or subsidized imports are imminent and whether material injury by reason of imports would occur unless an order is issued or a suspension agreement is accepted." The Commission may not make such a determination "on the basis of mere conjecture or supposition," and considers the threat factors "as a whole" in making its determination whether dumped or subsidized imports are imminent and whether material injury by reason of subject imports would occur unless an order is issued. In making our determination, we consider all statutory threat factors that are relevant to these investigations.

²⁷⁶ 19 U.S.C. § 1677(7)(F)(ii).

²⁷⁷ 19 U.S.C. § 1677(7)(F)(ii).

²⁷⁸ These factors are as follows:

⁽I) if a countervailable subsidy is involved, such information as may be presented to it by the administering authority as to the nature of the subsidy (particularly as to whether the countervailable subsidy is a subsidy described in Article 3 or 6.1 of the Subsidies Agreement) and whether imports of the subject merchandise are likely to increase,

⁽II) any existing unused production capacity or imminent, substantial increase in production capacity in the exporting country indicating the likelihood of substantially increased imports of the subject merchandise into the United States, taking into account the availability of other export markets to absorb any additional exports,

⁽III) a significant rate of increase of the volume or market penetration of imports of the subject merchandise indicating the likelihood of substantially increased imports,

⁽IV) whether imports of the subject merchandise are entering at prices that are likely to have a significant depressing or suppressing effect on domestic prices and are likely to increase demand for further imports,

⁽V) inventories of the subject merchandise,

⁽VI) the potential for product-shifting if production facilities in the foreign country, which can be used to produce the subject merchandise, are currently being used to produce other products,

⁽VIII) the actual and potential negative effects on the existing development and production efforts of the domestic industry, including efforts to develop a derivative or more advanced version of the domestic like product, and

⁽IX) any other demonstrable adverse trends that indicate the probability that there is likely to be material injury by reason of imports (or sale for importation) of the subject merchandise (whether or not it is actually being imported at the time).

D. Cumulation for Threat

Under section 771(7)(H) of the Tariff Act, the Commission may "to the extent practicable" cumulatively assess the volume and price effects of subject imports from all countries as to which petitions were filed on the same day if the requirements for cumulation in the material injury context are satisfied.²⁷⁹

Lonza argues that the Commission should exercise its discretion to cumulate imports from all subject sources, including Brazil, for purposes of any reasonable indication of threat analysis for the same reasons that it should cumulate subject imports for purposes of its reasonable indication of material injury analysis.²⁸⁰

The ACG Respondents confirmed at the staff conference that they are not contesting cumulation for purposes of the preliminary phase of these investigations. Suheung argues that subject imports from Vietnam should not be cumulated for threat because these imports allegedly serve customers that the domestic industry is incapable of serving.

As discussed above in Section VI.B., the petitions for these investigations were filed on the same day, and there is a reasonable overlap of competition between subject imports from China, India, and Vietnam, and among imports from each of these sources and the domestic like product. The record also indicates that the domestic industry competed with subject imports from Vietnam for sales to the same customers, contrary to Suheung's argument. There is no information on the record to suggest that the reasonable overlap of competition between and among imports from these subject sources and the domestic like product will not continue into the imminent future. ²⁸³

We also find that there will likely be a reasonable overlap of competition between and among subject imports from Brazil, subject imports from other sources, and the domestic like product. The record indicates that subject imports from Brazil are generally fungible with

¹⁹ U.S.C. § 1677(7)(F)(i). To organize our analysis, we discuss the applicable statutory threat factors using the same volume/price/impact framework that applies to our material injury analysis. Statutory threat factors (I), (II), (III), (V), and (VI) are discussed in the analysis of subject import volume. Statutory threat factor (IV) is discussed in the analysis of subject import price effects. Statutory factors (VIII) and (IX) are discussed in the analysis of impact. Statutory factor (VII) concerning agricultural products is inapplicable to this investigation.

²⁷⁹ 19 U.S.C. § 1677(7)(H).

²⁸⁰ Petitioner's Postconf. Br. at 18.

²⁸¹ See Conf. Tr. at 106 (Levinson).

²⁸² Suheung Postconf. Br. at 9, 11.

²⁸³ We reject Suheung's argument against cumulating subject imports from Vietnam for threat for the same reasons as we did so in the present material injury context.

subject imports from other sources and the domestic like product.²⁸⁴ Subject imports from Brazil overlapped with subject imports from other sources and the domestic like product in terms of channels of distribution and geographic markets, and were simultaneously present in the U.S. market with them.²⁸⁵ Based on this information, we find that the reasonable overlap of competition between and among subject imports from Brazil, subject imports from other sources, and the domestic like product is likely to continue into the imminent future.

We recognize the potential for some differences in the likely conditions of competition for subject imports from Brazil, including that ***, ²⁸⁶ and that ***. ²⁸⁷ However, we find these insufficient to warrant considering subject imports from Brazil separately for purposes of our threat analysis. Indeed, ***. Additionally, although ***, this is not the *** Brazilian producer, and indeed was the *** for which the Commission has data, nor is ***. ²⁸⁸ We therefore exercise our discretion to cumulate subject imports from Brazil, China, India, and Vietnam for our analysis of whether there is a reasonable indication of a threat of material injury to the domestic industry by reason of imports from Brazil.

E. Analysis of Threat of Material Injury Factors

1. Nature of the Subsidies

Commerce initiated a countervailing duty investigation on HECs from Brazil based on all 18 alleged subsidy programs. ²⁸⁹ Commerce initiated a countervailing duty investigation on HECs

²⁸⁴ CR/PR at Tables II-6-7.

²⁸⁵ CR/PR at Tables II-1-2; Table IV-9; Tables V-3-6.

²⁸⁶ CR/PR at Table III-4.

²⁸⁷ CR/PR at Table IV-3.

²⁸⁸ CR/PR at Table VII-2; Table III-1.

Republic of Vietnam: Initiation of Countervailing Duty Investigations, 89 Fed. Reg. 91680 (Nov. 20, 2024). The 18 alleged subsidy programs on which Commerce initiated its investigation are: Reintegra; Lei do Bem Research and Development (R&D) Tax Deduction Program; Sectoral Tax Treatment (TTS MG); ProGoiás – Goiás; Reduction of the ICMS Calculation Basis – Goiás; Tax Incentives to Encourage Local Investment – Pouso Alegre Municipality; Municipal Tax Exemptions – Anápolis Municipality; Brazil's National Bank for Economic and Social Development (BNDES) Finem – Production of Drugs and Medicines (BNDES Profarma); Research and Development Incentives INOVA Brasil Program; Export Financing from Banco de Brasil; Export Credit Insurance (ECI) Program; Constitutional Fund for Financing the Central-West (FCO); Pró-Inovação Program – Minas Gerais; Produzir – Programa de Desenvolvimento Industrial de Goiás; Export Promotion and Marketing Assistance; Provision of Electricity for Less Than Adequate Remuneration (LTAR); and Provision of Earthmoving Services for LTAR – Anápolis Municipality

from China based on 18 of the 19 alleged subsidy programs.²⁹⁰ Commerce initiated a countervailing duty investigation on HECs from India based on 22 of the 23 alleged subsidy programs.²⁹¹ Commerce initiated a countervailing duty investigation on HECs from Vietnam based on all 26 alleged subsidy programs.²⁹²

Access Road Funding—Pouso Alegre Municipality. *See* Hard Empty Capsules from Brazil: Enforcement and Compliance Office Of AD/CVD Operations Countervailing Duty Investigation Initiation Checklist, November 13, 2024.

²⁹⁰ Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Initiation of Countervailing Duty Investigations, 89 Fed. Reg. 91680 (Nov. 20, 2024). The 18 alleged subsidy programs on which Commerce initiated its investigation are: Income Tax Reductions for High-and New-Technology Enterprises; Enterprise Income Tax Law, Research and Development Program; Preferential Income Tax for Comprehensive Utilization Entitling Enterprise; Import Tariff Exemptions for Imported Equipment in Encouraged Industries; Policy Loans to the HEC Industry; Export Loans from Chinese State-Owned Banks; Export Seller's Credit; Export Buyer's Credit Program; Export Credit Insurance Subsidies Program; Export Credit Guarantees Program; Export Assistance Grants; Subsidies for Development of Famous Brands; Grants for Retiring/Replacing Outdated Capacity; Small and Medium-Sized Enterprises (SME) International Market Exploration Fund; Provision of Electricity for LTAR; Provision of Land-Use Rights to HEC Producers; and Land-Use Right in Industrial and Other Special Economic Zones; Land-Use Rights for Foreign-Invested Enterprises (FIEs). See Hard Empty Capsules from the People's Republic of China: Enforcement and Compliance Office Of AD/CVD Operations Countervailing Duty Investigation Initiation Checklist, November 13, 2024.

²⁹¹ Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Initiation of Countervailing Duty Investigations, 89 Fed. Reg. 91680 (Nov. 20, 2024). The 22 alleged subsidy programs on which Commerce initiated its investigation are: Status Holders Incentive Scrip (SHIS) Program (GOI Program); Duty Drawback (DDB) (GOI Program); Export Promotion of Capital Goods Scheme (EPCGS) (GOI Program); Merchandise Exports from India Scheme (MEIS) (GOI Program); Duty Free Import Authorization (DFIA) (GOI Program); Advance Authorization Program/Advance License Program (AAP) (GOI Program); Remission of Duties and Taxes on Export Products (RoDTEP) (GOI Program); Section 35(1)(iv) of the Income Tax Act (GOI Program); State Government of Gujarat Preferential Water Rates; State Government of Madhya Pradesh Sales Tax Incentive; State Government of Maharashtra Waiver of Stamp Duty; State Government of Maharashtra Electricity Duty Exemption; State Government of Punjab (SGOP) Electricity Duty Exemption; SGOP Property Tax Incentive; SGOP Exemption from Taxes on Raw Materials; State Government of Punjab State Goods and Services Tax (SGST) Reimbursement; Interest Equalization Scheme for Export Financing (IES) (GOI Program); Pre- and Post-Export Financing from the Export Import Bank of India (GOI Program); State Government of Gujarat Provision of Land LTAR; Status Certificate Program (GOI Program); Renewable Energy Certification (RECs) (GOI Program); and Production-Linked Incentive (PLI) Scheme (GOI Program). See Hard Empty Capsules from India: Enforcement and Compliance Office Of AD/CVD Operations Countervailing Duty Investigation Initiation Checklist, November 13, 2024.

²⁹² Hard Empty Capsules from Brazil, the People's Republic of China, India, and the Socialist Republic of Vietnam: Initiation of Countervailing Duty Investigations, 89 Fed. Reg. 91680 (Nov. 20, 2024). The 26 alleged subsidy programs on which Commerce initiated its investigation are: Income Tax

2. Likely Volume

As discussed in Section VII.C. above, we have found on a cumulated basis that the volume and the increase in volume of subject imports from China, India, and Vietnam are significant in both absolute terms and relative to apparent U.S. consumption and production. Including subject imports from Brazil, the volume of cumulated subject imports increased overall by *** percent from 2021 to 2023, increasing from *** units in 2021 to *** units in 2022 and then decreasing to *** units in 2023; they were *** percent greater in interim 2024, at *** units, than in interim 2023, at *** units. 293 Cumulated subject imports' share of apparent U.S. consumption increased by *** percentage points from 2021 to 2023, from *** percent in 2021 to *** percent in 2022 and *** percent in 2023; their share was *** percentage points greater in interim 2024, at *** percent, than in interim 2023, at *** percent.²⁹⁴ Cumulated subject imports relative to production in the United States increased overall by *** percentage points from 2021 to 2023, increasing from *** percent in 2021 to *** percent in 2022, then decreasing to *** percent in 2023. Cumulated subject imports relative to production in the United States were *** percentage points greater in interim 2024, at *** percent, than in interim 2023, at *** percent. 295 We find that cumulated subject imports are likely to maintain a significant presence in the U.S. market, and that the significant

Preferences for Encouraged Industries; Income Tax Preferences for Enterprises in Special Zones; Income Tax Preferences Under Law 14/2008; Tax Benefits for New Investments; Accelerated Depreciation and Increases of Deductible Expenses; Preferential Lending to Exporters by State-Owned Commercial Banks (SOCBs); Export Factoring by SOCBs; Guarantees for Export Activities from SOCBs; Investment Credits from the Vietnam Development Bank; Interest Rate Support Program from the State Bank of Vietnam; Export Promotion Grants; Investment Support Grants; Import Duty Exemptions for Imports Used to Produce Exported Goods; Refund for Import Duties on Raw Materials Used to Produce Exports; Exemption of Import Duties for Imports into Industrial Zones; Exemption of Import Duties for Foreign-Invested Enterprises; Import Duty Exemptions on Imported Raw Materials for Export Processing Enterprises and Export Processing Zones; Exemptions of Land-Use Taxes and Levies for Encouraged Industries or Industrial Zones; Exemption or Reduction from Land and Water Rents in Industrial Zones; Land Rent Exemptions and Reductions for Enterprises Located in Special Zones Under Decree No. 35/2022; Exemptions or Reductions of Rent for Foreign-Invested Enterprises; Provision of Electricity for LTAR in Industrial and Export Processing Zones; Provision of Water for LTAR in Long Thanh Industrial Zone; Export-Import Bank of Korea (KEXIM) Performance Guarantees; Export Facilitation Loans; and Overseas Business Facilitation Loans. See Hard Empty Capsules from the Socialist Republic of Vietnam: Enforcement and Compliance Office Of AD/CVD Operations Countervailing Duty Investigation Initiation Checklist, November 13, 2024.

- ²⁹³ Derived from CR/PR Table IV-2.
- ²⁹⁴ CR/PR at Table C-1.
- ²⁹⁵ Derived from CR/PR Table IV-2

increase in cumulated subject import volume observed during the period of investigation is likely to continue in the imminent future absent relief.

The record of the preliminary phase of these investigations indicates that cumulated subject producers have the ability and the incentive to increase their exports to the United States in the imminent future. Cumulated subject producers increased their capacity from *** units in 2021 to *** units in 2022 and *** units in 2023; their capacity was *** units in interim 2024, up from *** units in interim 2023.²⁹⁶

The cumulated subject producers' rate of capacity utilization decreased from *** percent in 2021 to *** percent in 2022 and *** percent in 2023; their rate was *** percent in interim 2024, compared to *** percent in interim 2023. In 2023, the cumulated subject producers possessed excess capacity of *** units, equivalent to *** percent of apparent U.S. consumption that year. They project that their capacity utilization will increase to 93.1 percent in 2024 and 94.0 percent in 2024, maintaining substantial, if reduced, excess capacity. 299

Cumulated subject producers' end-of-period inventories and U.S. importers' inventories both increased over the POI, with U.S. importers' inventories notably increasing overall by 95.8 percent from 2021 to 2023. In 2023, cumulated subject producers' end-of-period inventories were equivalent to *** percent of apparent U.S. consumption. 301

Cumulated subject producers also have the incentive to increase exports to the United States in the imminent future, given their export orientation and increasing reliance on the U.S. market toward the end of the POI. Cumulated subject producers increased their total exports of HECs from 90.9 billion units in 2021 to 101.7 billion units in 2022 then decreased them to 88.3 billion units in 2023; these exports were significantly higher in interim 2024, at 52.4 billion units, than in interim 2023, at 39.5 billion units. Cumulated subject producers also project that their exports will be at significantly higher levels in both 2024 and 2025, at 107.1 billion units

²⁹⁶ CR/PR at Table VII-9.

²⁹⁷ CR/PR at Table VII-12.

²⁹⁸ Derived from Tables VII-12 and C-1. The record does not indicate that subject producers have the ability to product shift, as no foreign producer reported any out-of-scope production using the same equipment and capacity used to produce HECs. *Id.* at VII-9; VII-23.

²⁹⁹ CR/PR Table VII-12.

³⁰⁰ CR/PR at Table VII-12 (showing end-of-period inventories increasing from 13.1 billion units in 2021 to 16.3 billion units in 2022 and 19.8 billion units in 2023; they were 19.1 billion units in interim 2023 and 19.4 billion units in 2024) and Table VII-18 (showing U.S. importer inventories of *** units in 2021, *** units in 2022, and *** units in 2023; they were *** units in interim 2023 and *** in interim 2024).

³⁰¹ Derived from Tables VII-18 and C-1.

and 115.2 billion, respectively.³⁰² Cumulated subject producers' exports accounted for between 34.3 and 40.8 percent of subject producers' total shipments during the POI.³⁰³ Cumulated subject producers' exports to the United States as a share of their total shipments increased from 16.7 percent in 2021 to 17.1 percent in 2022, before declining to 16.3 percent in 2023; exports to the United States accounted for a greater share of cumulated subject producers' total shipments in interim 2024, at 18.8 percent, than in interim 2023, at 14.4 percent. Shipments to third country export markets as a share of their total shipments increased from 22.2 percent in 2021 to 23.7 percent in 2022 then declined to 20.4 percent in 2023, but were higher in interim 2024, at 23.0 percent, than in interim 2023, at 21.3 percent.³⁰⁴ At the same time, the cumulated subject producers' shipments to home market customers as a share of their total shipments decreased from 55.7 percent in 2021 to 53.8 percent in 2022 then increased to 57.2 percent in 2023, but were lower in interim 2024, at 60.0 percent, than in interim 2023, at 65.7 percent.³⁰⁵ These data indicate that the cumulated subject industries were export oriented during the POI and exported an increasing share of their total shipments to the United States towards the end of the period; a share that is projected to remain elevated in 2024 and 2025 compared to 2023.306

In light of the significant increase in cumulated subject import volume and market share during the POI; the large and increasing capacity of the cumulated subject producers, including substantial excess capacity; the cumulated subject producers substantial inventories; and the cumulated subject producers' export orientation and increasing reliance on the U.S. market toward the end of the POI, we find that there is the likelihood of substantially increased cumulated subject import volume in the imminent future in the absence of relief.

3. Likely Price Effects

As addressed in Section VII.B.3. above, we have found at least a moderate degree of substitutability between subject imports and the domestic like product, and that price is an important factor in purchasing decisions. Additionally, as addressed in Section VII.D., we have found that subject imports from China, India, and Vietnam, on a cumulated basis, undersold the

³⁰² CR/PR at VII-12.

³⁰³ CR/PR at Table VII-12.

³⁰⁴ CR/PR at Table VII-12.

³⁰⁵ CR/PR at Table VII-2.

³⁰⁶ CR/PR at Table VII-2. Subject producers project that their exports to the United States will account for 18.7 percent of their total shipments in 2024 and 17.1 percent in 2025. *Id.*

domestic like product to a significant degree and took market share from the domestic industry. The domestic industry lost *** percentage points of market share to subject imports over the full years of the POI and *** percentage points of market share over the interim periods.

Including subject imports from Brazil, cumulated subject imports undersold the domestic like product in 140 of 141 quarterly comparisons, or in 99.3 percent of the comparisons, at margins ranging from *** percent to *** percent and averaging *** percent.³⁰⁷ In contrast, cumulated subject imports oversold the domestic like product in 1 of 141 quarterly comparisons, or in 0.7 percent of the comparisons, at a margin of *** percent. The cumulated subject import volume that undersold the domestic like product accounted for 99.98 percent of the reported volume of cumulated subject import sales (*** units), and the cumulated subject import volume that oversold the domestic like product accounted for 0.02 percent of the reported volume of cumulated subject import sales (*** units).³⁰⁸ Thus, cumulated subject imports nearly universally undersold the domestic like product on both a quarterly and volume basis during the POI.

In the absence of any evidence that the pattern of subject import underselling is likely to change, we find that cumulated subject imports are likely to continue to significantly undersell the domestic like product in the imminent future. Given the at least moderate degree of substitutability between subject imports and the domestic like product and the importance of price to purchasers, we find that the significant subject import underselling that is likely would increase demand for further imports in the imminent future, thereby contributing to an additional shift in market share from the domestic industry to subject imports, and/or result in subject imports entering at prices that are likely to have a significant depressing or suppressing effect on domestic prices.

4. Likely Impact

As discussed in Section VII.E. above, based on the record in the preliminary phase of these investigations, we have found that, as cumulated subject imports increased significantly during the period, driven by significant underselling, they took sales and captured *** percentage points of market share from the domestic industry from 2021 to 2023, and *** percentage points of market share from the industry in interim 2024 compared to interim

³⁰⁷ CR/PR at Table V-8.

³⁰⁸ CR/PR at Table V-8.

2023.³⁰⁹ Including subject imports from Brazil, cumulated subject imports captured *** percentage points of market share from the domestic industry from 2021 to 2023 and *** percentage points of market share from the industry in interim 2024 compared to interim 2023.³¹⁰ As subject imports took market share from the domestic industry, the industry's production, employment, and financial performance deteriorated significantly during the POI, and particularly in interim 2024 compared to interim 2023, despite apparent U.S. consumption being *** percent higher in interim 2024 than in interim 2023.

In light of our findings that cumulated subject import volume is likely to increase further from already significant levels and continue to undersell the domestic like product, and particularly given the declines in the domestic industry's performance in the interim period, we conclude that cumulated subject imports would likely have a significant impact on the domestic industry in the imminent future, in the absence of relief. Specifically, the likely increased volumes of low-priced cumulated subject imports would likely depress or suppress domestic prices and/or displace sales of the domestic like product and cause the domestic industry to lose additional market share, adversely affecting the domestic industry's production, employment, revenues, and financial performance. *** responding U.S. producers reported anticipating negative effects from subject imports in the absence of relief.³¹¹

We have also considered whether factors other than subject imports threaten to injure the domestic industry. As discussed in Section VII.E. above, nonsubject imports had a significant presence in the U.S. market during the POI and increased their share of apparent U.S. consumption in interim 2024 compared to interim 2023 at the domestic industry's expense. Additionally, Brazil's imposition of antidumping duties on HECs from the United States in May 2023 was accompanied by a *** percent decline in the domestic industry's exports in interim 2024 compared to interim 2023. Nevertheless, just as nonsubject imports and decreased domestic industry exports do not explain the injury caused by the domestic industry's loss of market share to low-priced cumulated subject imports over the interim periods, they cannot explain the injury that would likely be caused by the significant increase in low-priced cumulated subject import volume that is likely in the imminent future absent relief. As discussed in Section VII.B.1 above, although apparent U.S. consumption declined by *** percent from 2021 to 2023, all parties agree that after demand spiked in 2021 due to the COVID-19 pandemic and then declined through 2023, as purchasers destocked, demand

³⁰⁹ CR/PR at Tables IV-10 and C-1.

³¹⁰ CR/PR at Tables IV-10 and C-1.

³¹¹ CR/PR at Tables VI-12-VI-13.

³¹² CR/PR at Table III-8.

normalized in 2023 and is expected to grow at an annual rate in the single digits. Apparent U.S. consumption was *** percent higher in interim 2024 compared to interim 2023.³¹³

In sum, based on the record of the preliminary phase of the investigations, we determine that there is a reasonable indication that an industry in the United States is threatened with material injury by reason of imports of HECs from Brazil.

IX. Conclusion

For the reasons stated above, we determine that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of HECs from China, India, and Vietnam that are allegedly sold in the United States at less than fair value and subsidized by the governments of China, India, and Vietnam. We also determine that there is a reasonable indication that an industry in the United States is threatened with material injury by reason of imports of HECs from Brazil that are allegedly sold at less than fair value and subsidized by the government of Brazil.

³¹³ CR/PR at Table C-1.

Part I: Introduction

Background

These investigations result from petitions filed with the U.S. Department of Commerce ("Commerce") and the U.S. International Trade Commission ("USITC" or "Commission") by Lonza Greenwood LLC ("Lonza"), Greenwood, South Carolina, on October 24, 2024, alleging that an industry in the United States is materially injured and threatened with material injury by reason of subsidized and less-than-fair-value ("LTFV") imports of hard empty capsules ("HECs")¹ from Brazil, China, India, and Vietnam. Table I-1 presents information relating to the background of these investigations.²

Table I-1
HECs: Information relating to the background and schedule of this proceeding

Effective date	Action
	Petitions filed with Commerce and the Commission; institution of the
October 24, 2024	Commission investigations (89 FR 86370, October 30, 2024)
November 14, 2024	Commission's conference
	Commerce's notice of initiation (89 FR 91680 and 89 FR 91684,
November 13, 2024	November 20, 2024)
December 6, 2024	Commission's vote
December 9, 2024	Commission's determinations
December 16, 2024	Commission's views

¹ See the section entitled "The subject merchandise" in Part I of this report for a complete description of the merchandise subject in this proceeding.

² Pertinent Federal Register notices are referenced in appendix A, and may be found at the Commission's website (www.usitc.gov).

³ A list of witnesses appearing at the conference is presented in appendix B of this report.

Statutory criteria

Section 771(7)(B) of the Tariff Act of 1930 (the "Act") (19 U.S.C. § 1677(7)(B)) provides that in making its determinations of injury to an industry in the United States, the Commission--

shall consider (I) the volume of imports of the subject merchandise, (II) the effect of imports of that merchandise on prices in the United States for domestic like products, and (III) the impact of imports of such merchandise on domestic producers of domestic like products, but only in the context of production operations within the United States; and. . . may consider such other economic factors as are relevant to the determination regarding whether there is material injury by reason of imports.

Section 771(7)(C) of the Act (19 U.S.C. § 1677(7)(C)) further provides that--4

In evaluating the volume of imports of merchandise, the Commission shall consider whether the volume of imports of the merchandise, or any increase in that volume, either in absolute terms or relative to production or consumption in the United States is significant.... In evaluating the effect of imports of such merchandise on prices, the Commission shall consider whether. . .(I) there has been significant price underselling by the imported merchandise as compared with the price of domestic like products of the United States, and (II) the effect of imports of such merchandise otherwise depresses prices to a significant degree or prevents price increases, which otherwise would have occurred, to a significant degree.... In examining the impact required to be considered under subparagraph (B)(i)(III), the Commission shall evaluate (within the context of the business cycle and conditions of competition that are distinctive to the affected industry) all relevant economic factors which have a bearing on the state of the industry in the United States, including, but not limited to. . . (I) actual and potential decline in output, sales, market share, gross profits, operating profits, net profits, ability to service debt, productivity, return on investments, return on assets, and utilization of capacity, (II) factors affecting domestic prices, (III) actual and potential negative effects on cash flow, inventories, employment, wages, growth, ability to raise capital, and investment, (IV) actual and potential negative effects on the existing development and production efforts of the domestic industry, including efforts to develop a derivative or more advanced version of the domestic like product, and (V) in {an antidumping investigation}, the magnitude of the margin of dumping.

⁴ Amended by PL 114-27 (as signed, June 29, 2015), Trade Preferences Extension Act of 2015.

In addition, Section 771(7)(J) of the Act (19 U.S.C. § 1677(7)(J)) provides that -5

(J) EFFECT OF PROFITABILITY.—The Commission may not determine that there is no material injury or threat of material injury to an industry in the United States merely because that industry is profitable or because the performance of that industry has recently improved.

Organization of report

Part I of this report presents information on the subject merchandise, alleged subsidy/dumping margins, and domestic like product. Part II of this report presents information on conditions of competition and other relevant economic factors. Part III presents information on the condition of the U.S. industry, including data on capacity, production, shipments, inventories, and employment. Parts IV and V present the volume of subject imports and pricing of domestic and imported products, respectively. Part VI presents information on the financial experience of U.S. producers. Part VII presents the statutory requirements and information obtained for use in the Commission's consideration of the question of threat of material injury as well as information regarding nonsubject countries.

Market summary

HECs are generally used to hold and deliver medicine. The leading U.S. producer of HECs is Lonza, while leading producers of HECs outside the United States include ACG do Brasil S.A. ("ACG Brazil") of Brazil, Suzhou Capsugel Ltd. ("Suzhou") of China, ACG Associated Capsules Private Limited ("ACG Associated") of India, and Suheung Vietnam Co., Ltd. ("Suheung") of Vietnam. The leading U.S. importer of HECs from Brazil and India is ACG North America LLC ("ACG North America"); the leading U.S. importers of HECs from China are Bright Pharma Caps Inc. ("Bright Pharma Caps") and SD Head USA LLC ("SD Head USA"); and the leading U.S. importer of HECs from Vietnam is Suheung-America Corp ("Suheung-America"). The leading importer of HECs from nonsubject countries is Lonza. A large majority of Lonza's imports are from ***. U.S. purchasers of HECs are firms that produce pharmaceuticals and nutraceuticals, and leading purchasers include ***.

Apparent U.S. consumption of HECs totaled approximately *** units (\$***) in 2023. Currently, two firms are known to produce HECs in the United States. U.S. producers' U.S. shipments of HECs totaled *** units (\$***) in 2023, and

⁵ Amended by PL 114-27 (as signed, June 29, 2015), Trade Preferences Extension Act of 2015.

accounted for *** percent of apparent U.S. consumption by quantity and *** percent by value. U.S. imports from subject sources totaled *** units (\$***) in 2023 and accounted for *** percent of apparent U.S. consumption by quantity and *** percent by value. U.S. imports from nonsubject sources totaled *** units (\$***) in 2023 and accounted for *** percent of apparent U.S. consumption by quantity and *** percent by value.

Summary data and data sources

A summary of data collected in these investigations is presented in appendix C, table C-1. Except as noted, U.S. industry data are based on questionnaire responses of two firms that accounted for all known U.S. production of HECs during 2023. U.S. imports are based on questionnaire data.

Previous and related investigations

HECs have not been the subject of prior countervailing and antidumping duty investigations in the United States.

Nature and extent of alleged subsidies and sales at LTFV

Alleged subsidies

On November 20, 2024, Commerce published a notice in the Federal Register of the initiation of its countervailing duty investigations on HECs from Brazil, China, India, and Vietnam.⁶

Alleged sales at LTFV

On November 20, 2024, Commerce published a notice in the Federal Register of the initiation of its antidumping duty investigations on HECs from Brazil, China, India, and Vietnam. Commerce has initiated antidumping duty investigations based on estimated dumping margins of 78.52 to 99.11 percent for HECs from Brazil, 128.01 to 158.04 percent for HECs from China, 54.81 to 82.95 percent for HECs from India, and 63.53 percent to 86.04 percent for HECs from Vietnam.

⁶ For further information on the alleged subsidy programs see Commerce's notice of initiation and related CVD Initiation Checklist. 89 FR 91680, November 20, 2024.

⁷ 89 FR 91684, November 20, 2024.

The subject merchandise

Commerce's scope

In the current proceeding, Commerce has defined the scope as follows:8

The merchandise subject to the scope of these investigations is hard empty capsules, which are comprised of two prefabricated, hollowed cylindrical sections (cap and body). The cap and body pieces each have one closed and rounded end and one open end, and are constructed with different or equal diameters at their open ends.

Hard empty capsules are unfilled cylindrical shells composed of at least 80 percent by weight of a water soluble polymer that is considered non-toxic and appropriate for human or animal consumption by the United States Pharmacopeia—National Formulary (USP—NF), Food Chemical Codex (FCC), or equivalent standards. The most common polymer materials in HECs are gelatin derived from animal collagen (including, but not limited to, pig, cow, or fish collagen), hydroxypropyl methylcellulose (HPMC), and pullulan.

Hard empty capsules may also contain water and additives, such as opacifiers, colorants, processing aids, controlled release agents, plasticizers, and preservatives. Hard empty capsules may also be imprinted or otherwise decorated with markings.

Hard empty capsules are covered by the scope of these investigations regardless of polymer material, additives, transparency, opacity, color, imprinting, or other markings.

Hard empty capsules are also covered by the scope of these investigations regardless of their size, weight, length, diameter, thickness, and filling capacity.

Cap and body pieces of hard empty capsules are covered by the scope of these investigations regardless of whether they are imported together or separately, and regardless of whether they are imported in attached or detached form.

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⁸ 89 FR 91680, November 20, 2024.

Hard empty capsules covered by the scope of these investigations are those that disintegrate in water within 2 hours under tests specified in Chapter 701 of the USP–NF, or equivalent disintegration tests.

Tariff treatment

Based upon the scope set forth by Commerce, information available to the Commission indicates that the merchandise subject to these investigations is imported under statistical reporting numbers 9602.00.1040 and 9602.00.5010 of the Harmonized Tariff Schedule of the United States ("HTS").9 The general rate of duty is 3 percent ad valorem for HTS subheading 9602.00.10 and 2.7 percent ad valorem for HTS subheading 9602.00.50. Decisions on the tariff classification and treatment of imported goods are within the authority of U.S. Customs and Border Protection.

Effective February 14, 2020, products of China within the scope of this petition that are provided for in HTS subheadings 9602.00.10 and 9602.00.50 have been subject to additional 7.5 percent ad valorem Section 301 duties under heading 9903.88.15.

The product

Description and applications

HECs are hard, cylindrical shells with a cap (shorter part) and a body (longer part). 9

Both pieces have one closed, rounded end and one open end with rings or indentations for interlocking (figure I-1). 10 The joined pieces – primarily derived from either gelatin or plant-based polymers – form a hermetically sealed chamber for substances, including powdered, liquid, viscous, or granular materials. 11 Gelatin capsules are the most popular type of HEC, and are produced with the collagen of cows, pigs, and sometimes fish. 12 Plant-based polymers, such as hydroxypropyl methylcellulose (HPMC) and pullulan, are derived from fibrous plant

⁹ Petition, p. 3.

¹⁰ Lonza Technical Reference File, 2023, 9.

¹¹ Kline & Company, "Empty Hard Capsules: United States, 2021-2022, forecast to 2027 (Q1 2023)," 2023, p. 9.

¹² Petition, p. 11.

materials.¹³ HECs are available in a variety of sizes, which typically range from size 5 (approximately 11 mm closed length) to size 000 (approximately 26 mm closed length).¹⁴ HECs also vary according to weight, length, diameter, and filling capacity.¹⁵

In the United States, pharmaceutical and nutrition companies use HECs as vehicles to deliver formulations as finished products to patients and consumers. ¹⁶ Companies may design HECs for either an immediate or delayed release of their contents upon consumption. ¹⁷ Companies also manufacture HECs in many colors, color combinations and opacity levels, and frequently imprint them with the brand or contents. ¹⁸

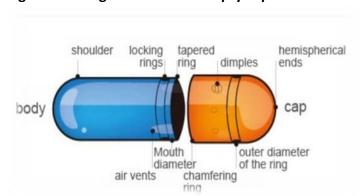


Figure I-1: Diagram of a hard empty capsule

Source: Adinath International

¹³ Petition, p. 11.

¹⁴ Petition, p. 13.

¹⁵ Petition, p. 13.

¹⁶ The tasteless and odorless capsules also enable more precise dosing and make medicine and supplements easier to consume.

¹⁷ Petition, p. 13.

¹⁸ Although HECs must meet standards (e.g., weights, cap and body lengths), minor differences in factors such as cap and body profiles and tooling dimensions may lead to varying performance during capsule filling. Tablets & Capsules, "Requirements for the Use," June 1, 2024, <a href="https://www.tabletscapsules.com/3641-Technical-Articles/613476-Requirements-For-the-Use-of-Alternative-Empty-Hard-Gelatin-Capsule-Suppliers-for-the-Manufacture-of-Pharmaceutical-Products/#:~:text=Though%20empty%20hard%20gelatin%20capsules,tooling%20dimensions%20may%20result%20inPerformance%20standard.

Manufacturing processes

HECs of all polymer types are produced in several main stages (figure I-2). The manufacturing process for hard gelatin capsules begins with the preparation of a gelatin solution, which is dip coated on metal pins. ¹⁹ The dip-coated pins are then spun and rotated. They proceed to the next stage of the process, drying, in a series of kilns. ²⁰ After the moisture content is reduced to the necessary level, the shaped material is stripped from the metal pins, and formed into cap and body pieces. The pieces are then cut and finished in cylinders of specified lengths which are imprinted with information such as the type or dose of the medicine the finished capsule will contain. ²¹ After completing quality testing, manufacturers supply the finished empty cap and body to pharmaceutical and nutritional companies, which fill them with medications and supplements, respectively, and then join and package the capsules for distribution. ²²

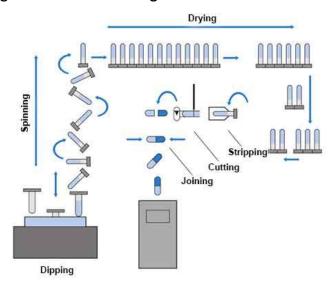
¹⁹ Adinath International, "Hard Gelatin Capsule Manufacturing," (accessed November 20, 2024, https://www.adinath.co.in/hard-gelatin-capsule-step-by-step-manufacturing-process/#

²⁰ Adinath International, "Hard Gelatin Capsule Manufacturing," (accessed November 20, 2024, https://www.adinath.co.in/hard-gelatin-capsule-step-by-step-manufacturing-process/#; Gelita, "Hard Capsules," (accessed November 19, 2024), Hard Capsules everything you need to know | Gelita.

²¹ Adinath International, "Hard Gelatin Capsule Manufacturing," (accessed November 20, 2024, https://www.adinath.co.in/hard-gelatin-capsule-step-by-step-manufacturing-process/#

²² iPharmachine, "Capsule Manufacturing Process," (accessed November 21, 2024), <u>A Complete Guide To Capsule Manufacturing Process - IPharmachine</u>.

Figure I-2: Manufacturing Process for Hard Gelatin Capsules



Source: Adinath International

Domestic and foreign HEC manufacturing processes are similar in some areas and different in others. Similarities exist, for example, in the use of gelatin or plant-based materials in a two-piece capsule design. Additionally, both domestic and foreign HEC manufacturers need to meet Food and Drug Administration (FDA) requirements for pharmaceutical capsules when sold in the U.S. market.²³ However, U.S. and foreign HEC manufacturing processes differ in areas such as quality control, materials, and cost.²⁴

²³The FDA monitors and enforces the U.S. Pharmacopeia-National Formulary standards for medicines manufactured and marketed in the United States. U.S. Pharmacopeia, "Legal Recognition – Standards," (accessed November 24, 2024), https://www.usp.org/about/legal-recognition/standard-categories.

²⁴ Tablets & Capsules, Vol. 18, No. 6, "Capsules: Gelatin Supply Disruptions," September 10, 2020, September 2020.

Domestic like product issues

The petitioner proposes the Commission define a single domestic like product that is co-extensive with the scope of HECs. ²⁵ Respondent Associated Capsules Group ("Respondent ACG") argues the Commission should find gelatin capsules and vegetable-based capsules to be separate like products. ²⁶ Respondent ACG argues gelatin capsules and vegetable-based capsules are distinguished by "clear differences in their physical characteristics, including their basic raw material composition, production processes and customer and producer perceptions". ²⁷ Additionally, Respondent ACG argues HECs larger than 1.45 milliliters should be a separate like product as HECs larger than 1.45 milliliters are used in the veterinary market by a different category of customers and are physically different. ²⁸ The respondent testified that no U.S. producer has made large HECs for over 25 years. ²⁹

²⁵ Conference transcript, p. 13 (Pal).

²⁶ Respondent ACG's postconference brief, p. 10.

²⁷ Respondent ACG's postconference brief, p. 11.

²⁸ Respondent ACG's postconference brief, pp. 17-18.

²⁹ Conference transcript, p. 13 (Tahil).

Part II: Conditions of competition in the U.S. market

U.S. market characteristics

HECs are two-piece unfilled cylindrical shells that are composed primarily of a non-toxic, biodegradable, biocompatible, and water-soluble polymer material. They are produced from either animal-derived gelatin or plant-based polymers, such as hydroxypropyl methylcellulose ("HPMC" or "hypromellose") or pullulan. HECs are produced in a variety of sizes with differing weights, lengths, diameters, and filling capacities. HECs promote ease of swallowing, and they may also mask unpleasant taste or odor, hide or improve the appearance of fill material, facilitate blinding in clinical studies, present a unique appearance, and mediate the release time of their contents.

HECs are used by the pharmaceutical and nutraceutical industries.⁴ HECs may be imprinted to identify the manufacturer or brand (or generic) name of the pharmaceutical or nutraceutical product contained inside.⁵ Typically, pharmaceutical manufacturers utilize imprinted HECs while nutraceutical manufacturers do not.⁶ HECs are considered food ingredients, excipients (i.e., non-active ingredients), or even pharmaceuticals, and need to comply with applicable health and safety standards in terms of manufacturing and composition.⁷

*** U.S. producers and 12 of 15 importers indicated that the market was subject to distinctive conditions of competition. Firms reported the following conditions: some downstream products changing from using capsules to powder or tablet forms, differences in machineability, differences between the raw material used in production, increasing imports are driving prices down, new suppliers have entered the market, precision is important, regulatory changes drive new products, existence of market tiers, Lonza shifted its focus in 2021 to high-value pharmaceuticals leaving other customers to seek alternative manufacturers, and the pharmaceutical part of the market is stable while nutraceutical demand is more volatile.

¹ They may also contain additives, colorants and/or opacifying agents, and processing agents. Petition, p. 4.

² Petition, p. 13.

³ Petition, pp. 25 to 26.

⁴ Petition, p. 4.

⁵ Petition, p. 13.

⁶ Petition, p. 26.

⁷ Petition, p. 22.

Apparent U.S. consumption of HECs decreased between 2021 and 2023. Apparent U.S. consumption was higher in January to June 2024 than it had been in January to June 2023.

Impact of section 301 tariffs

U.S. producers and importers were asked to report the impact of section 301 tariffs.

*** reported that the tariffs did not have an impact. In contrast, 7 of the 17 responding importers⁸ reported that the section 301 tariffs had an impact including: duties have reduced the profitability of some importers, duties have reduced sales of HECs imported from China and increased sales from other import sources, and decreased overall demand for HECs.

Channels of distribution

*** sold mainly to pharmaceutical end users and importers of imports from all sources sold mainly to nutraceutical end users, as shown in table II-1. All subject import countries except India sold over 90 percent of their HECs to nutraceutical end users in 2021, 2022, 2023, and during the first half of 2024.

⁸ Three importers reported no impact and seven importers reported that they did not know.

Table II-1 HECs: Share of U.S. shipments by source, channel of distribution, and period

Shares in percent

Shares in percent					_	
	O I .	2024	0000	0000	Jan-Jun	Jan-Jun
Source	Channel	2021	2022	2023	2023	2024
United States	Distributors/retailers					
United States	Pharmaceutical end users	***	***	***	***	***
United States	Nutraceutical end users	***	***	***	***	***
United States	Other end users	***	***	***	***	***
Brazil	Distributors/retailers	***	***	***	***	***
Brazil	Pharmaceutical end users	***	***	***	***	***
Brazil	Nutraceutical end users	***	***	***	***	***
Brazil	Other end users	***	***	***	***	***
China	Distributors/retailers	***	***	***	***	***
China	Pharmaceutical end users	***	***	***	***	***
China	Nutraceutical end users	***	***	***	***	***
China	Other end users	***	***	***	***	***
India	Distributors/retailers	***	***	***	***	***
India	Pharmaceutical end users	***	***	***	***	***
India	Nutraceutical end users	***	***	***	***	***
India	Other end users	***	***	***	***	***
Vietnam	Distributors/retailers	***	***	***	***	***
Vietnam	Pharmaceutical end users	***	***	***	***	***
Vietnam	Nutraceutical end users	***	***	***	***	***
Vietnam	Other end users	***	***	***	***	***
Subject sources	Distributors/retailers	***	***	***	***	***
Subject sources	Pharmaceutical end users	***	***	***	***	***
Subject sources	Nutraceutical end users	***	***	***	***	***
Subject sources	Other end users	***	***	***	***	***
Subject sources less						
Brazil	Distributors/retailers	***	***	***	***	***
Subject sources less						
Brazil	Pharmaceutical end users	***	***	***	***	***
Subject sources less						
Brazil	Nutraceutical end users	***	***	***	***	***
Subject sources less						
Brazil	Other end users	***	***	***	***	***
Nonsubject sources	Distributors/retailers	***	***	***	***	***
Nonsubject sources	Pharmaceutical end users	***	***	***	***	***
Nonsubject sources	Nutraceutical end users	***	***	***	***	***
Nonsubject sources	Other end users	***	***	***	***	***
Nonsubject sources						
plus Brazil	Distributors/retailers	***	***	***	***	***
Nonsubject sources	_ :_:::::::::::::::::::::::::::::::::::					
plus Brazil	Pharmaceutical end users	***	***	***	***	***
Nonsubject sources	amaccanon ona acoro					
plus Brazil	Nutraceutical end users	***	***	***	***	***
Nonsubject sources	TELEGORISCH OHR GOOTS					
plus Brazil	Other end users	***	***	***	***	***
PIGO DIGEN	0 1.101 0114 40010					

Table continued.

Table II-1 Continued

HECs: Share of U.S. shipments by source, channel of distribution, and period

Shares in percent

Source	Channel	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
All import sources	Distributors/retailers	***	***	***	***	***
All import sources	Pharmaceutical end users	***	***	***	***	***
All import sources	Nutraceutical end users	***	***	***	***	***
All import sources	Other end users	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Shares shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Geographic distribution

U.S. producers and importers reported selling HECs to all regions of United States (table II-2). For U.S. producers, *** percent of sales were within 100 miles of their production facility, *** percent were between 101 and 1,000 miles, and *** percent were over 1,000 miles. Importers sold *** percent within 100 miles of their U.S. point of shipment, *** percent between 101 and 1,000 miles, and *** percent over 1,000 miles.

Table II-2
HECs: Count of U.S. producers' and U.S. importers' geographic markets

Region	U.S. producers	Brazil	China	India	Vietnam	Subject sources	Subject sources except Brazil
Northeast	***	***	8	4	***	12	***
Midwest	***	***	5	3	***	9	***
Southeast	***	***	8	4	***	12	***
Central Southwest	***	***	9	3	***	13	***
Mountain	***	***	10	3	***	14	***
Pacific Coast	***	***	11	3	***	15	***
Other	***	***	4	2	***	6	***
All regions (except Other)	***	***	5	3	***	9	***
Reporting firms	2	1	11	4	1	15	15

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Other U.S. markets include AK, HI, PR, and VI.

Supply and demand considerations

U.S. supply

Table II-3 provides a summary of the supply factors regarding HECs from U.S. producers and from subject countries. All responding producers reported that they were not able to produce other products on the same equipment used to produce HECs. U.S. producers reported that a slight majority of shipments in 2023 were to export markets. Producers in Brazil, China, and India reported that most of their shipments were to their respective home markets in 2023 whereas producers in Vietnam reported shipping mainly to export markets.

Table II-3 HECs: Supply factors that affect the ability to increase shipments to the U.S. market, by country

Quantity in million units; ratio and share in percent

Factor	Measure	United States	Brazil	China	India	Vietnam	Subject suppliers	Subject suppliers except Brazil
Capacity 2021	Quantity	***	***	***	***	***	***	***
Capacity 2023	Quantity	***	***	***	***	***	***	***
Capacity utilization 2021	Ratio	***	***	***	***	***	***	***
Capacity utilization 2023	Ratio	***	***	***	***	***	***	***
Inventories to total shipments 2021	Ratio	***	***	***	***	***	***	***
Inventories to total shipments 2023	Ratio	***	***	***	***	***	***	***
Home market shipments 2023	Share	***	***	***	***	***	***	***
Non-US export market shipments 2023	Share	***	***	***	***	***	***	***
Ability to shift production (firms reporting "yes")	Count	***	***	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Responding U.S. producers accounted for virtually all of U.S. production of HECs in 2023. Responding foreign producer/exporter firms accounted for all known U.S. imports of HECs from Brazil during 2023. Responding foreign producer/exporter firms accounted for less than half of U.S. imports of HECs from China during 2023. Responding foreign producer/exporter firms accounted for more than 75 percent of U.S. imports of HECs from India and Vietnam during 2023. For additional data on the number of responding firms and their share of U.S. production and of U.S. imports from each subject country, please refer to Part I, "Summary Data and Data Sources."

Domestic production

Based on available information, U.S. producers of HECs have the ability to respond to changes in demand with large changes in the quantity of shipments of U.S.-produced HECs to the U.S. market. The main contributing factors to this degree of responsiveness of supply are the availability of some unused capacity, the availability of moderate levels of inventories, and ability to shift shipments from alternate markets. A factor mitigating responsiveness of supply is limited ability to shift production to or from alternate products.

While both U.S. production and capacity decreased between 2021 and 2023, capacity decreases outpaced production decreases, resulting in increased capacity utilization. U.S. producers reported that *** of their total shipments were to export markets in 2023. Major export markets include Canada, Mexico, ***.

Subject imports from Brazil

Based on available information, producers of HECs from Brazil have the ability to respond to changes in demand with moderate to large changes in the quantity of shipments of HECs to the U.S. market. The main contributing factors to this degree of responsiveness of supply are the availability of some unused capacity, the availability of some inventories, and some ability to shift shipments from alternate markets. A factor mitigating responsiveness of supply is limited ability to shift production to or from alternate products.

Brazilian capacity increased while production and capacity utilization decreased between 2021 and 2023. Brazilian inventories levels were largely constant throughout the period. Brazilian producers reported that most of their shipments in 2023 were to the Brazilian home market.

Subject imports from China

Based on available information, producers of HECs from China have the ability to respond to changes in demand with moderate to large changes in the quantity of shipments of HECs to the U.S. market. The main contributing factors to this degree of responsiveness of supply are the availability of some unused capacity, the availability of low to moderate levels of inventories, and ability to shift shipments from alternate markets. Factors mitigating responsiveness of supply include limited ability to shift production to or from alternate products.

Chinese capacity increased while production and capacity utilization decreased between 2021 and 2023. Chinese inventories increased throughout the period. Chinese producers reported selling *** of their commercial shipments to markets other than the United States in 2023, with about three-quarters of shipments going to the Chinese home market.

Subject imports from India

Based on available information, producers of HECs from India have the ability to respond to changes in demand with moderate to large changes in the quantity of shipments of HECs to the U.S. market. The main contributing factors to this degree of responsiveness of supply are the availability of some unused capacity, and ability to shift shipments from alternate markets. Factors mitigating responsiveness of supply include limited inventories and limited ability to shift production to or from alternate products.

Indian capacity and production increased between 2021 and 2023 with capacity increasing more than production, resulting in decreased capacity utilization. Indian producers reported that *** percent of shipments in 2023 were to the Indian home market, with the remainder nearly evenly divided between exports to the U.S. market and exports to other markets. Export markets other than the United States include Europe, Asia Pacific, Africa, and the Middle East.

Subject imports from Vietnam

Based on available information, producers of HECs from Vietnam have the ability to respond to changes in demand with moderate changes in the quantity of shipments of HECs to the U.S. market. The main contributing factors to this degree of responsiveness of supply are the availability of a limited amount of unused capacity, the availability of moderate levels of inventories, and ability to shift shipments from alternate markets. Factors mitigating responsiveness of supply include limited ability to shift production to or from alternate products.

Vietnamese capacity and production both increased throughout the period, with production increasing more than capacity leading to an increase in capacity utilization. Vietnamese inventories increased throughout the period. The Vietnamese producer reported shipping mainly to export markets, with shipments to non-U.S. markets comprising about *** percent of total shipments in 2023.

Imports from nonsubject sources

Nonsubject imports accounted for 43.0 percent of total U.S. imports in 2023 according to the questionnaire data which is used in the remainder of this report. Customs data was the only source in which nonsubject imports were available broken out by country. The largest sources of nonsubject imports based on Customs data during January 2021 to June 2024 were Canada, Mexico, and South Korea. Combined, these countries accounted for 86.8 percent of nonsubject imports in 2023.

Supply constraints

*** and 9 of 15 importers reported that they had experienced supply constraints since January 1, 2021. U.S. producer ***. Importers report the COVID-19 pandemic caused major difficulties in the supply chain causing purchasers to seek new sources of supply and place multiple orders (international freight costs were high in 2021 and 2022 with delivery delays of 6 to 9 months). In addition, importers reported that the COVID-19 pandemic caused traditional suppliers to drop some of their customers which turned to imports, the COVID-19 pandemic increased demand for supplements, and Lonza reduced production to upgrade its facilities.

U.S. demand

Based on available information, the overall demand for HECs is likely to experience small changes in response to changes in price. The main contributing factors are the lack of substitute products and the relatively small cost share of HECs in most of its end-use products.

⁹ According to Customs data nonsubject imports accounted for 25.9 percent of total imports in 2023.

End uses and cost share

U.S. demand for HECs depends on the demand for U.S.-produced downstream products. The petitioner stated that demand for HECs for pharmaceutical use is determined by pharmaceutical use in the United States, with the following factors influencing demand for pharmaceuticals: (1) U.S. health trends (including the prevalence of contagious diseases and certain chronic conditions); (2) willingness of U.S. patients to seek medical care and accept prescription treatments; (3) the age distribution of the U.S. population; (4) drug prices; and (5) government healthcare and tax policies that either promote or disincentivize pharmaceutical use.¹⁰

The petitioner claims that U.S. demand for nutraceutical HECs is tied to U.S. demand for products such as dietary supplements and vitamins, mineral supplements, and probiotics. U.S. demand for these products is growing over the long term, because the U.S. population is aging and consumers are increasingly focused on proactive healthcare, such as immune system health, gut and digestive health, neurological health, and weight management.¹¹

HECs account for a small share of the cost of the end-use products in which they are used. Reported cost shares for pharmaceutical use ranged from 1 to 5 percent, for supplements/nutraceuticals ranged from 3 to 50 percent, and for veterinary use ranged from 13 to 34 percent. Petitioner estimates that for inexpensive medicine and nutraceuticals the cost share would range from 1 to 5 percent while for drugs under IP protection it would typically be less than 1 percent. Respondents estimate that the cost share for pharmaceuticals ranged from zero to 2 percent while for nutraceuticals it ranged between 2 and 5 percent. Percent.

¹⁰ Petition, pp. 62 to 63.

¹¹ Petition p. 63.

¹² Conference transcripts pp. 70-71 (Pal).

¹³ Conference transcripts p. 119 (Singh).

Business cycles

*** U.S. producers and the majority of importers (11 of 15) indicated that the market was subject to business cycles. Firms reported seasonal variation in sales and two firms also reported longer-term cycles. *** reported that seasonal viruses and allergies can have an impact on demand for HECs and that economic slowdowns may cause people to reduce supplemental purchases and reduce the use of medicines to save money. Five importers reported seasonality of sales: *** reported lower sales in the third quarter of the year, *** reported that there is a slight increase in the fall due to upcoming cold season and increased demand for immunity boosting or allergy relief products, *** reported that sales are slower in the summer months and around the winter holidays in November and December, *** reported that there is high demand in spring, fall, and winter, and *** reported that people consume more HECs in summer and winter. Another importer, *** reported that there is a larger cycle of 2 to 3 good years of sales followed by 2 to 3 medium years.

Demand trends

U.S. producers had mixed responses regarding changes to domestic and foreign demand since January 1, 2021 (table II-4). The majority of importers reported that domestic and foreign demand had steadily increased or fluctuated up since January 1, 2021.

Table II-4
HECs: Count of firms' responses regarding overall domestic and foreign demand, by firm type

Market	Firm type	Steadily Increase	Fluctuate Up	No change	Fluctuate Down	Steadily Decrease
Domestic demand	U.S. producers	***	***	***	***	***
Domestic demand	Importers	5	8	3	3	1
Foreign demand	U.S. producers	***	***	***	***	***
Foreign demand	Importers	4	4	2	2	0

Petitioner stated that the COVID-19 pandemic caused demand to increase but that demand softened in 2023 and there was a drawdown of HECs purchasers' inventories. ¹⁴ ¹⁵ Petitioner stated that demand for HECs has grown steadily, around 4 percent per year, in the U.S. pharmaceutical and nutraceutical markets over the last 10 years. ¹⁶ Petitioner stated that in 2021 and 2022, growth was slowed by destocking but that demand returned to normal levels in late 2023. ¹⁷

Respondents stated that until 2021 there was heightened demand for product made using HECs and there were major supply chain disruptions with lead times rising to as high as 48 weeks. According to respondents, in 2021 to 2022, consumers increased their purchases of supplements and medications because of the COVID-19 pandemic, which led to increased purchases of HECs up and down the supply chain. They added that by the end of the 2021 the supply chain was stocked up and consumer demand had returned to normal. Thus, respondents claim, consumers' purchases of products made from HECs declined at the same time destocking began and lead times dropped 48 from to 24 weeks. According to the respondents, worldwide demand for HECs returned to normal during the first quarter of 2024.

Substitute products

*** and the majority of importers (10 of 14) reported that there were no substitutes for HECs. Four importers (***) reported that there were substitutes, including tablets, soft gelatin capsules, gummies, loose powder, and packets.

¹⁴ Conference transcript p. 26, 34 (Goetter, Schropp).

¹⁵ Conference transcript p. 35 (Schropp).

¹⁶ Conference transcripts p. 55, 57 (Romanski Goetter).

¹⁷ Petitioner's postconference brief, Responses to staff questions to respondents, pp. 2, 4.

¹⁸ Conference transcripts pp. 113-115 (Singh).

¹⁹ Conference transcripts p. 116 (Singh).

²⁰ Conference transcript, p. 124 (Singh).

Substitutability issues

This section assesses the degree to which U.S.-produced HECs and imports of HECs from subject countries can be substituted for one another by examining the importance of certain purchasing factors and the comparability of HECs from domestic and imported sources based on those factors. Based on available data, staff believes that there is a moderate degree of substitutability between domestically produced HECs and HECs imported from subject sources. Factors contributing to this level of substitutability include the same legal requirements for HECs from all sources, and the relative ease of substituting HECs from different sources for nutraceutical use. Factors reducing substitutability include regulations that increase the difficulty of changing the HECs in pharmaceutical uses, the small share of U.S. production that is non-gelatin capsules combined with the difficulty in switching machinery between gelatin and other types of capsules, 22 certain sizes of HECs may be available only from import sources, and the very limited pharmaceutical use of imports from most subject countries.

²¹ The degree of substitution between domestic and imported HECs depends upon the extent of product differentiation between the domestic and imported products and reflects how easily purchasers can switch from domestically produced HECs to the HECs imported from subject countries (or vice versa) when prices change. The degree of substitution may include such factors as regulatory requirements, quality differences (e.g., grade standards, defect rates, compatibility with the filling machine, etc.), and differences in sales conditions (e.g., lead times between order and delivery dates, reliability of supply, product services, etc.).

²² For example, according to the respondents, the FDA does not allow HPMC and gelatin capsules to be produced in the same "hall" because of the risk of cross contamination. Respondent AGC estimated converting HEC production in India from gelatin to HPMC capsules would require *** and cost ***. AGC's postconference brief, responses to staff questions pp. 7-8 and exhibit 9.

²³ Overall, the substitutability is higher for nutraceutical uses than for pharmaceutical end uses.

Petitioner reported that the FDA considers the quality, safety and efficacy of a candidate drug as a whole, including any HECs used, when assessing whether to approve a new drug.²⁴ If a change of HEC supplier results in a pharmaceutical manufacturer using HECs with new specifications or a new composition, that change will be subject to FDA approval.²⁵ FDA policies also provide that a drug applicant that changes its supplier of its of HECs post-approval of its drug—but keeps the composition and specifications of its HECs constant—should submit information about that new supplier in an annual report.²⁶ These requirements make it more costly and time consuming for a pharmaceutical manufacturer to switch even among suppliers of equivalent HECs.²⁷

Gelatin HECs must comply with Food Chemicals Codex ("FCC") standards for "food grade" gelatin and those intended to pharmaceutical use all must meet USP-NF standards for gelatin while HPMC used in both pharmaceutical and nutraceutical applications should comply with the USP-NF standards for HPMC.²⁸ Petitioner stated that the qualification times for HECs in the pharmaceutical industry range from 6 to 18 months while in the nutraceutical industry it would be less than 6 months.²⁹ Respondents stated that the qualification times for HECs in the pharmaceutical industry ranges from 1 to 2 years while in the nutraceutical industry it would be up to 6 months.³⁰

Domestic HECs are predominantly produced from gelatin whereas subject imports are nearly evenly divided between gelatin and HPMC. In 2023, U.S. production was *** percent gelatin HECs, while overall subject import shipments were *** percent gelatin HECs.³¹ Some purchasers may prefer HECs made from HPMC because it is vegetarian. Pharmaceutical end users would find it difficult to shift between gelatin and HPMC HECs because that change will be subject to FDA approval.³² Pharmaceutical users particularly may be unable to change suppliers within a year even if they are purchasing equivalent HECs from different producers, however once a second supplier has been accepted, switching between the accepted suppliers will require much less time.³³

²⁴ Petition, p. 23.

²⁵ Petition, p. 24.

²⁶ Petition, p. 24.

²⁷ Petition, p. 25.

²⁸ Petition, pp. 22-25.

²⁹ Conference transcript p. 62 (Romanski).

³⁰ Conference transcript p. 92 (Singh).

³¹ Table IV-5.

³² Petition, pp. 24.

³³ Conference transcript p. 62-63, 138 (Romanski, Zhang).

Factors affecting purchasing decisions

Purchasers responding to lost sales lost revenue allegations³⁴ were asked to identify the main purchasing factors their firm considered in their purchasing decisions for HECs. The major purchasing factors identified by firms include price, quality, lead time, availability, supplier diversity, performance on machines, and risk management (table II-5).³⁵

Table II-5
HECs: Count of ranking of factors used in purchasing decisions as reported by U.S. purchasers by factor

Factor	First	Second	Third	Total
Price/cost	1	2	4	7
Quality	5	0	1	6
Lead time	0	1	2	3
Availability	0	2	0	2
Supplier diversity	1	0	0	1
Performance on machines and risk management	0	2	0	2

Source: Compiled from data submitted in response to Commission questionnaires.

Lead times

U.S. producers reported primarily producing HECs to order. They reported that *** percent of their commercial shipments were produced-to-order, with lead times averaging 133 days. The remaining *** percent of their commercial shipments came from inventories, with lead times averaging 3 days. Importers reported primarily selling HEC's from U.S. inventories. They reported that *** percent of their commercial shipments were produced-to-order, with lead times averaging 90 days and *** percent of their commercial shipments came from U.S. inventories, with lead times averaging 4 days.

 $^{^{34}}$ This information is compiled from responses by purchasers identified by petitioner to the lost sales lost revenue allegations. See Part V for additional information. 35 ***

Comparison of U.S.-produced and imported HECs

In order to determine whether U.S.-produced HECs can generally be used in the same applications as imports from subject countries, U.S. producers and importers were asked whether the products can always, frequently, sometimes, or never be used interchangeably. As shown in tables II-6 to II-7, *** and half of responding importers reported that HECs from the United States, subject and nonsubject countries were always or frequently interchangeable. Importer *** reported that there is no U.S. production for 95 percent of the capsules that it sells in the U.S. market. Importer *** reported that the HECs that it produces in Korea and Vietnam are uniquely designed for filling liquids, semi-solids, or fill powders and therefore cannot be interchanged with other HECs.

Table II-6
HECs: Count of U.S. producers reporting the interchangeability between product produced in the United States and in other countries, by country pair

Country pair	Always	Frequently	Sometimes	Never
U.S. vs. Brazil	***	***	***	***
U.S. vs. China	***	***	***	***
U.S. vs. India	***	***	***	***
U.S. vs. Vietnam	***	***	***	***
U.S. vs. other	***	***	***	***
Brazil vs. China	***	***	***	***
Brazil vs. India	***	***	***	***
Brazil vs. Vietnam	***	***	***	***
China vs. India	***	***	***	***
China vs. Vietnam	***	***	***	***
India vs. Vietnam	***	***	***	***
Brazil vs. Other	***	***	***	***
China vs. Other	***	***	***	***
India vs. Other	***	***	***	***
Vietnam vs. Other	***	***	***	***

Table II-7
HECs: Count of importers reporting the interchangeability between product produced in the United States and in other countries, by country pair

Country pair	Always	Frequently	Sometimes	Never
U.S. vs. Brazil	3	0	1	0
U.S. vs. China	2	7	2	0
U.S. vs. India	2	1	2	1
U.S. vs. Vietnam	2	1	1	0
U.S. vs. other	3	0	1	0
Brazil vs. China	2	2	0	0
Brazil vs. India	2	1	1	1
Brazil vs. Vietnam	2	0	0	0
China vs. India	3	1	0	1
China vs. Vietnam	2	0	0	0
India vs. Vietnam	2	0	0	1
Brazil vs. Other	2	0	0	0
China vs. Other	2	0	0	0
India vs. Other	2	0	0	1
Vietnam vs. Other	2	0	0	0

Source: Compiled from data submitted in response to Commission questionnaires.

In addition, U.S. producers and importers were asked to assess how often differences other than price were significant in sales of HECs from the United States, subject, or nonsubject countries. As seen in tables II-8 to II-9, *** and at least half of responding importers reported that there were sometimes or never differences other than price between HEC from the United States, subject, and nonsubject countries, with one exception. The majority of importers reported that there were always differences between HECs produced in the United States and India. Differences reported by importers include differences in machineability and residual impurities (reported by ***) and lead times on custom orders and technical support (reported by ***). Importer *** also reported that qualification to supply pharmaceutical customers can take up to two years to obtain and is dependent on quality consistency, reliability, and regulatory compliance.

Table II-8
HECs: Count of U.S. producers reporting the significance of differences other than price between product produced in the United States and in other countries, by country pair

Country pair	Always	Frequently	Sometimes	Never
U.S. vs. Brazil	***	***	***	***
U.S. vs. China	***	***	***	***
U.S. vs. India	***	***	***	***
U.S. vs. Vietnam	***	***	***	***
U.S. vs. other	***	***	***	***
Brazil vs. China	***	***	***	***
Brazil vs. India	***	***	***	***
Brazil vs. Vietnam	***	***	***	***
China vs. India	***	***	***	***
China vs. Vietnam	***	***	***	***
India vs. Vietnam	***	***	***	***
Brazil vs. Other	***	***	***	***
China vs. Other	***	***	***	***
India vs. Other	***	***	***	***
Vietnam vs. Other	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Table II-9
HECs: Count of importers reporting the significance of differences between product produced in the United States and in other countries, by country pair

Country pair	Always	Frequently	Sometimes	Never
U.S. vs. Brazil	1	0	0	2
U.S. vs. China	3	2	2	4
U.S. vs. India	4	0	1	1
U.S. vs. Vietnam	0	1	0	2
U.S. vs. other	1	1	0	1
Brazil vs. China	0	0	1	2
Brazil vs. India	1	0	1	2
Brazil vs. Vietnam	0	0	0	2
China vs. India	1	0	1	2
China vs. Vietnam	0	0	0	2
India vs. Vietnam	1	0	1	1
Brazil vs. Other	0	0	0	2
China vs. Other	0	0	1	1
India vs. Other	1	0	0	2
Vietnam vs. Other	0	0	0	2

Part III: U.S. producers' production, shipments, and employment

The Commission analyzes a number of factors in making injury determinations (see 19 U.S.C. §§ 1677(7)(B) and 1677(7)(C)). Information on the subsidies and dumping margins were presented in Part I of this report and information on the volume and pricing of imports of the subject merchandise is presented in Part IV and Part V. Information on the other factors specified is presented in this section and/or Part VI and (except as noted) is based on the questionnaire responses of two firms that accounted for all known U.S. production of HECs during 2023.

U.S. producers

The Commission issued a U.S. producer questionnaire to two firms based on information contained in the petition. Lonza and Qualicaps Inc. ("Qualicaps") provided usable data on their operations. Table III-1 lists U.S. producers of HECs, their production locations, positions on the petition, and shares of total production.

Table III-1
HECs: U.S. producers, their positions on the petition, production locations, and shares of reported production, 2023

Firm	Position on petition	Production location(s)	Share of production
Lonza	Petitioner	Greenwood, SC	***
Qualicaps	***	Whitsett, NC	***
All firms	Various	Various	100.0

Source: Compiled from data submitted in response to Commission questionnaires.

Note: ***.

Table III-2 presents information on U.S. producers' ownership, related and/or affiliated firms.

Table III-2 HECs: U.S. producers' ownership, related and/or affiliated firms

Reporting firm	Relationship type and related firm	Details of relationship
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

As indicated in table III-2, *** are related to foreign producers of the subject merchandise and to U.S. importers of the subject merchandise. In addition, as discussed in greater detail below, *** U.S. producers directly import the subject merchandise.

Table III-3 presents events in the U.S. industry since January 1, 2021.

Table III-3 HECs: Important events in the U.S. industry, since January 1, 2021

Item	Firm and Event
Expansion	Vivion: Launched a new empty capsule product range on February 2, 2023.
Expansion	Bright Pharma: Launched the world's first NOP Certified Organic vegetable capsule on August 8, 2023.
Acquisition	Milliken: Acquired Encapsys on October 20, 2021.
Acquisition	ACG (Vantage Nutrition): Acquired AquaCaps on December 1, 2022.
Acquisition	ACG (Vantage Nutrition): Acquired ComboCap on March 27, 2023.
Acquisition	Lonza: Acquired Roche's large-scale biologics plant for \$1.2 billion in October 2024.

Source: PRNewswire, "Vivion Inc. Launches," February 2, 2023, https://www.prnewswire.com/news-releases/vivion-inc-launches-new-empty-capsules-product-range-301737483.html; SupplySide Supplement Journal, "Innovation leads," August 8, 2023, Innovation leads to the first certified organic Bright-Poly capsules; CHEManager, "Milliken Completes Acquisition," October 20,2021, Milliken Completes Acquisition of Encapsys | CHEManager; Nutrition Insight, "Vantage Nutrition-acquires-aquacap," December 1, 2022; https://www.nutritioninsight.com/news/vantage-nutrition-acquires-aquacap-for-north-american-manufacturing-expansion.html; Biospace, "Vantage Nutrition, an ACG Group," March 27, 2023, https://www.biospace.com/vantage-nutrition-llc-acquires-combocap-incLonza; "Lonza Completes Acquisition," October 1, 2024, https://www.lonza.com/news/2024-10-01-16-45#:~:text=Basel%2C%20Switzerland%20and%20Vacaville%2C%20US,Roche%20for%20USD%201.2">https://www.lonza.com/news/2024-10-01-16-45#:~:text=Basel%2C%20Switzerland%20and%20Vacaville%2C%20US,Roche%20for%20USD%201.2">https://www.lonza.com/news/2024-10-01-16-45#:~:text=Basel%2C%20Switzerland%20and%20Vacaville%2C%20US,Roche%20for%20USD%201.2"%20billion.

Producers in the United States were asked to report any change in the character of their operations or organization relating to the production of HECs since 2021. Both U.S. producers indicated in their questionnaires that they had experienced such changes. Table III-4 presents the changes identified by these producers.

Table III-4 HECs: U.S. producers' reported changes in operations, since January 1, 2021

Item	Firm name and narrative response on changes in operations
Prolonged	***
shutdowns	
Prolonged	***
shutdowns	
Production	***
curtailments	
Production	***
curtailments	
Expansions	***
Acquisitions	***
Other	***

U.S. production, capacity, and capacity utilization

Table III-5 presents U.S. producers' installed and practical capacity and production on the same equipment. During 2021-23, U.S. producers' installed overall capacity increased by *** percent and was *** in January-June ("interim") 2024 compared to interim 2023. There was no known production of out-of-scope products on the same equipment and machinery used to produce HECs. Therefore, practical overall capacity, production, and utilization were the same as practical HECs capacity, production, and utilization during the period for which data were collected. During 2021-23, practical capacity decreased by *** percent and was *** percent lower in interim 2024 compared to interim 2023. During 2021-23, ***.¹ While installed overall capacity utilization decreased annually and also overall by *** percent, practical capacity utilization remained *** during 2021-23. Installed overall capacity utilization and practical capacity utilization were both lower in interim 2024 compared to interim 2023.

¹ Lonza reports ***. Response to staff questions from petitioners, November 18, 2024, p. 5.

Table III-5
HECs: U.S. producers' installed and practical capacity and production on the same equipment as in-scope production, by period

Capacity and production in 1,000 units; utilization in percent

Item	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Installed						
overall	Capacity	***	***	***	***	***
Installed						
overall	Production	***	***	***	***	***
Installed						
overall	Utilization	***	***	***	***	***
Practical						
overall	Capacity	***	***	***	***	***
Practical						
overall	Production	***	***	***	***	***
Practical						
overall	Utilization	***	***	***	***	***
Practical HECs	Capacity	***	***	***	***	***
Practical HECs	Production	***	***	***	***	***
Practical HECs	Utilization	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Table III-6 presents U.S. producers' reported narratives regarding practical capacity constraints.

Table III-6
HECs: U.S. producers' reported capacity constraints since January 1, 2021

Item	Firm name and narrative response on constraints to practical overall capacity
Existing	***
labor force	
Supply of	***
material	
inputs	
Other	***
constraints	

Source: Compiled from data submitted in response to Commission questionnaires.

Table III-7 and figure III-1 present U.S. producers' production, capacity, and capacity utilization. During 2021-23, production of HECs decreased by *** percent and was *** percent lower in interim 2024 compared to interim 2023. While Lonza, accounting for over *** percent of production, drove industry trends, both firms' production decreased during 2021-23 and were lower in interim 2024 compared to interim 2023. Additionally, both Lonza and Qualicaps followed the same capacity trends decreasing annually and overall, during 2021-23 and reporting lower capacity in interim 2024 compared to interim 2023. During the period for which data were collected both firms had different capacity utilization trends. *

. During 2021-23 *. ***.

Table III-7

HECs: U.S. producers' output, by firm and period

Practical capacity

Capacity in 1,000 units

Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

Table continued.

Table III-7 Continued

HECs: U.S. producers' output, by firm and period

Production

Production in 1,000 units

Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

Table continued.

Table III-7 Continued

HECs: U.S. producers' output, by firm and period

Capacity utilization

Capacity utilization in percent

oupuity damination in possibility								
Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024			
Lonza	***	***	***	***	***			
Qualicaps	***	***	***	***	***			
All firms	***	***	***	***	***			

Note: Capacity utilization ratio represents the ratio of the U.S. producer's production to its production capacity.

Table continued.

Table III-7 Continued

HECs: U.S. producers' output, by firm and period

Share of production

Share in percent

Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	100.0	100.0	100.0	100.0	100.0

Source: Compiled from data submitted in response to Commission questionnaires.

Figure III-1

HECs: U.S. producers' output, by period

* * * * * * * *

Source: Compiled from data submitted in response to Commission questionnaires.

Alternative products

U.S. producers did not report any out-of-scope products being produced on the same equipment and machinery used to produce in-scope HECs.²

² Petitioners confirm "the HEC machines are developed specifically for making two-piece HECs and its hard to imagine another product that can be made on that said machine." conference transcript p. 45 (Mccutcheon).

U.S. producers' U.S. shipments and exports

Table III-8 presents U.S. producers' U.S. shipments, export shipments, and total shipments. During 2021-23, U.S. producers' U.S. shipments of HECs decreased overall by *** percent, in terms of quantity, and by *** percent, in terms of value. Export shipments fluctuated during 2021-23 and overall increased by *** percent, in terms of quantity, and by *** percent, in terms of value.³ U.S. shipments and exports shipments were both lower in interim 2024 compared to interim 2023 (both in terms of quantity by *** percent and by *** percent, respectively; and in terms of value by *** percent and by *** percent, respectively). During 2021-23, the unit value of U.S. producers' U.S. shipments increased by *** percent and was *** percent lower in interim 2024 compared to interim 2023.

Table III-8 HECs: U.S. producers' shipments, by destination and period

Quantity in 1,000 units; value in 1,000 dollars; unit value in dollars per 1,000 units; shares in percent

Item	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
U.S. shipments	Quantity	***	***	***	***	***
Export shipments	Quantity	***	***	***	***	***
Total shipments	Quantity	***	***	***	***	***
U.S. shipments	Value	***	***	***	***	***
Export shipments	Value	***	***	***	***	***
Total shipments	Value	***	***	***	***	***
U.S. shipments	Unit value	***	***	***	***	***
Export shipments	Unit value	***	***	***	***	***
Total shipments	Unit value	***	***	***	***	***
U.S. shipments	Share of quantity	***	***	***	***	***
Export shipments	Share of quantity	***	***	***	***	***
Total shipments	Share of quantity	100.0	100.0	100.0	100.0	100.0
U.S. shipments	Share of value	***	***	***	***	***
Export shipments	Share of value	***	***	***	***	***
Total shipments	Share of value	100.0	100.0	100.0	100.0	100.0

³ Principal export markets are ***. *** U.S. producer questionnaire responses, section II-8.

Table III-9 presents U.S. producers' U.S. shipments by type. During the period for which data were collected, U.S. producers' commercial U.S. shipments accounted for between *** percent and *** percent of total U.S. shipments, in terms of quantity. During 2021-23, U.S. producers' commercial U.S. shipments decreased, in terms of quantity, by *** percent and *** percent, in terms of value. Commercial U.S. shipments, in terms of quantity and in terms of value, were lower in interim 2024 compared to interim 2023 (by *** percent and by *** percent, respectively). During 2021-22, internal consumption, in terms of quantity, decreased by *** percent then increased by *** percent during 2022-23, ending the period *** percent lower in 2021 compared to 2023. Internal consumption, in terms of quantity, was *** percent lower in interim 2024 compared to interim 2023. Internal consumption, in terms of quantity, ranged from *** percent of U.S. shipments in 2022 to *** percent of U.S. shipments in 2021. During 2021-23, transfers to related firms were highest in 2022 and overall increased by *** percent, in terms of quantity. Transfers, in terms of quantity, were lower in interim 2024 compared to interim 2023. Transfers accounted for less than *** percent of U.S. shipments during the period for which data were collected. *** reported internal consumption and transfers.

Table III-9 HECs: U.S. producers' <u>U.S. shipments</u>, by type and period

Quantity in 1,000 units; value in 1,000 dollars; unit value in dollars per 1,000 units; shares in percent

Item	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Commercial U.S. shipments	Quantity	***	***	***	***	***
Internal consumption	Quantity	***	***	***	***	***
Transfers to related firms	Quantity	***	***	***	***	***
U.S. shipments	Quantity	***	***	***	***	***
Commercial U.S. shipments	Value	***	***	***	***	***
Internal consumption	Value	***	***	***	***	***
Transfers to related firms	Value	***	***	***	***	***
U.S. shipments	Value	***	***	***	***	***
Commercial U.S. shipments	Unit value	***	***	***	***	***
Internal consumption	Unit value	***	***	***	***	***
Transfers to related firms	Unit value	***	***	***	***	***
U.S. shipments	Unit value	***	***	***	***	***
Commercial U.S. shipments	Share of quantity	***	***	***	***	***
Internal consumption	Share of quantity	***	***	***	***	***
Transfers to related firms	Share of quantity	***	***	***	***	***
U.S. shipments	Share of quantity	100.0	100.0	100.0	100.0	100.0
Commercial U.S. shipments	Share of value	***	***	***	***	***
Internal consumption	Share of value	***	***	***	***	***
Transfers to related firms	Share of value	***	***	***	***	***
U.S. shipments	Share of value	100.0	100.0	100.0	100.0	100.0

U.S. producers' inventories

Table III-10 presents U.S. producers' end-of-period inventories and the ratio of these inventories to U.S. producers' production, U.S. shipments, and total shipments. *** reported end-of-period inventories during 2021-23 and both interim periods. *** share of inventories was similar to its share of overall U.S. production, driving inventory trends during the period for which data were collected. During 2021-23, inventories increased by *** percent and were *** percent lower in interim 2024 compared to interim 2023. During 2021-23, U.S. producers' end-of-period inventories as a ratio to U.S. production, U.S. shipments, and total shipments increased annually and overall with the three ratios ending *** percentage points, *** percentage points, and *** percentage points, respectively, higher in 2023 compared to 2021. U.S. producers' end-of-period inventories as a ratio to U.S. production, U.S. shipments, and total shipments were each higher in interim 2024 compared to interim 2023.

Table III-10 HECs: U.S. producers' inventories and their ratio to select items, by period

Quantity in 1,000 units; ratio in percent

Item	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
End-of-period inventory					
quantity	***	***	***	***	***
Inventory ratio to U.S.					
production	***	***	***	***	***
Inventory ratio to U.S.					
shipments	***	***	***	***	***
Inventory ratio to total					
shipments	***	***	***	***	***

U.S. producers' imports from subject sources

U.S. producers' imports of HECs are presented in tables III-11 and III-12. U.S. producers' reasons for importing are presented in table III-13. *** reported imports of HECs from subject sources.

Table III-11

HECs: *** U.S. production, subject imports, and ratio of subject imports to production, by source and period

Quantity in 1,000 units; ratio in percent

Item	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	
U.S.							
production	Quantity	***	***	***	***	***	
Imports from							
***	Quantity	***	***	***	***	***	
Imports from							
*** to U.S.							
production	Ratio	***	***	***	***	***	

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Ratios shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Table III-12

HECs: *** U.S. production, subject imports, and ratio of subject imports to production, by source and period

Quantity in 1,000 units; ratio in percent

Item	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
U.S. production	Quantity	***	***	***	***	***
Imports from ***	Quantity	***	***	***	***	***
Imports from *** to U.S.						
production	Ratio	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Ratios shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Table III-13

HECs: U.S. producers' reasons for importing

Item	Narrative response on reasons for importing
***'s reason for	***
importing	
***'s reason for	***
importing	

U.S. producers' purchases of imports from subject sources

No responding U.S. producer reported purchases of HECs during 2021-23 and both interim periods.

U.S. employment, wages, and productivity

Table III-14 shows U.S. producers' employment-related data. The number of production and related workers ("PRWs") increased by *** percent from 2021 to 2023 and was *** percent lower in interim 2024 compared to interim 2023.⁴ During 2021-23, total hours worked, wages paid, hourly wages, and unit labor costs increased by *** percent, by *** percent, by *** percent, and by *** percent, respectively. Meanwhile, hours worked per PRW and productivity decreased by *** percent and by *** percent. Hourly wages and unit labor costs were higher in interim 2024 compared to interim 2023 while total hours worked, hours worked per PRW, wages, and productivity were lower in interim 2024 compared to interim 2023.⁵

Table III-14
HECs: U.S. producers' employment related information. by period

Item	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Production and related workers (PRWs)					
(number)	***	***	***	***	***
Total hours worked (1,000 hours)	***	***	***	***	***
Hours worked per PRW (hours)	***	***	***	***	***
Wages paid (\$1,000)	***	***	***	***	***
Hourly wages (dollars per hour)	***	***	***	***	***
Productivity (1,000 units per hour)	***	***	***	***	***
Unit labor costs (dollars per 1,000					
units)	***	***	***	***	***

⁴ On account of its large share of the industry, Lonza's data drove employment data trends. During 2021-23, ***. *** number of PRWs were lower in interim 2024 compared to interim 2023.

⁵ ***. *** U.S. producer questionnaire response, section II-10.

Part IV: U.S. imports, apparent U.S. consumption, and market shares

U.S. importers

The Commission issued importer questionnaires to 54 firms believed to be importers of subject HECs, as well as to all U.S. producers of HECs. Usable questionnaire responses were received from 18 companies, representing the following percentages of U.S. imports in 2023 under HTS statistical reporting numbers 9602.00.1040, and 9602.00.5010, as adjusted.

- Brazil: *** percent
- China: *** percent
- India: *** percent
- Vietnam: *** percent
- Subject sources: *** percent
- Nonsubject sources: *** percent
- All imports sources: *** percent

Table IV-1 lists all responding U.S. importers of HECs from Brazil, China, India, Vietnam, and other sources, their locations, and their shares of U.S. imports, in 2023.

¹ The Commission issued questionnaires to those firms identified in the petition; staff research; and proprietary, Census-edited Customs' import records.

² Import coverage was calculated as a share of imports, as reported in questionnaire responses, divided by official import statistics of the U.S. Department of Commerce Census Bureau using HTS statistical reporting numbers 9602.00.1040 and 9602.00.5010 adjusted to include imports classified under the secondary HTS statistical reporting numbers as reported in questionnaire responses. Official import statistics maybe overstated due to out-of-scope merchandise imported under those HTS number.

Table IV-1 Continued

HECs: U.S. importers, their headquarters, and share of imports within each source, 2023

Share in percent

		Subject sources less	Nonsubject	Nonsubject sources	All import
Firm	Headquarters	Brazil	sources	plus Brazil	sources
ACB Pharma	New York, NY	***	***	***	***
ACG North America	Piscataway, NJ	***	***	***	***
Alfacaps	Lewes, DE	***	***	***	***
Biocaps	El Monte, CA	***	***	***	***
Bright Pharma Caps	Hood River, OR	***	***	***	***
Capsuline	Dania Beach, FL	***	***	***	***
Catherych	Warren, NJ	***	***	***	***
Granules Pharmaceuticals	Chantilly, VA	***	***	***	***
HealthCaps	Hialeah, FL	***	***	***	***
Huangshan	Ontario, CA	***	***	***	***
LFA Machines	Fort Worth, TX	***	***	***	***
Lonza	Greenwood, SC	***	***	***	***
Qualicaps	Whitsett, NC	***	***	***	***
SD Head USA	Syosset, NY	***	***	***	***
Suheung-America	Brea, CA	***	***	***	***
Time-Cap	Farmingdale, NY	***	***	***	***
Torpac	Fairfield, NJ	***	***	***	***
Vivion	Fort Worth, TX	***	***	***	***
All firms	Various	100.0	100.0	100.0	100.0

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Shares shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

U.S. imports

Table IV-2, IV-3, and figure IV-1 present data for U.S. imports of HECs from Brazil, China, India, Vietnam, and all other sources.

U.S. imports from subject sources by quantity increased in 2022 and then decreased in 2023, for an overall increase of *** percent, and were higher in interim 2024 compared interim 2023 by *** percent. U.S. imports from subject sources by value increased in 2022 and then decreased in 2023, for an overall increase of *** percent, and were higher in interim 2024 compared to interim 2023 by *** percent. The unit value of imports from subject sources increased in 2022 and then decreased in 2023, for an overall increase of *** percent but was *** percent lower in interim 2024 compared to interim 2023.

U.S. imports from Brazil by quantity decreased in 2022 and then increased in 2023, for an overall decrease of *** percent, but were higher in interim 2024 compared interim 2023 by *** percent. U.S. imports from Brazil by value decreased in 2022 and then increased in 2023, for an overall decrease of *** percent, but were higher in interim 2024 compared to interim 2023 by *** percent. The unit value of imports from Brazil increased in 2022 and then decreased in 2023, for an overall increase of *** percent but was *** percent lower in interim 2024 compared to interim 2023.

U.S. imports from China by quantity increased in 2022 and then decreased in 2023, for an overall decrease of *** percent, but were higher in interim 2024 compared interim to interim 2023 by *** percent. U.S. imports from China by value increased in 2022 and then decreased in 2023, for an overall decrease of *** percent, but were higher in interim 2024 compared to interim 2023 by *** percent. The unit value of imports from China increased in 2022 and then decreased in 2023, for an overall increase of *** percent but was *** percent lower in interim 2024 compared to interim 2023.

U.S. imports from India by quantity increased in 2022 and then decreased in 2023, for an overall increase of *** percent, and were higher in interim 2024 compared interim to interim 2023 by *** percent. U.S. imports from India by value increased in 2022 and then decreased in 2023, for an overall increase of *** percent, but were lower in interim 2024 compared to interim 2023 by *** percent. The unit value of imports from India increased in 2022 and then decreased in 2023, for an overall increase of *** percent and was *** percent lower in interim 2024 compared to interim 2023.

U.S. imports from Vietnam by quantity increased in 2022 and then decreased in 2023, for an overall increase of *** percent, and were higher in interim 2024 compared interim to interim 2023 by *** percent. U.S. imports from Vietnam by value increased in 2022 and then decreased in 2023, for an overall decrease of *** percent, but were higher in interim 2024 compared to interim 2023 by *** percent. The unit value of imports from Vietnam decreased in every year from 2021 to 2023, ending *** percent lower and was *** percent lower in interim 2024 compared to interim 2023.

U.S. imports from nonsubject sources by quantity increased in 2022 and then decreased in 2023, for an overall decrease of *** percent, but were higher in interim 2024 compared interim to interim 2023 by *** percent. U.S. imports from nonsubject sources by value increased in 2022 and then decreased in 2023, for an overall decrease of *** percent, and were higher in interim 2024 compared to interim 2023 by *** percent. The unit value of imports from nonsubject sources increased in 2022 and then decreased in 2023, for an overall increase

of *** percent but was *** percent lower in interim 2024 compared to interim 2023.

U.S. imports from all import sources by quantity increased in 2022 and then decreased in 2023, for an overall decrease of *** percent, but were higher in interim 2024 compared interim to interim 2023 by *** percent. U.S. imports from all import sources by value increased in 2022 and then decreased in 2023, for an overall increase of *** percent, and were higher in interim 2024 compared to interim 2023 by *** percent. The unit value of imports from total import sources increased in 2022 and then decreased in 2023, for an overall increase of *** percent but was *** percent lower in interim 2024 compared to interim 2023.

Table IV-2 HECs: U.S. imports by source and period

Quantity in 1,000 units; value in 1,000 dollars; unit value in dollars per 1,000 units

Source	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Brazil	Quantity	***	***	***	***	***
China	Quantity	***	***	***	***	***
India	Quantity	***	***	***	***	***
Vietnam	Quantity	***	***	***	***	***
Subject sources	Quantity	***	***	***	***	***
Subject sources less Brazil	Quantity	***	***	***	***	***
Mexico	Quantity	***	***	***	***	***
All other sources	Quantity	***	***	***	***	***
Nonsubject sources	Quantity	***	***	***	***	***
Nonsubject sources plus Brazil	Quantity	***	***	***	***	***
All import sources	Quantity	84,273,341	94,641,726	78,514,622	34,501,065	45,990,861
Brazil	Value	***	***	***	***	***
China	Value	***	***	***	***	***
India	Value	***	***	***	***	***
Vietnam	Value	***	***	***	***	***
Subject sources	Value	***	***	***	***	***
Subject sources less Brazil	Value	***	***	***	***	***
Mexico	Value	***	***	***	***	***
All other sources	Value	***	***	***	***	***
Nonsubject sources	Value	***	***	***	***	***
Nonsubject sources plus Brazil	Value	***	***	***	***	***
All import sources	Value	261,356	340,456	262,012	125,172	142,894

Table IV-2 Continued HECs: Share of U.S. imports by source and period

Unit values in dollars per 1,000 units; Shares in percent

Source	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Brazil	Unit value	***	***	***	***	***
China	Unit value	***	***	***	***	***
India	Unit value	***	***	***	***	***
Vietnam	Unit value	***	***	***	***	***
Subject sources	Unit value	***	***	***	***	***
Subject sources less Brazil	Unit value	***	***	***	***	***
Mexico	Unit value	***	***	***	***	***
All other sources	Unit value	***	***	***	***	***
Nonsubject sources	Unit value	***	***	***	***	***
Nonsubject sources plus Brazil	Unit value	***	***	***	***	***
All import sources	Unit value	3.10	3.60	3.34	3.63	3.11
Brazil	Share of quantity	***	***	***	***	***
China	Share of quantity	***	***	***	***	***
India	Share of quantity	***	***	***	***	***
Vietnam	Share of quantity	***	***	***	***	***
Subject sources	Share of quantity	***	***	***	***	***
Subject sources less Brazil	Share of quantity	***	***	***	***	***
Mexico	Share of quantity	***	***	***	***	***
All other sources	Share of quantity	***	***	***	***	***
Nonsubject sources	Share of quantity	***	***	***	***	***
Nonsubject sources plus Brazil	Share of quantity	***	***	***	***	***
All import sources	Share of quantity	100.0	100.0	100.0	100.0	100.0

Table IV-2 Continued

HECs: Share of U.S. imports by source and period

Share and ratio in percent

Source	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Brazil	Share of value	***	***	***	***	***
China	Share of value	***	***	***	***	***
India	Share of value	***	***	***	***	***
Vietnam	Share of value	***	***	***	***	***
Subject sources	Share of value	***	***	***	***	***
Subject sources less Brazil	Share of value	***	***	***	***	***
Mexico	Share of value	***	***	***	***	***
All other sources	Share of value	***	***	***	***	***
Nonsubject sources	Share of value	***	***	***	***	***
Nonsubject sources plus Brazil	Share of value	***	***	***	***	***
All import sources	Share of value	100.0	100.0	100.0	100.0	100.0
Brazil	Ratio	***	***	***	***	***
China	Ratio	***	***	***	***	***
India	Ratio	***	***	***	***	***
Vietnam	Ratio	***	***	***	***	***
Subject sources	Ratio	***	***	***	***	***
Subject sources less Brazil	Ratio	***	***	***	***	***
Mexico	Ratio	***	***	***	***	***
All other sources	Ratio	***	***	***	***	***
Nonsubject sources	Ratio	***	***	***	***	***
Nonsubject sources plus Brazil	Ratio	***	***	***	***	***
All import sources	Ratio	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Shares shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Note: Share of quantity is the share of U.S. imports by quantity; share of value is the share of U.S. imports by value; ratio are U.S. imports to production.

Table IV-3 HECs: Changes in U.S. imports, by source and period

Changes in percent

Source	Measure	2021-23	2021-22	2022-23	Jan-Jun 2023-24
Brazil	%Δ Quantity	***	***	***	***
China	%∆ Quantity	***	***	***	^ ***
India	%∆ Quantity	***	***	***	^ ***
Vietnam	%Δ Quantity	***	***	***	***
Subject sources	%∆ Quantity	***	***	***	***
Subject sources less Brazil	%∆ Quantity	***	***	***	***
Mexico	%∆ Quantity	***	***	***	^ ***
All other sources	%∆ Quantity	***	***	***	^ ***
Nonsubject sources	%∆ Quantity	***	***	***	***
Nonsubject sources plus Brazil	%Δ Quantity	***	***	***	^ ***
All import sources	%∆ Quantity	▼(6.8)	▲ 12.3	▼ (17.0)	▲33.3
Brazil	%∆ Value	***	***	***	^ ***
China	%∆ Value	***	***	***	^ ***
India	%∆ Value	***	***	***	***
Vietnam	%∆ Value	***	***	***	***
Subject sources	%∆ Value	***	***	***	^ ***
Subject sources less Brazil	%∆ Value	***	***	***	^ ***
Mexico	%∆ Value	***	***	***	^ ***
All other sources	%∆ Value	***	***	***	^ ***
Nonsubject sources	%∆ Value	***	***	***	^ ***
Nonsubject sources plus Brazil	%∆ Value	***	***	***	^ ***
All import sources	%∆ Value	▲0.3	▲30.3	▼ (23.0)	▲ 14.2
Brazil	%∆ Unit value	***	***	***	***
China	%∆ Unit value	***	***	***	***
India	%∆ Unit value	***	***	***	***
Vietnam	%∆ Unit value	***	***	***	***
Subject sources	%∆ Unit value	***	***	***	***
Subject sources less Brazil	%∆ Unit value	***	***	***	***
Mexico	%Δ Unit value	***	A ***	A ***	***
All other sources	%Δ Unit value	***	***	***	***
Nonsubject sources	%Δ Unit value	***	***	***	***
Nonsubject sources plus Brazil	%Δ Unit value	***	A ***	A ***	***
All import sources	%∆ Unit value	▲ 7.6	▲ 16.0	▼ (7.2)	▼ (14.4)

Source: Compiled from data submitted in response to Commission questionnaires.



Figure IV-1 HECs: U.S. import quantities and average unit values, by source and period

Source: Compiled from data submitted in response to Commission questionnaires.

Table IV-4 presents data for U.S. producers' and/or their affiliates, U.S. imports, by source and period.

Table IV-4 HECs: U.S. producers' and/or their affiliates' U.S. imports, by source and period

Quantity in 1,000 units; share of quantity in percent

Quality III 1,00	Jo ariito, orial	e of quantity in	SCICCIN		Jan-Jun	Jan-Jun
Source	Measure	2021	2022	2023	2023	2024
Brazil	Quantity	***	***	***	***	***
China	Quantity	***	***	***	***	***
India	Quantity	***	***	***	***	***
Vietnam	Quantity	***	***	***	***	***
Subject	G.G.G.I.I.I.					
sources	Quantity	***	***	***	***	***
Subject						
sources less						
Brazil	Quantity	***	***	***	***	***
Nonsubject						
sources	Quantity	***	***	***	***	***
Nonsubject						
sources plus		***	***	***	***	
Brazil	Quantity	***	***	***	***	***
All import	0	***	***	***	***	***
sources	Quantity	***	***			
Drozil	Share of	***	***	***	***	***
Brazil	quantity Share of					
China	quantity	***	***	***	***	***
Offilia	Share of					
India	quantity	***	***	***	***	***
	Share of					
Vietnam	quantity	***	***	***	***	***
Subject	Share of					
sources	quantity	***	***	***	***	***
Subject						
sources less	Share of					
Brazil	quantity	***	***	***	***	***
Nonsubject	Share of	***	***	***	***	***
sources	quantity	***	***	***	***	***
Nonsubject	Chara of					
sources plus Brazil	Share of	***	***	***	***	***
All import	quantity Share of					
sources	quantity	***	***	***	***	***
3001063	quantity					

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Shares shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Negligibility

The statute requires that an investigation be terminated without an injury determination if imports of the subject merchandise are found to be negligible.³ Negligible imports are generally defined in the Act, as amended, as imports from a country of merchandise corresponding to a domestic like product where such imports account for less than 3 percent of the volume of all such merchandise imported into the United States in the most recent 12-month period for which data are available that precedes the filing of the petition or the initiation of the investigation. However, if there are imports of such merchandise from a number of countries subject to investigations initiated on the same day that individually account for less than 3 percent of the total volume of the subject merchandise, and if the imports from those countries collectively account for more than 7 percent of the volume of all such merchandise imported into the United States during the applicable 12-month period, then imports from such countries are deemed not to be negligible.⁴

Table IV-5 presents information on imports from the subject countries in the most recent 12-month period for which data are available (i.e., October 2023 through September 2024). Imports from Brazil, China, India, and Vietnam accounted for *** percent, *** percent, and *** percent, respectively, of total imports of HECs in this period.

³ Sections 703(a)(1), 705(b)(1), 733(a)(1), and 735(b)(1) of the Act (19 U.S.C. §§ 1671b(a)(1), 1671d(b)(1), 1673b(a)(1), and 1673d(b)(1)).

⁴ Section 771 (24) of the Act (19 U.S.C § 1677(24)).

Table IV-5
HECs: U.S. imports in the twelve-month period preceding the filing of the petition, October 2023 through September 2024

Quantity in 1,000 units; share in percent

Source of imports	Questionnaire quantity	Share of questionnaire quantity	Adjusted official statistics quantity	Share of adjusted official statistics quantity
Brazil	***	***	***	***
China	***	***	***	***
India	***	***	***	***
Vietnam	***	***	***	***
All other sources	***	***	***	***
All import sources	90,921,574	100.0	86,200,349	100.0

Source: Compiled from data submitted in response to Commission questionnaires and from official U.S. import statistics of the U.S. department of Commerce using HTS statistical reporting numbers 9602.00.1040 and 9602.00.5010, accessed November 14, 2024, adjusted to add in in-scope HECs imported under other HTS numbers as reported by U.S. importers in Commission questionnaires. No responding U.S. importer reported any out-of-scope products under the primary HTS numbers and none of the certified No questionnaire response were importers identified under the primary HTS numbers within the proprietary, Census-edited Customs records, otherwise hypothetically the adjustment to official U.S. imports statistics would have included those two additional adjustments.

Table IV-6 and figure IV-2 provide additional information concerning Brazil.

Table IV-6
HECs: U.S. imports from Brazil and all sources in various twelve-month periods leading up to the twelve months immediately prior to the filing of the petition

Quantity in 1,000 units; share of quantity in percent

12 month period ending in	Brazil quantity	All other sources quantity	All import sources quantity	Brazil share	All other sources share	All import sources share
2022: January	***	***	***	***	***	100.0
2022: February	***	***	***	***	***	100.0
2022: March	***	***	***	***	***	100.0
2022: April	***	***	***	***	***	100.0
2022: May	***	***	***	***	***	100.0
2022: June	***	***	***	***	***	100.0
2022: July	***	***	***	***	***	100.0
2022: August	***	***	***	***	***	100.0
2022: September	***	***	***	***	***	100.0
2022: October	***	***	***	***	***	100.0
2022: November	***	***	***	***	***	100.0
2022: December	***	***	***	***	***	100.0
2023: January	***	***	***	***	***	100.0
2023: February	***	***	***	***	***	100.0
2023: March	***	***	***	***	***	100.0

12 month period ending in	Brazil quantity	All other sources quantity	All import sources quantity	Brazil share	All other sources share	All import sources share
2023: April	***	***	***	***	***	100.0
2023: May	***	***	***	***	***	100.0
2023: June	***	***	***	***	***	100.0
2023: July	***	***	***	***	***	100.0
2023: August	***	***	***	***	***	100.0
2023: September	***	***	***	***	***	100.0
2023: October	***	***	***	***	***	100.0
2023: November	***	***	***	***	***	100.0
2023: December	***	***	***	***	***	100.0
2024: January	***	***	***	***	***	100.0
2024: February	***	***	***	***	***	100.0
2024: March	***	***	***	***	***	100.0
2024: April	***	***	***	***	***	100.0
2024: May	***	***	***	***	***	100.0
2024: June	***	***	***	***	***	100.0
2024: July	***	***	***	***	***	100.0
2024: August	***	***	***	***	***	100.0
2024: September	***	***	***	***	***	100.0

Source: Compiled from data submitted in response to Commission questionnaires and from official U.S. import statistics of the U.S. department of Commerce using HTS statistical reporting numbers 9602.00.1040 and 9602.00.5010, accessed November 14, 2024, adjusted to add in in-scope HECs imported under other HTS numbers as reported by U.S. importers in Commission questionnaires. No responding U.S. importer reported any out-of-scope products under the primary HTS numbers and none of the certified No questionnaire response were importers identified under the primary HTS numbers within the proprietary, Census-edited Customs records, otherwise hypothetically the adjustment to official U.S. imports statistics would have included those two additional adjustments.

Note: Shares shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Figure IV-2

HEC: Share of U.S. imports from Brazil out of total imports in the various twelve-month periods in the lead up to the twelve months immediately prior to the filing of the petition

* * * * * * * *

Source: Compiled from data submitted in response to Commission questionnaires and from official U.S. import statistics of the U.S. department of Commerce using HTS statistical reporting numbers 9602.00.1040 and 9602.00.5010, accessed November 14, 2024, adjusted to add in in-scope HECs imported under other HTS numbers as reported by U.S. importers in Commission questionnaires. No responding U.S. importer reported any out-of-scope products under the primary HTS numbers and none of the certified No questionnaire responses were importers identified under the primary HTS numbers within the proprietary, Census-edited Customs records, otherwise hypothetically the adjustment to official U.S. imports statistics would have included those two additional adjustments.

Note: Shares shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Cumulation considerations

In assessing whether imports should be cumulated, the Commission determines whether U.S. imports from the subject countries compete with each other and with the domestic like product and has generally considered four factors: (1) fungibility, (2) presence of sales or offers to sell in the same geographical markets, (3) common or similar channels of distribution, and (4) simultaneous presence in the market. Information regarding channels of distribution, market areas, and interchangeability appear in Part II. Additional information concerning fungibility, geographical markets, and simultaneous presence in the market is presented below.

Fungibility

Table IV-7 and figure IV-3 present U.S. producers' and U.S. importers' 2023 U.S. shipments by type. In 2023, gelatin HECs comprised *** percent, and non-gelatin HECs comprised *** percent of U.S. producers' U.S. shipments in 2023. During the same year U.S. shipments from subject sources of gelatin HECs comprised *** percent, and non-gelatin HECs comprised *** percent. In 2023, gelatin HEC comprised *** percent, and non-gelatin HECs comprised *** percent of non-subject U.S. shipments in 2023.

Table IV-7 HECs: U.S. producers' and U.S. importers' U.S. shipments, by source and type, 2023

Quantity in 1,000 units

Source	Gelatin	Non-gelatin	All types	
U.S. producers	***	***	***	
Brazil	***	***	***	
China	***	***	***	
India	***	***	***	
Vietnam	***	***	***	
Subject sources	***	***	***	
Subject sources less Brazil	***	***	***	
Nonsubject sources	***	***	***	
Nonsubject sources plus Brazil	***	***	***	
All import sources	***	***	***	
All sources	51,013,280	46,768,327	97,781,607	

Table IV-7 Continued

HECs: U.S. producers' and U.S. importers' U.S. shipments, by source and type, 2023

Share across in percent

Source	Gelatin	Non-gelatin	All types
U.S. producers	***	***	100.0
Brazil	***	***	100.0
China	***	***	100.0
India	***	***	100.0
Vietnam	***	***	100.0
Subject sources	***	***	100.0
Subject sources less Brazil	***	***	100.0
Nonsubject sources	***	***	100.0
Nonsubject sources plus Brazil	***	***	100.0
All import sources	***	***	100.0
All sources	52.2	47.8	100.0

Table continued.

Table IV-7 Continued

HECs: U.S. producers' and U.S. importers' U.S. shipments, by source and type, 2023

Share down in percent

Source	Gelatin	Non-gelatin	All types
U.S. producers	***	***	***
Brazil	***	***	***
China	***	***	***
India	***	***	***
Vietnam	***	***	***
Subject sources	***	***	***
Subject sources less Brazil	***	***	***
Nonsubject sources	***	***	***
Nonsubject sources plus Brazil	***	***	***
All import sources	***	***	***
All sources	100.0	100.0	100.0

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Shares shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Figure IV-3

HECs: U.S. producers' and U.S. importers' U.S. shipments, by source and type, 2023

* * * * * * *

Source: Compiled from data submitted in response to Commission questionnaires.

Geographical markets

Table IV-8 presents data on U.S. imports by source and border of entry in 2023. Imports from all sources entered through all borders of entry in 2023, except that no imports from Brazil and Vietnam entered through Northern borders of entry. The majority of U.S. imports from subject and nonsubject sources entered through the Eastern borders of entry in 2023.

Table IV-8 HECs: U.S. imports by source and border of entry, 2023

Quantity in 1,000 units

					All
Source	East	North	South	West	borders
Brazil	678,576		761,250	278,600	1,718,426
China	3,338,563	90,567	2,718,516	3,446,521	9,594,167
India	15,509,001	231	793,694	2,394,408	18,697,334
Vietnam	4,106,710		219,050	4,793,351	9,119,111
Subject sources	23,632,850	90,798	4,492,510	10,912,880	39,129,038
Subject sources less Brazil	22,954,274	90,798	3,731,260	10,634,280	37,410,612
Nonsubject sources	4,017,779	5,028,855	1,625,051	2,991,897	13,663,582
Nonsubject sources plus Brazil	4,696,355	5,028,855	2,386,301	3,270,497	15,382,008
All import sources	27,650,629	5,119,653	6,117,561	13,904,777	52,792,620

Table continued.

Table IV-8 Continued

HECs: U.S. imports by source and border of entry, 2023

Share across in percent

Source	East	North	South	West	All borders
Brazil	39.5		44.3	16.2	100.0
China	34.8	0.9	28.3	35.9	100.0
India	82.9	0.0	4.2	12.8	100.0
Vietnam	45.0		2.4	52.6	100.0
Subject sources	60.4	0.2	11.5	27.9	100.0
Subject sources less Brazil	61.4	0.2	10.0	28.4	100.0
Nonsubject sources	29.4	36.8	11.9	21.9	100.0
Nonsubject sources plus Brazil	30.5	32.7	15.5	21.3	100.0
All import sources	52.4	9.7	11.6	26.3	100.0

Table continued.

Table IV-8 Continued

HECs: U.S. imports by source and border of entry, 2023

Share down in percent

					All
Source	East	North	South	West	borders
Brazil	2.5		12.4	2.0	3.3
China	12.1	1.8	44.4	24.8	18.2
India	56.1	0.0	13.0	17.2	35.4
Vietnam	14.9		3.6	34.5	17.3
Subject sources	85.5	1.8	73.4	78.5	74.1
Subject sources less Brazil	83.0	1.8	61.0	76.5	70.9
Nonsubject sources	14.5	98.2	26.6	21.5	25.9
Nonsubject sources plus Brazil	17.0	98.2	39.0	23.5	29.1
All import sources	100.0	100.0	100.0	100.0	100.0

Source: Compiled from official U.S. import statistics of the U.S. Department of Commerce Census Bureau using statistical reporting numbers 9602.00.1040 and 9602.00.5010, accessed November 14, 2024. Imports are based on the imports for consumption data series.

Note: Shares shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Presence in the market

Table IV-9 and figures IV-4 and IV-5 present data on U.S. imports by source and month from January 2020 to August 2023. Imports from both aggregate subject sources and nonsubject sources were present in every month from January 2021 to August 2024. Imports from China, India, Vietnam and nonsubject sources were present in 42 of 42 months in this period. Imports from Brazil were present in 31 of the 42 months in this period.

Table IV-9 HECs: Quantity of U.S. imports, by source and month

Quantity in 1,000 units

Year	Month	Brazil	China	India	Vietnam
2021	January	319,375	859,845	1,128,958	658,645
2021	February	174,200	665,023	530,190	808,320
2021	March	147,075	1,046,500	1,347,689	575,220
2021	April	209,700	943,640	873,534	979,530
2021	May	106,100	998,527	1,003,694	592,020
2021	June	35,900	1,178,267	1,408,278	837,304
2021	July	143,100	771,161	1,365,624	800,330
2021	August	135,375	1,315,746	1,589,451	465,115
2021	September	44,375	1,184,737	1,355,092	883,583
2021	October	68,100	1,434,275	1,417,123	786,501
2021	November	106,154	2,064,753	1,459,790	577,747
2021	December	143,200	1,604,278	1,392,908	917,595
2022	January	294,225	2,049,586	1,481,667	557,810
2022	February	187,275	1,930,608	1,345,200	851,065
2022	March	245,325	2,019,608	2,078,426	1,187,395
2022	April	267,400	1,494,343	1,088,567	988,620
2022	May	1	1,030,118	1,642,082	981,520
2022	June		1,321,337	1,340,597	837,080
2022	July		963,915	1,343,689	824,931
2022	August		1,393,154	1,393,365	1,062,335
2022	September		712,632	1,678,207	780,738
2022	October		618,673	1,270,329	1,258,550
2022	November		889,115	1,612,761	716,595
2022	December	1	595,129	1,135,898	945,960

Table IV-9 Continued

HECs: Quantity of U.S. imports, by source and month

Quantity in 1,000 units

Year	Month	Brazil	China	India	Vietnam
2023	January		357,331	1,680,337	686,016
2023	February		385,793	693,371	459,430
2023	March		429,442	1,864,382	473,620
2023	April	23,325	813,678	1,707,465	693,855
2023	May		624,617	1,159,104	722,045
2023	June		1,111,760	1,417,917	506,995
2023	July	1	1,074,618	1,711,762	867,880
2023	August	143,475	540,376	1,960,578	745,850
2023	September	199,775	871,757	1,863,746	829,970
2023	October	628,400	1,116,875	1,680,395	846,320
2023	November	517,350	1,127,773	1,541,267	1,061,510
2023	December	206,100	1,140,147	1,417,010	1,225,620
2024	January	190,625	1,082,538	992,719	981,670
2024	February	176,750	910,655	1,160,137	1,248,615
2024	March	35,800	1,087,489	2,066,358	1,287,730
2024	April	113,050	1,240,409	1,176,920	1,343,610
2024	May	55,925	1,064,708	1,328,505	689,941
2024	June	68,675	925,043	1,582,180	1,569,420

Table IV-9 Continued HECs: Quantity of U.S. imports, by source and month

Quantity in 1,000 units

Year	Month	Subject sources	Nonsubject sources	All import sources
2021	January	2,966,823	1,743,420	4,710,243
2021	February	2,177,733	1,923,286	4,101,019
2021	March	3,116,484	1,971,619	5,088,103
2021	April	3,006,404	1,893,325	4,899,729
2021	May	2,700,341	2,132,054	4,832,395
2021	June	3,459,749	1,959,759	5,419,508
2021	July	3,080,215	1,742,204	4,822,419
2021	August	3,505,687	1,660,003	5,165,690
2021	September	3,467,787	1,860,404	5,328,191
2021	October	3,705,999	1,764,598	5,470,597
2021	November	4,208,444	1,690,015	5,898,459
2021	December	4,057,981	1,122,617	5,180,598
2022	January	4,383,288	1,858,721	6,242,009
2022	February	4,314,148	1,961,258	6,275,406
2022	March	5,530,754	2,246,231	7,776,985
2022	April	3,838,930	1,467,623	5,306,553
2022	May	3,653,721	1,753,072	5,406,793
2022	June	3,499,014	1,556,619	5,055,633
2022	July	3,132,535	1,326,407	4,458,942
2022	August	3,848,854	1,311,893	5,160,747
2022	September	3,171,577	1,739,932	4,911,509
2022	October	3,147,552	1,812,467	4,960,019
2022	November	3,218,471	1,752,172	4,970,643
2022	December	2,676,988	1,014,930	3,691,918

Table IV-9 Continued

HECs: Quantity of U.S. imports, by source and month

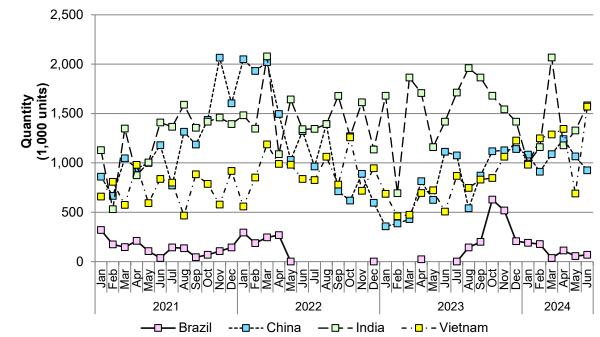
Quantity in 1,000 units

Year	Month	Subject sources	Nonsubject sources	All import sources
2023	January	2,723,684	1,082,557	3,806,241
2023	February	1,538,594	896,050	2,434,644
2023	March	2,767,444	1,037,629	3,805,073
2023	April	3,238,323	1,212,624	4,450,947
2023	May	2,505,766	1,189,720	3,695,486
2023	June	3,036,672	1,224,856	4,261,528
2023	July	3,654,261	1,259,490	4,913,751
2023	August	3,390,279	1,160,932	4,551,211
2023	September	3,765,248	1,123,985	4,889,233
2023	October	4,271,990	1,241,289	5,513,279
2023	November	4,247,900	1,326,875	5,574,775
2023	December	3,988,877	907,575	4,896,452
2024	January	3,247,552	1,443,595	4,691,147
2024	February	3,496,157	1,143,861	4,640,018
2024	March	4,477,377	1,306,866	5,784,243
2024	April	3,873,989	1,340,478	5,214,467
2024	May	3,139,079	1,425,613	4,564,692
2024	June	4,145,318	1,159,543	5,304,861

Source: Compiled from official U.S. import statistics of the U.S. Department of Commerce Census Bureau using statistical reporting numbers 9602.00.1040 and 9602.00.5010, accessed November 14, 2024. Imports are based on the imports for consumption data series.

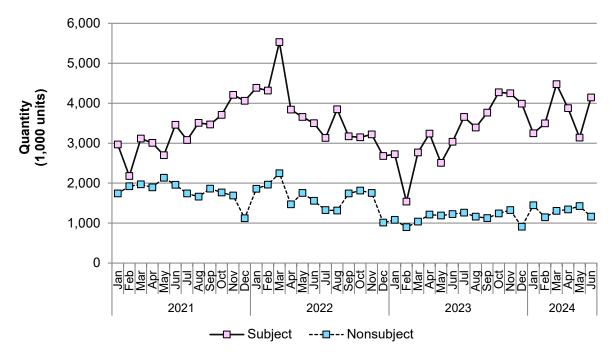
Note: Zeroes, null values, and undefined calculations are suppressed and shown as "---".





Source: Compiled from official U.S. import statistics of the U.S. Department of Commerce Census Bureau using statistical reporting numbers 9602.00.1040 and 9602.00.5010, accessed November 14, 2024. Imports are based on the imports for consumption data series.





Source: Compiled from official U.S. import statistics of the U.S. Department of Commerce Census Bureau using statistical reporting numbers 9602.00.1040 and 9602.00.5010, accessed November 14, 2024. Imports are based on the imports for consumption data series.

Apparent U.S. consumption and market shares

Quantity

Table IV-10 and figure IV-6 present data on apparent U.S. consumption and U.S. market shares by quantity for HECs. Apparent U.S. consumption fluctuated year to year between 2021 and 2023, decreasing from 2021 to 2022 then slightly increasing from 2022 to 2023, ending *** percent lower. Apparent U.S. consumption was *** percent higher in interim 2024 compared to interim 2023. The share of quantity held by U.S. producers decreased by *** percentage points from 2021 to 2023 and was *** percentage points lower in interim 2024 than in interim 2023.

The share of quantity held by subject imports increased by *** percentage points from 2021 to 2023 and was *** percentage points higher in interim 2024 than in interim 2023.⁵ The share of quantity held by nonsubject imports increased by *** percentage points from 2021 to 2023 and was *** percentage points higher in interim 2024 than in interim 2023.

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⁵ U.S. shipments of subject imports by quantity increased year to year, from *** billion units in 2021 to *** billion units in 2022 then increasing to *** billion units in 2023, and was higher in interim 2024 (*** billion units) than in interim 2023 (*** billion units).

Table IV-10 HECs: Apparent U.S. consumption and market shares based on quantity, by source and period

Quantity in 1.000 units: shares in percent

Source	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
U.S. producers	Quantity	***	***	***	***	***
Brazil	Quantity	***	***	***	***	***
China	Quantity	***	***	***	***	***
India	Quantity	***	***	***	***	***
Vietnam	Quantity	***	***	***	***	***
Subject sources	Quantity	***	***	***	***	***
Subject sources less Brazil	Quantity	***	***	***	***	***
Nonsubject sources	Quantity	***	***	***	***	***
Nonsubject sources plus	0	***	***	***	***	***
Brazil	Quantity	***	***	***	***	***
All import sources	Quantity					
All sources	Quantity	108,057,349	96,159,481	97,786,607	47,099,179	51,022,995
U.S. producers	Share	***	***	***		***
Brazil	Share	***	***	***	***	***
China	Share	***	***	***	***	***
India	Share	***	***	***	***	***
Vietnam	Share	***	***	***	***	***
Subject sources	Share	***	***	***	***	***
Subject sources less Brazil	Share	***	***	***	***	***
Nonsubject sources	Share	***	***	***	***	***
Nonsubject sources plus Brazil	Share	***	***	***	***	***
All import sources	Share	***	***	***	***	***
All sources	Share	100.0	100.0	100.0	100.0	100.0

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Shares shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".



* * * * * * *

Source: Compiled from data submitted in response to Commission questionnaires

Value

Table IV-11 and figure IV-7 presents data on apparent U.S. consumption and U.S. market shares by value for HECs. Apparent U.S. consumption decreased year to year between 2021 and 2023, ending *** percent lower. Apparent U.S. consumption was *** percent lower in interim 2024 compared to interim 2023. The share of value held by U.S. producers decreased by *** percentage points from 2021 to 2023 and was *** percentage points lower in interim 2024 than in interim 2023. The share of value held by subject imports increased by *** percentage points from 2021 to 2023 and was *** percentage points higher in interim 2024 than in interim 2023. The share of value held by nonsubject imports decreased by *** percentage points from 2021 to 2023 but was *** percentage points higher in interim 2024 than in interim 2023.

⁶ U.S. producers' U.S. shipments by value decreased year to year, decreasing from *** million in 2021 to *** million in 2022 then decreasing to *** million in 2023, and was lower in interim 2024 (*** million) than in interim 2023 (*** million).

Table IV-11 HECs: Apparent U.S. consumption and market shares based on value, by source and period

Value in 1.000 dollars: shares in percent

Source	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
U.S. producers	Value	***	***	***	***	***
Brazil	Value	***	***	***	***	***
China	Value	***	***	***	***	***
India	Value	***	***	***	***	***
Vietnam	Value	***	***	***	***	***
Subject sources	Value	***	***	***	***	***
Subject sources less Brazil	Value	***	***	***	***	***
Nonsubject sources	Value	***	***	***	***	***
Nonsubject sources plus Brazil	Value	***	***	***	***	***
All import sources	Value	***	***	***	***	***
All sources	Value	520,665	487,018	472,589	232,822	228,753
U.S. producers	Share	***	***	***	***	***
Brazil	Share	***	***	***	***	***
China	Share	***	***	***	***	***
India	Share	***	***	***	***	***
Vietnam	Share	***	***	***	***	***
Subject sources	Share	***	***	***	***	***
Subject sources less Brazil	Share	***	***	***	***	***
Nonsubject sources	Share	***	***	***	***	***
Nonsubject sources plus Brazil	Share	***	***	***	***	***
All import sources	Share	***	***	***	***	***
All sources	Share	100.0	100.0	100.0	100.0	100.0

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Shares shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".



* * * * * * *

Source: Compiled from data submitted in response to Commission questionnaires

Part V: Pricing data

Factors affecting prices

Raw material costs

The major raw materials for HECs are the gelatin or plant-based polymers used in their production. U.S. producers reported that in 2023, gelatin accounted for the largest share of their raw materials costs (***) percent, followed by *** percent for HPMC, *** percent for pullulan.

Transportation costs to the U.S. market

Transportation costs for HECs shipped from subject countries to the United States averaged 3.6 percent for Brazil, 3.2 percent for China, 3.1 percent for India, and 4.2 percent for Vietnam during 2023. These estimates were derived from official import data and represent the transportation and other charges on imports.¹

U.S. inland transportation costs

*** and 15 of 16 responding importers reported that they typically arrange transportation to their customers. U.S. producers reported that their U.S. inland transportation costs ranged from 2 to 5 percent while most importers reported costs of 1 to 7 percent.

Pricing practices

Pricing methods

U.S. producers and importers reported setting prices using transaction-by-transaction negotiations, contracts, and price lists (table V-1). *** three importers reported other methods including: pricing based on order size, type of product, distance, payment history, and capsule filling equipment; price negotiation based on customer specifications; price guidelines used in negotiations; and set a price floor based on gross or variable margin.

¹ The estimated transportation costs were obtained by subtracting the customs value from the c.i.f. value of the imports for 2023 and then dividing by the customs value based on the HTS statistical reporting numbers 9602.00.1040 and 9602.00.5010.

Table V-1 HECs: Count of U.S. producers' and importers' reported price setting methods

Method	U.S. producers	Importers
Transaction-by-transaction	***	10
Contract	***	8
Set price list	***	10
Other	***	3
Responding firms	2	16

Source: Compiled from data submitted in response to Commission questionnaires.

Note: The sum of responses down may not add up to the total number of responding firms as each firm was instructed to check all applicable price setting methods employed.

U.S. producers reported selling most of their HECs in the *** (table V-2). Importers reported selling most of their HECs under short-term contracts or in the spot market, with most of the remainder under annual contracts.

Table V-2 HECs: U.S. producers' and importers' shares of commercial U.S. shipments by type of sale, 2023

Share in percent

Type of sale	U.S. producers	Subject importers
Long-term contracts	***	4.6
Annual contracts	***	28.2
Short-term contracts	***	34.8
Spot sales	***	32.4
Total	100.0	100.0

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Because of rounding, figures may not add to the totals shown.

U.S. producer ***. ***. Importers generally reported that their short-term contracts fixed price and quantity and were not indexed to raw materials. Most responding importers reported that their annual contracts did not allow price renegotiation, fixed price, and were not indexed to raw materials and that their long-term contracts allowed price renegotiation, fixed price and were not indexed to raw materials.

Sales terms and discounts

*** 9 of 14 importers typically quote prices on a delivered basis. Producers reported ***. Some importers reported offering quantity and total volume discounts, while 7 of 16 importers reported no discount policy.²

Price data

The Commission requested U.S. producers and importers to provide quarterly data for the total quantity and f.o.b. value of the following HECs products shipped to unrelated U.S. customers during January 2021 to June 2024.

- **Product 1.--** Hard empty gelatin capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), imprinted, and sold in per 1,000 unit increments.
- **Product 2.**--Hard empty gelatin capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), **NOT** imprinted, and sold in per 1,000 unit increments.
- **Product 3.--**Hard empty hydroxypropyl methylcellulose ("HPMC") capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), imprinted, and sold in per 1,000 unit increments.
- Product 4.--Hard empty hydroxypropyl methylcellulose ("HPMC") capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), NOT imprinted, and sold in per 1,000 unit increments.

² One importer reported other discounts but did not explain what these were.

Two U.S. producers and 12 importers provided usable pricing data for sales of the requested products, although not all firms reported pricing for all products for all quarters.³ Pricing data reported by these firms accounted for approximately *** percent of U.S. producers' U.S. commercial shipments of HECs and *** percent of U.S. commercial shipments of subject imports from Brazil, *** percent from China, *** percent from India, and *** percent from Vietnam in 2023.⁴

Price data for products 1-4 are presented in tables V-3 to V-6 and figures V-1 to V-4.

Table V-3 HECs: Weighted-average f.o.b. prices and quantities of domestic and imported product 1 and margins of underselling/(overselling), by source and quarter

Price in dollars per 1,000 units, quantity in 1,000 units, margin in percent.

Period	U.S. price	U.S. quantity	India price	India quantity	India margin	Vietnam price	Vietnam quantity	Vietnam margin
2021 Q1	***	***	***	***	***	***	***	***
2021 Q2	***	***	***	***	***	***	***	***
2021 Q3	***	***	***	***	***	***	***	***
2021 Q4	***	***	***	***	***	***	***	***
2022 Q1	***	***	***	***	***	***	***	***
2022 Q2	***	***	***	***	***	***	***	***
2022 Q3	***	***	***	***	***	***	***	***
2022 Q4	***	***	***	***	***	***	***	***
2023 Q1	***	***	***	***	***	***	***	***
2023 Q2	***	***	***	***	***	***	***	***
2023 Q3	***	***	***	***	***	***	***	***
2023 Q4	***	***	***	***	***	***	***	***
2024 Q1	***	***	***	***	***	***	***	***
2024 Q2	***	***	***	***	***	***	***	***

Source: Compiled from data submitted in response to Commission guestionnaires.

Note: Product 1: Hard empty gelatin capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), imprinted, and sold in per 1,000 unit increments.

³ Per-unit pricing data are calculated from total quantity and total value data provided by U.S. producers and importers. The precision and variation of these figures may be affected by rounding, limited quantities, and producer or importer estimates.

⁴ Pricing coverage is based on U.S. commercial shipments reported in questionnaires.

Table V-4
HECs: Weighted-average f.o.b. prices and quantities of domestic and imported product 2 and margins of underselling/(overselling), by source and quarter

Price in dollars per 1,000 units, quantity in 1,000 units, margin in percent.

Period	U.S. price	U.S. quantity	Brazil price	Brazil quantity	Brazil margin	China price	China quantity	China margin
2021 Q1	***	***	***	***	***	***	***	***
2021 Q2	***	***	***	***	***	***	***	***
2021 Q3	***	***	***	***	***	***	***	***
2021 Q4	***	***	***	***	***	***	***	***
2022 Q1	***	***	***	***	***	***	***	***
2022 Q2	***	***	***	***	***	***	***	***
2022 Q3	***	***	***	***	***	***	***	***
2022 Q4	***	***	***	***	***	***	***	***
2023 Q1	***	***	***	***	***	***	***	***
2023 Q2	***	***	***	***	***	***	***	***
2023 Q3	***	***	***	***	***	***	***	***
2023 Q4	***	***	***	***	***	***	***	***
2024 Q1	***	***	***	***	***	***	***	***
2024 Q2	***	***	***	***	***	***	***	***

Period	India price	India quantity	India margin	Vietnam Price	Vietnam quantity	Vietnam margin
2021 Q1	***	***	***	***	***	***
2021 Q2	***	***	***	***	***	***
2021 Q3	***	***	***	***	***	***
2021 Q4	***	***	***	***	***	***
2022 Q1	***	***	***	***	***	***
2022 Q2	***	***	***	***	***	***
2022 Q3	***	***	***	***	***	***
2022 Q4	***	***	***	***	***	***
2023 Q1	***	***	***	***	***	***
2023 Q2	***	***	***	***	***	***
2023 Q3	***	***	***	***	***	***
2023 Q4	***	***	***	***	***	***
2024 Q1	***	***	***	***	***	***
2024 Q2	***	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Product 2: Hard empty gelatin capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), **NOT** imprinted, and sold in per 1,000 unit increments.

Table V-5
HECs: Weighted-average f.o.b. prices and quantities of domestic and imported product 3 and margins of underselling/(overselling), by source and quarter

Price in dollars per 1,000 units, quantity in 1,000 units, margin in percent.

Period	U.S. price	U.S. quantity	India price	India quantity	India margin	Vietnam price	Vietnam quantity	Vietnam margin
2021 Q1	***	***	***	***	***	***	***	***
2021 Q2	***	***	***	***	***	***	***	***
2021 Q3	***	***	***	***	***	***	***	***
2021 Q4	***	***	***	***	***	***	***	***
2022 Q1	***	***	***	***	***	***	***	***
2022 Q2	***	***	***	***	***	***	***	***
2022 Q3	***	***	***	***	***	***	***	***
2022 Q4	***	***	***	***	***	***	***	***
2023 Q1	***	***	***	***	***	***	***	***
2023 Q2	***	***	***	***	***	***	***	***
2023 Q3	***	***	***	***	***	***	***	***
2023 Q4	***	***	***	***	***	***	***	***
2024 Q1	***	***	***	***	***	***	***	***
2024 Q2	***	***	***	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Product 3: Hard empty hydroxypropyl methylcellulose ("HPMC") capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), imprinted, and sold in per 1,000 unit increments.

Table V-6
HECs: Weighted-average f.o.b. prices and quantities of domestic and imported product 4 and margins of underselling/(overselling), by source and quarter

Price in dollars per 1,000 units, quantity in 1,000 units, margin in percent.

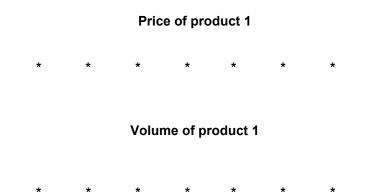
Period	U.S. price	U.S. quantity	Brazil price	Brazil quantity	Brazil margin	China price	China quantity	China margin
2021 Q1	***	***	***	***	***	***	***	***
2021 Q2	***	***	***	***	***	***	***	***
2021 Q3	***	***	***	***	***	***	***	***
2021 Q4	***	***	***	***	***	***	***	***
2022 Q1	***	***	***	***	***	***	***	***
2022 Q2	***	***	***	***	***	***	***	***
2022 Q3	***	***	***	***	***	***	***	***
2022 Q4	***	***	***	***	***	***	***	***
2023 Q1	***	***	***	***	***	***	***	***
2023 Q2	***	***	***	***	***	***	***	***
2023 Q3	***	***	***	***	***	***	***	***
2023 Q4	***	***	***	***	***	***	***	***
2024 Q1	***	***	***	***	***	***	***	***
2024 Q2	***	***	***	***	***	***	***	***

Period	India price	India quantity	India margin	Vietnam Price	Vietnam Quantity	Vietnam margin
2021 Q1	***	***	***	***	***	***
2021 Q2	***	***	***	***	***	***
2021 Q3	***	***	***	***	***	***
2021 Q4	***	***	***	***	***	***
2022 Q1	***	***	***	***	***	***
2022 Q2	***	***	***	***	***	***
2022 Q3	***	***	***	***	***	***
2022 Q4	***	***	***	***	***	***
2023 Q1	***	***	***	***	***	***
2023 Q2	***	***	***	***	***	***
2023 Q3	***	***	***	***	***	***
2023 Q4	***	***	***	***	***	***
2024 Q1	***	***	***	***	***	***
2024 Q2	***	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Product 4: Hard empty hydroxypropyl methylcellulose ("HPMC") capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), **NOT** imprinted, and sold in per 1,000 unit increments.

HECs: Weighted-average f.o.b. prices and quantities of domestic and imported product 1, by source and quarter



Source: Compiled from data submitted in response to Commission questionnaires.

Note: Product 1: Hard empty gelatin capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), imprinted, and sold in per 1,000 unit increments.

HECs: Weighted-average f.o.b. prices and quantities of domestic and imported product 2, by source and quarter

Price of product 2

* * * * * * *

Volume of product 2

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Product 2: Hard empty gelatin capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), **NOT** imprinted, and sold in per 1,000 unit increments.

HECs: Weighted-average f.o.b. prices and quantities of domestic and imported product 3, by source and quarter

Price of product 3

* * * * * * *

Volume of product 3

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Product 3: Hard empty hydroxypropyl methylcellulose ("HPMC") capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), imprinted, and sold in per 1,000 unit increments.

HECs: Weighted-average f.o.b. prices and quantities of domestic and imported product 4, by source and quarter

Price of product 4 * * * * * * * Volume of product 4

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Product 4: Hard empty hydroxypropyl methylcellulose ("HPMC") capsules (including cap and body) for human consumption, in all sizes between 00 to 3 (whether regular, elongated, or enrobing), **NOT** imprinted, and sold in per 1,000 unit increments.

Price trends

U.S. producer prices fluctuated over the period and overall price trends were mixed during January 2021 to June 2024, with prices of two products increasing and two decreasing. Table V-7 summarizes the price trends, by country and by product. As shown in the table, domestic price increases ranged from 1.1 to 6.6 percent and decreases ranged from 3.7 to 57.4 percent during January 2021 to June 2024. Import price increases ranged from 4.6 to 6.2 percent and import price decreases ranged from 1.6 to 27.9 percent.

Table V-7 HECs: Summary of price data, by product and source, January 2021 to June 2024

Quantity in 1,000 units, price in dollars per 1,000 units

Product	Source	Number of quarters	Quantity of shipments	Low price	High price	First quarter price	Last quarter price	Percent change in price over period
Product 1	United States	14	***	***	***	***	***	***
Product 1	Brazil	0	***	***	***	***	***	***
Product 1	China	0	***	***	***	***	***	***
Product 1	India	14	***	***	***	***	***	***
Product 1	Vietnam	14	***	***	***	***	***	***
Product 2	United States	14	***	***	***	***	***	***
Product 2	Brazil	14	***	***	***	***	***	***
Product 2	China	14	***	***	***	***	***	***
Product 2	India	14	***	***	***	***	***	***
Product 2	Vietnam	14	***	***	***	***	***	***
Product 3	United States	14	***	***	***	***	***	***
Product 3	Brazil	0	***	***	***	***	***	***
Product 3	China	0	***	***	***	***	***	***
Product 3	India	14	***	***	***	***	***	***
Product 3	Vietnam	1	***	***	***	***	***	***
Product 4	United States	14	***	***	***	***	***	***
Product 4	Brazil	0	***	***	***	***	***	***
Product 4	China	14	***	***	***	***	***	***
Product 4	India	14	***	***	***	***	***	***
Product 4	Vietnam	14	***	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Percent change column is percentage change from the first quarter 2021 to the second quarter in 2024.

Price comparisons

As shown in tables V-8 to V-10, prices for product imported from subject countries were below those for U.S.-produced product in 140 of 141 instances: for Brazil, in all 14 instances (*** units), for China all 28 instances (*** units), for India all 56 instances (*** units), and for Vietnam 42 of 43 instances (*** units). Margins of underselling ranged from *** percent for Brazil, *** percent for China, *** percent for India, and *** percent for Vietnam. In one instance (*** units), prices for product from Vietnam were *** percent above prices for the domestic product.

Table V-8 HECs: Instances of underselling and overselling and the range and average of margins, by product

Quantity in 1,000 units; margin in percent

Quartery iii 1,0	Joo units, marg	Jan an percent	Number				
			of		Average	Min	Max
Product	Type	Aggregation	quarters	Quantity	margin	margin	margin
Product 1	Underselling	All subject sources	27	***	***	***	***
Product 2	Underselling	All subject sources	56	***	***	***	***
Product 3	Underselling	All subject sources	15	***	***	***	***
Product 4	Underselling	All subject sources	42	***	***	***	***
All products	Underselling	All subject sources	140	***	***	***	***
Product 1	Overselling	All subject sources	1	***	***	***	***
Product 2	Overselling	All subject sources	0	***	***	***	***
Product 3	Overselling	All subject sources	0	***	***	***	***
Product 4	Overselling	All subject sources	0	***	***	***	***
All products	Overselling	All subject sources	1	***	***	***	***
Product 1	Underselling	Subject sources less Brazil	27	***	***	***	***
Product 2	Underselling	Subject sources less Brazil	42	***	***	***	***
Product 3	Underselling	Subject sources less Brazil	15	***	***	***	***
Product 4	Underselling	Subject sources less Brazil	42	***	***	***	***
All products	Underselling	Subject sources less Brazil	126	***	***	***	***
Product 1	Overselling	Subject sources less Brazil	1	***	***	***	***
Product 2	Overselling	Subject sources less Brazil	0	***	***	***	***
Product 3	Overselling	Subject sources less Brazil	0	***	***	***	***
Product 4	Overselling	Subject sources less Brazil	0	***	***	***	***
All products	Overselling	Subject sources less Brazil	1	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Margins shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---". These data include only quarters in which there is a comparison between the U.S. and subject product.

Table V-9 HECs: Instances of underselling and overselling and the range and average of margins, by source

Quantity in 1,000 units; margin in percent

Source	Туре	Number of quarters	Quantity	Average margin	Min margin	Max margin
Brazil	Underselling	14	***	***	***	***
China	Underselling	28	***	***	***	***
India	Underselling	56	***	***	***	***
Vietnam	Underselling	42	***	***	***	***
All subject sources	Underselling	140	***	***	***	***
Subject sources less Brazil	Underselling	126	***	***	***	***
Brazil	Overselling	0	***	***	***	***
China	Overselling	0	***	***	***	***
India	Overselling	0	***	***	***	***
Vietnam	Overselling	1	***	***	***	***
All subject sources	Overselling	1	***	***	***	***
Subject sources less Brazil	Overselling	1	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Margins shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---". These data include only quarters in which there is a comparison between the U.S. and subject product.

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Table V-10 HECs: Instances of underselling and overselling and the range and average of margins, by year

Quantity in 1,000 units; margin in percent

			Number				
Period	Туре	Aggregation	of quarters	Quantity	Average margin	Min margin	Max margin
2021	Underselling	All subject sources	39	***	***	***	***
2022	Underselling	All subject sources	40	***	***	***	***
2023	Underselling	All subject sources	41	***	***	***	***
JanJune 2024	Underselling	All subject sources	20	***	***	***	***
All periods	Underselling	All subject sources	140	***	***	***	***
2021	Overselling	All subject sources	1	***	***	***	***
2022	Overselling	All subject sources	0	***	***	***	***
2023	Overselling	All subject sources	0	***	***	***	***
JanJune 2024	Overselling	All subject sources	0	***	***	***	***
All periods	Overselling	All subject sources	1	***	***	***	***
2021	Underselling	Subject sources less Brazil	35	***	***	***	***
2022	Underselling	Subject sources less Brazil	36	***	***	***	***
2023	Underselling	Subject sources less Brazil	37	***	***	***	***
JanJune 2024	Underselling	Subject sources less Brazil	18	***	***	***	***
All periods	Underselling	Subject sources less Brazil	126	***	***	***	***
2021	Overselling	Subject sources less Brazil	1	***	***	***	***
2022	Overselling	Subject sources less Brazil	0	***	***	***	***
2023	Overselling	Subject sources less Brazil	0	***	***	***	***
JanJune 2024	Overselling	Subject sources less Brazil	0	***	***	***	***
All periods	Overselling	Subject sources less Brazil	1	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Margins shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---". These data include only quarters in which there is a comparison between the U.S. and subject product.

Lost sales and lost revenue

The Commission requested that U.S. producers of HECs report purchasers with which they experienced instances of lost sales or revenue due to competition from imports of HECs from Brazil during January 2021 to June 2024. *** responding U.S. producers reported that they had to either reduce prices or roll back announced price increases, and *** firms reported that they had lost sales. *** U.S. producers (***) submitted lost sales and lost revenue allegations, identifying 17 firms with which they lost sales or revenue (4 consisting lost sales allegations, 2 consisting of lost revenue allegations, and 11 consisting of both types of allegations). Fifteen allegations involved Brazil, 1 involved China, 13 involved India, and 4 involved Vietnam. The allegations covered the entire period of investigation.

Staff contacted 17 purchasers and received responses from 8 purchasers.⁵ Responding purchasers reported purchasing or importing 50.2 billion units of HECs during January 2021 to June 2024 (tables V-11 and V-12).

Table V-11 HECs: Purchasers' reported purchases and imports, by firm and source

Quantity in 1,000 units, Change in shares in percentage points

Purchaser	Domestic quantity	Subject quantity	All other quantity	Change in domestic share	Change in subject country share
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
All firms	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: The all other category includes unknown sources. Changes in shares represent the share of the firm's total purchases of domestic and/or subject country imports between first and last years and are presented in percentage points. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

^{5 ***}

Table V-12 HECs: Purchasers' reported purchases and imports, by firm and source (Brazil excluded from subject sources)

Quantity in 1,000 units, Change in shares in percentage points

Purchaser	Domestic quantity	Subject less Brazil quantity	All other quantity	Change in domestic share	Change in subject less Brazil share
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
All firms	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: The all other category includes unknown sources and Brazil. Changes in shares represent the share of the firm's total purchases of domestic and/or subject country imports between first and last years and are presented in percentage points. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Changes in purchasing patterns

During 2023, responding purchasers purchased 72.1 percent from U.S. producers, 0.8 percent from Brazil, 7.2 percent from China, 13.4 percent from India, 3.5 percent from Vietnam, and 3.1 percent from nonsubject countries.⁶ No firms reported purchases from "unknown sources."

⁶ Shares include purchasers' reported purchases and imports.

Purchasers were asked about changes in their purchasing patterns from different sources since 2021. Of the eight responding purchasers, five reported decreased purchases from domestic producers, one reported increased purchases, one reported no change, and one (***) did not purchase any domestic product. Explanations for decreased purchases of domestic product included: U.S. producers did not provide HECs according to contracted terms, decreased demand, quality, availability/supply, and product discontinued. The firm reporting increased purchases of domestic product reported increased demand as its market share increased, it added new products, and it increased inventories. All purchasers responding to this question reported they did not purchase HECs from Brazil. One purchaser reported increased purchases from China due to continuity planning and supplier diversification efforts. Three purchasers reported increased purchases from India: one purchaser cited addressing supply and quality issues and one reported it was a result of reviewing its supply chain. Two purchasers reported decreased purchases from India, with one of these firms stating the reason was decreased demand. One purchaser decreased purchases from Vietnam due to other suppliers offering the same quality, on-time delivery, and business continuity at a competitive cost.

Table V-13 HECs: Count of purchasers' responses regarding changes in purchase patterns from U.S., subject, and nonsubject countries

Source of purchases	Steadily Increase	Fluctuate Up	No change	Fluctuate Down	Steadily Decrease	Did not purchase
United States	1	0	1	4	1	1
Brazil	0	0	0	0	0	5
China	0	1	0	0	0	4
India	2	1	0	2	0	2
Vietnam	0	0	0	1	0	4
Nonsubject sources	1	1	0	1	0	2

Source: Compiled from data submitted in response to Commission questionnaires.

Note: ***

Of the eight responding purchasers, five reported that, since 2021, they had purchased imported HECs from subject countries instead of U.S.-produced product (one for Brazil, one for China, five for India, and one for Vietnam) (tables V-14 and V-15). Three of these purchasers reported that subject import prices were lower than U.S.-produced product, and two of these purchasers reported that price was a primary reason for the decision to purchase imported product rather than U.S.-produced product. *** ***. Five purchasers identified non-price reasons for purchasing imported rather than U.S.-produced product including: problems with domestic supply continuity (increasing the number of suppliers to reduce risk of having to pay failure to supply penalties; high lead times from domestic supplier led to identifying alternative source); U.S. produced HECs were not compatible with capsule filling machines; quality; and customer support.

Table V-14 HECs: Purchasers' responses to purchasing subject imports instead of domestic product, by firm

Quantity in 1,000 units

Purchaser	Purchased subject imports instead of domestic	Imports priced lower	Choice based on price	Quantity	Explanation
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
***	***	***	***	***	***
All firms	Yes5; No3	Yes4; No1	Yes2; No3	***	NA

Source: Compiled from data submitted in response to Commission questionnaires.

Note: ***. These responses were counted as a yes in the summary.

Table V-15
HECs: Purchasers' responses to purchasing subject imports instead of domestic product, by source

Quantity in 1,000 units

Source	Count of purchasers reporting subject instead of domestic	Count of purchasers reported that imports were priced lower	Count of purchasers reporting that price was a primary reason for shift	Quantity
Brazil	1	0	0	***
China	1	1	0	***
India	5	3	2	***
Vietnam	1	1	0	***
Subject source	5	3	2	***
Subject source less Brazil	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Of the six responding purchasers, two reported that U.S. producers had reduced prices in order to compete with lower-priced imports from subject countries; two reported that they did not know (table V-16). The reported estimated price reduction ranged from *** to *** percent. ***. *** No purchasers reported price reductions because of imports from other subject countries.

Table V-16

HECs: Purchasers' responses to U.S. producer price reductions, by firm

Purchaser	Reported producers lowered	Estimated percent of U.S. price reduction	Explanation
Purchaser	prices	reduction	Expialiation
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
	Yes2; No4		
All firms	No—4	NA	NA

Source: Compiled from data submitted in response to Commission questionnaires.

Note: ***

In responding to the lost sales lost revenue survey, some purchasers provided additional information on purchases and market dynamics.

Part VI: Financial experience of U.S. producers

Background¹

Two U.S. producers, Lonza Greenwood ("Lonza") and Qualicaps, provided usable financial results on their HEC operations. *** reported financial data for a fiscal year ending December 31.^{2 3} *** provided their financial data on the basis of IFRS and *** provided their financial data on the basis of GAAP.

*** accounted for *** percent of sales by quantity and sales value from 2021 to June 2024. Figure VI-1 presents each responding firm's share of the total reported net sales quantity in 2023.

¹ The following abbreviations are used in the tables and/or text of this section: generally accepted accounting principles ("GAAP"), international financial reporting standards ("IFRS"), fiscal year ("FY"), net sales ("NS"), cost of goods sold ("COGS"), selling, general, and administrative expenses ("SG&A expenses"), average unit values ("AUVs"), research and development expenses ("R&D expenses"), and return on assets ("ROA").

^{2 ***.}

³ *** U.S. producer's questionnaire response, question II-2a.



HECs: U.S. producers' share of net sales quantity in 2023, by firm

* * * * * * *

Source: Compiled from data submitted in response to Commission questionnaires.

Operations on HECs

Table VI-1 presents aggregated data on U.S. producers' operations in relation to HECs, while table VI-2 presents corresponding changes in AUVs. Table VI-3 presents selected company-specific financial data.

Table VI-1 HECs: U.S. producers' results of operations, by item and period

Quantity in 1,000 units; value in 1,000 dollars; ratios in percent

Quantity in 1,000 units; valu	10 11 1,000 40				Jan-Jun	Jan-Jun
Item	Measure	2021	2022	2023	2023	2024
Commercial sales	Quantity	***	***	***	***	***
Internal consumption	Quantity	***	***	***	***	***
Transfers to related firms	Quantity	***	***	***	***	***
Total net sales	Quantity	***	***	***	***	***
Commercial sales	Value	***	***	***	***	***
Internal consumption	Value	***	***	***	***	***
Transfers to related firms	Value	***	***	***	***	***
Total net sales	Value	***	***	***	***	***
COGS: Raw materials	Value	***	***	***	***	***
COGS: Direct labor	Value	***	***	***	***	***
COGS: Other factory	Value	***	***	***	***	***
COGS: Total	Value	***	***	***	***	***
Gross profit or (loss)	Value	***	***	***	***	***
SG&A expenses	Value	***	***	***	***	***
Operating income or (loss)	Value	***	***	***	***	***
Interest expense	Value	***	***	***	***	***
All other expenses	Value	***	***	***	***	***
All other income	Value	***	***	***	***	***
Net income or (loss)	Value	***	***	***	***	***
Depreciation/amortization	Value	***	***	***	***	***
Cash flow	Value	***	***	***	***	***
COGS: Raw materials	Ratio to NS	***	***	***	***	***
COGS: Direct labor	Ratio to NS	***	***	***	***	***
COGS: Other factory	Ratio to NS	***	***	***	***	***
COGS: Total	Ratio to NS	***	***	***	***	***
Gross profit	Ratio to NS	***	***	***	***	***
SG&A expense	Ratio to NS	***	***	***	***	***
Operating income or (loss)	Ratio to NS	***	***	***	***	***
Net income or (loss)	Ratio to NS	***	***	***	***	***

Table VI-1 Continued HECs: U.S. producers' results of operations, by item and period

Shares in percent; unit values in dollars per 1,000 units; count in number of firms reporting

Item	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
COGS: Raw materials	Share	***	***	***	***	***
COGS: Direct labor	Share	***	***	***	***	***
COGS: Other factory	Share	***	***	***	***	***
COGS: Total	Share	***	***	***	***	***
Commercial sales	Unit value	***	***	***	***	***
Internal consumption	Unit value	***	***	***	***	***
Transfers to related firms	Unit value	***	***	***	***	***
Total net sales	Unit value	***	***	***	***	***
COGS: Raw materials	Unit value	***	***	***	***	***
COGS: Direct labor	Unit value	***	***	***	***	***
COGS: Other factory	Unit value	***	***	***	***	***
COGS: Total	Unit value	***	***	***	***	***
Gross profit or (loss)	Unit value	***	***	***	***	***
SG&A expenses	Unit value	***	***	***	***	***
Operating income or (loss)	Unit value	***	***	***	***	***
Net income or (loss)	Unit value	***	***	***	***	***
Operating losses	Count	***	***	***	***	***
Net losses	Count	***	***	***	***	***
Data	Count	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Shares represent the share of COGS. Shares and ratios shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Table VI-2 HECs: Changes in AUVs between comparison periods

Changes in percent

Item	2021-23	2021-22	2022-23	Jan-Jun 2023-24
Commercial sales	***	***	^ ***	***
Internal consumption	^ ***	***	^ ***	***
Transfers to related firms	^ ***	***	^ ***	***
Total net sales	^ ***	***	^ ***	***
COGS: Raw materials	^ ***	***	^ ***	***
COGS: Direct labor	^ ***	***	***	***
COGS: Other factory	^ ***	***	^ ***	^ ***
COGS: Total	***	^ ***	^ ***	^ ***

Table continued.

Table VI-2 Continued

HECs: Changes in AUVs between comparison periods

Changes in dollars per 1,000 units

Item	2021-23	2021-22	2022-23	Jan-Jun 2023-24
Commercial sales	***	^ ***	***	***
Internal consumption	^ ***	^ ***	^ ***	***
Transfers to related firms	A ***	^ ***	^ ***	***
Total net sales	^ ***		^ ***	
COGS: Raw materials	^ ***	^ ***	^ ***	***
COGS: Direct labor	^ ***	^ ***	***	▲ ***
COGS: Other factory	^ ***	^ ***	***	▲ ***
COGS: Total	^ ***		^ ***	
Gross profit or (loss)	A ***	***	^ ***	***
SG&A expense	^ ***	^ ***	^ ***	_
Operating income or (loss)	***	***	^ ***	***
Net income or (loss)	***	***	^ ***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Percentages and unit values shown as "0.0" or "0.00" represent values greater than zero, but less than "0.05" or "0.005," respectively. Zeroes, null values, and undefined calculations are suppressed and shown as "---". Period changes preceded by a "▼" represent an increase, while period changes preceded by a "▼" represent a decrease.

Table VI-3

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Net sales quantity

Quantity in 1.000 units

Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

Table continued.

Table VI-3 Continued

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Net sales value

Value in 1.000 dollars

Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

Table continued.

Table VI-3 Continued

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

COGS

Value in 1,000 dollars

	Gido III 1,000 dellaio						
Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024		
Lonza	***	***	***	***	***		
Qualicaps	***	***	***	***	***		
All firms	***	***	***	***	***		

Table continued.

Table VI-3 Continued

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Gross profit or (loss)

Value in 1,000 dollars

value iii 1,000 uollais						
Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	
Lonza	***	***	***	***	***	
Qualicaps	***	***	***	***	***	
All firms	***	***	***	***	***	

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

SG&A expenses

Value in 1.000 dollars

Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

Table continued.

Table VI-3 Continued

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Operating income or (loss)

Value in 1.000 dollars

value in 1,000 dollaro					
Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

Table continued.

Table VI-3 Continued

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Net income or (loss)

Value in 1,000 dollars

Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	
Lonza	***	***	***	***	***	
Qualicaps	***	***	***	***	***	
All firms	***	***	***	***	***	

Table continued.

Table VI-3 Continued

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

COGS to net sales ratio

Ratios in percent

teta o III poi o III						
Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	
Lonza	***	***	***	***	***	
Qualicaps	***	***	***	***	***	
All firms	***	***	***	***	***	

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Gross profit or (loss) to net sales ratio

Ratios in percent

Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

Table continued.

Table VI-3 Continued

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

SG&A expenses to net sales ratio

Ratios in percent

Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

Table continued.

Table VI-3 Continued

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Operating income or (loss) to net sales ratio

Ratios in percent

Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

Table continued.

Table VI-3 Continued

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Net income or (loss) to net sales ratio

Ratios in percent

. to.t. 0 0 11 1 p 0	oo iii porooni					
Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	
Lonza	***	***	***	***	***	
Qualicaps	***	***	***	***	***	
All firms	***	***	***	***	***	

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Unit net sales value

Unit values in dollars per 1,000 units

Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

Table continued.

Table VI-3 Continued

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Unit raw material costs

Unit values in dollars per 1.000 units

Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

Table continued.

Table VI-3 Continued

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Unit direct labor costs

Unit values in dollars per 1.000 units

one values in dendis per 1,000 dines					
Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

Table continued.

Table VI-3 Continued

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Unit other factory costs

Unit values in dollars per 1.000 units

Crit valaco	,				
Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Unit COGS

Unit values in dollars per 1,000 units

Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	
Lonza	***	***	***	***	***	
Qualicaps	***	***	***	***	***	
All firms	***	***	***	***	***	

Table continued.

Table VI-3 Continued

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Unit gross profit or (loss)

Unit values in dollars per 1.000 units

		1				
Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	
Lonza		***	***	***	***	
Qualicaps		***	***	***	***	
All firms		***	***	***	***	

Table continued.

Table VI-3 Continued

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Unit SG&A expenses

Unit values in dollars per 1,000 units

one values in dendis per 1,000 dines					
Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

Table continued.

Table VI-3 Continued

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Unit operating income or (loss)

Unit values in dollars per 1.000 units

Crit valaco	,				
Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

Table VI-3 Continued

HECs: U.S. producers' sales, costs/expenses, and profitability, by firm and period

Unit net income or (loss)

Unit values in dollars per 1,000 units

Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Shares and ratios shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Net sales

Total net sales are composed of commercial sales and transfers to related firms with a small amount of internal consumption.^{4 5 6} As shown in table VI-1, total net sales quantity decreased from 2021 to 2023 and was lower in January – June 2024 ("interim 2024") compared to January – June 2023 ("interim 2023"). Total net sales value fluctuated but overall increased from 2021 to 2023 and was lower in interim 2024 compared to interim 2023. Regarding net sales quantity, *** showed the same directional trends, a decrease in total net sales quantity from 2021 to 2023 and lower net sales quantity in interim 2024 compared to interim 2023. Regarding net sales value, *** reported an overall decrease in net sales value from 2021 to 2023 and *** reported a decrease in net sales value from 2021 to 2022, then an increase from 2022 to 2023. *** reported lower net sales value in interim

^{4 ***}

^{5 ***} Email from ***.

^{6 ***} Email from ***.

2024 compared to interim 2023. The net sales AUV increased from \$*** per 1,000 units in 2021 to \$*** per 1,000 units in 2023 and was lower in interim 2024 at \$*** per 1,000 units compared to interim 2023 at \$*** per 1,000 units. *** showed the same directional trends from 2021 to 2023, *** reported a lower net sales AUV in interim 2024 while *** net sales AUV was stable from interim 2023 to interim 2024.

Cost of goods sold and gross profit or loss

Raw materials, direct labor and other factory costs accounted for ***, *** and *** percent of COGS, respectively, in 2023. Raw material costs increased by *** percent from 2021 to 2022, then decreased by *** percent from 2022 to 2023, and overall increased by *** percent from 2021 to 2023. Raw material costs were lower in interim 2024 by *** percent compared to interim 2023. The raw materials AUV increased from \$*** per 1,000 units in 2021 to \$*** per 1,000 units in 2023 and was lower in interim 2024 at \$*** per 1,000 units compared to interim 2023 at \$*** per 1,000 units. As shown in table VI-3, *** reported an overall increase in raw materials AUVs from 2021 to 2023, and lower raw materials AUVs in interim 2024 compared to interim 2023. As a ratio to net sales, raw material costs irregularly increased from *** percent in 2021 to *** percent in 2022, then decreased to *** percent in 2023, and were higher in interim 2024 at *** percent compared to interim 2023 at *** percent. Table VI-4 presents raw materials, by type. Gelatin accounted for the largest share of raw material costs. Other material inputs include inks, dyes, and packaging.

Table VI-4 HECs: U.S. producers' raw material costs in 2023

Value in 1,000 dollars; share of value in percent

Item	Value	Share of value
Gelatin	***	***
HPMC	***	***
Pullulan	***	***
Other material inputs	***	***
All raw materials	***	100.0

⁷ *** U.S. producer questionnaire responses, question III-9b.

Direct labor costs increased by *** percent from 2021 to 2022, then decreased by *** percent from 2022 to 2023 and increased overall by *** percent from 2021 to 2023. Direct labor costs were lower in interim 2024 by *** percent compared to interim 2023. Direct labor AUVs increased irregularly from \$*** per 1,000 units in 2021 to \$*** per 1,000 units in 2022, then decreased to \$*** per 1,000 units in 2023 and were higher in interim 2024 at \$*** per 1,000 units compared to interim 2023 at \$*** per 1,000 units. As shown in table VI-3, *** reported an overall increase in direct labor AUVs from 2021 to 2023, and higher direct labor AUVs in interim 2024 compared to interim 2023.8 As a ratio to net sales, direct labor increased from *** percent in 2021 to *** percent in 2022, then decreased to *** percent in 2023, and was higher in interim 2024 at *** percent compared to interim 2023 at *** percent.

Other factory costs increased by *** percent from 2021 to 2023 and were higher in interim 2024 by *** percent compared to interim 2023. Other factory costs AUVs increased from \$*** per 1,000 units in 2021 to \$*** per 1,000 units in 2023 and were higher in interim 2024 at \$*** per 1,000 units compared to interim 2023 at \$*** per 1,000 units. As shown in table VI-3, *** reported an overall increase in other factory costs AUVs from 2021 to 2023, and higher other factory costs AUVs in interim 2024 compared to interim 2023. *** reported higher other factory costs AUVs in interim 2024 compared to interim 2023. 9 As a ratio to net sales, other factory costs irregularly increased from *** percent in 2021 to *** percent in 2023, and was higher in interim 2024 at *** percent compared to interim 2023 at *** percent.

Total COGS increased overall by *** percent from 2021 to 2023 and was lower in interim 2024 by *** percent compared to interim 2023. Total COGS AUVs increased from \$*** per 1,000 units in 2021 to \$*** per 1,000 units in 2023 and were higher in interim 2024 at \$*** per 1,000 units compared to interim 2023 at \$*** per 1,000 units. *** companies reported an overall increase in total COGS AUVs from 2021 to 2023 and higher total

⁸ *** U.S. producer questionnaire responses, question III-9b.

^{***} U.S. producer questionnaire responses, question III-9b.

^{9 ***} Email from ***.

^{***} U.S. producer questionnaire responses, question III-9b.

COGS AUVs in interim 2024 compared to interim 2023. As a ratio to net sales, total COGS irregularly increased from *** percent in 2021 to *** in 2023 and was higher in interim 2024 at *** percent compared to interim 2023 at *** percent.

As shown in table VI-1, gross profit decreased irregularly from \$*** million in 2021 to \$*** million in 2022, then to \$*** million in 2023 due to the larger increase in total COGS over the smaller increase in net sales value from 2021 to 2023. The decrease in net sales value was larger than the decrease in total COGS for the interim periods, resulting in gross profit being lower in interim 2024 at \$*** million compared to interim 2023 at \$*** million. The gross profit margin decreased irregularly from *** percent in 2021 to *** percent in 2022, then to *** percent in 2023 and was lower in interim 2024 at *** percent compared to interim 2023 at *** percent. ***

SG&A expenses and operating income or loss

SG&A expenses increased from 2021 to 2023 and were lower in interim 2024 compared to interim 2023. *** reported decreasing SG&A expenses from 2021 to 2023 and *** SG&A expenses in interim 2024 compared to interim 2023. *** reported increasing SG&A expenses from 2021 to 2023 and *** SG&A expense in interim 2024 compared to interim 2023. ¹⁰ As a ratio to net sales, SG&A expenses increased irregularly from *** percent in 2021 to *** percent in 2022, then to *** percent in 2023 and were higher in interim 2024 at *** percent compared to interim 2023 at *** percent.

Operating income irregularly decreased from \$*** million in 2021 to \$*** million in 2022, then to \$*** million in 2023 and was lower in interim 2024 at \$*** million compared to interim 2023 at \$*** million. The operating income margin (operating income as a ratio to net sales) decreased irregularly from *** percent in 2021 to *** percent in 2022 then to *** percent in 2023 and was lower in interim 2024 at *** percent compared to interim 2023 at *** percent. ***.

¹⁰ *** U.S. producer's questionnaire, question III-9b.

All other expenses and net income or loss

Classified below the operating income level are interest expenses, other expenses and other income. Interest expenses increased from 2021 to 2023 and were higher in interim 2024 than interim 2023. Other expenses increased irregularly from 2021 to 2023 and were lower in interim 2024 than in interim 2023, while other income decreased irregularly and was lower in interim 2024 compared to interim 2023. Other expenses increased irregularly and was lower in interim 2024 compared to interim 2023.

Net income decreased irregularly from \$*** million in 2021 to \$*** million in 2022, then to \$*** million in 2023 and was lower in interim 2024 at *** million compared to interim 2023 at \$*** million. The net income margin decreased irregularly from *** percent in 2021 to *** percent in 2022, then to *** percent in 2023 and was lower in interim 2024 at *** percent compared to interim 2023 at *** percent. ***

¹¹ *** U.S. producer's questionnaire, question III-9b.

^{***} Email from ***. *** U.S. producer's questionnaire, question III-9b.

¹² The *** other income in interim 2024 compared to interim 2023 largely reflects *** U.S. producer's questionnaire, question III-9b and email from ***.

^{***} U.S. producer's questionnaire, question III-10.

Variance analysis

A variance analysis for the operations of U.S. producers of HECs is presented in table VI-5.¹³ The information for this variance analysis is derived from table VI-1. The decrease in operating income from 2021 to 2023 was due to greater unfavorable cost and volume variances compared to a smaller favorable price variance (indicating that costs and expenses increased more than prices). The lower operating income in interim 2024 was due to unfavorable price, cost and volume variances (indicating a decrease in prices while costs and expenses increased).

Table VI-5 HECs: Variance analysis on the operations of U.S. producers between comparison periods

Value in 1,000 dollars

Item	2021-23	2021-22	2022-23	Jan-Jun 2023- 24
Net sales price variance	***	***	***	***
Net sales volume variance	***	***	***	***
Net sales total variance	***	***	***	***
COGS cost variance	***	***	***	***
COGS volume variance	***	***	***	***
COGS total variance	***	***	***	***
Gross profit variance	***	***	***	***
SG&A cost variance	***	***	***	***
SG&A volume variance	***	***	***	***
SG&A total variance	***	***	***	***
Operating income price variance	***	***	***	***
Operating income cost variance	***	***	***	***
Operating income volume variance	***	***	***	***
Operating income total variance	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: These data are derived from the data in table VI-1. Unfavorable variances (which are negative) are shown in parentheses, all others are favorable (positive).

¹³ The Commission's variance analysis is calculated in three parts: Sales variance, cost of sales variance (COGS variance), and SG&A expense variance. Each part consists of a price variance (in the case of the sales variance) or a cost or expense variance (in the case of the COGS and SG&A expense variance), and a volume variance. The sales or cost/expense variance is calculated as the change in unit price or per-unit cost/expense times the new volume, while the volume variance is calculated as the change in volume times the old unit price or per-unit cost/expense. Summarized at the bottom of the table, the price variance is from sales; the cost/expense variance is the sum of those items from COGS and SG&A variances, respectively, and the volume variance is the sum of the volume components of the net sales, COGS, and SG&A expense variances. The overall volume component of the variance analysis is generally small.

Capital expenditures and research and development expenses

Table VI-6 presents capital expenditures, by firm, and tables VI-7 present the firms' narrative explanations of the nature, focus, and significance of their capital expenditures.

Capital expenditures decreased irregularly from \$*** million in 2021 to \$*** million in 2023 and were lower in interim 2024 at \$*** million compared to interim 2023 at \$*** million. ***14

Table VI-6 HECs: U.S. producers' capital expenditures, by firm and period

Value in 1.000 dollars

- S. C.					
Firm	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Lonza	***	***	***	***	***
Qualicaps	***	***	***	***	***
All firms	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Table VI-7
HECs: U.S. producers' narrative descriptions of their capital expenditures, by firm

Firm	Narrative on capital expenditures
Lonza	***
Qualicaps	***

¹⁴ *** U.S. producer questionnaire response, question III-13c.

Assets and return on assets

Table VI-8 presents data on the U.S. producers' total assets while table VI-9 presents their operating ROA. ¹⁵ Operating ROA decreased irregularly from *** percent in 2021 to *** percent in 2023. Table VI-10 presents U.S. producers' narrative responses explaining their major asset categories and any significant changes in asset levels over time.

Table VI-8 HECs: U.S. producers' total net assets, by firm and period

Value in 1.000 dollars

Firm	2021	2022	2023
Lonza	***	***	***
Qualicaps	***	***	***
All firms	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Table VI-9

HECs: U.S. producers' ROA, by firm and period

Ratio in percent

Firm	2021	2022	2023
Lonza	***	***	***
Qualicaps	***	***	***
All firms	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Table VI-10

HECs: U.S. producers' narrative descriptions of their total net assets, by firm

Firm	Narrative on assets
Lonza	***
Qualicaps	***

¹⁵ The operating ROA is calculated as operating income divided by total assets. With respect to a firm's overall operations, the total asset value reflects an aggregation of a number of assets which are generally not product specific. Thus, high-level allocations are generally required in order to report a total asset value on a product-specific basis.

Capital and investment

The Commission requested U.S. producers of HECs to describe any actual or potential negative effects of imports of HECs from Brazil, China, India and Vietnam on their firms' growth, investment, ability to raise capital, development and production efforts, or the scale of capital investments. Table VI-11 presents the number of firms reporting an impact in each category and table VI-12 provides the U.S. producers' narrative responses.

Table VI-11
HECs: Count of firms indicating actual and anticipated negative effects of imports from subject sources on investment, growth, and development since January 1, 2021, by effect

Number of firms reporting

Effect	Category	Count
Cancellation, postponement, or rejection of		***
expansion projects	Investment	
Denial or rejection of investment proposal	Investment	***
Reduction in the size of capital investments	Investment	***
Return on specific investments negatively impacted	Investment	***
Other investment effects	Investment	***
Any negative effects on investment	Investment	***
Rejection of bank loans	Growth	***
Lowering of credit rating	Growth	***
Problem related to the issue of stocks or bonds	Growth	***
Ability to service debt	Growth	***
Other growth and development effects	Growth	***
Any negative effects on growth and development	Growth	***
Anticipated negative effects of imports	Future	***

Table VI-12
HECs: U.S. producers' narratives relating to actual and anticipated negative effects of imports on investment, growth, and development, since January 1, 2021, by firm and effect

Item	Firm name and narrative on impact of imports
***	***
***	***
***	***
***	***
***	***
***	***
***	***
***	***
***	***
***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Part VII: Threat considerations and information on nonsubject countries

Section 771(7)(F)(i) of the Act (19 U.S.C. § 1677(7)(F)(i)) provides that—

In determining whether an industry in the United States is threatened with material injury by reason of imports (or sales for importation) of the subject merchandise, the Commission shall consider, among other relevant economic factors¹--

- if a countervailable subsidy is involved, such information as may be presented to it by the administering authority as to the nature of the subsidy (particularly as to whether the countervailable subsidy is a subsidy described in Article 3 or 6.1 of the Subsidies Agreement), and whether imports of the subject merchandise are likely to increase,
- (II) any existing unused production capacity or imminent, substantial increase in production capacity in the exporting country indicating the likelihood of substantially increased imports of the subject merchandise into the United States, taking into account the availability of other export markets to absorb any additional exports,
- (III) a significant rate of increase of the volume or market penetration of imports of the subject merchandise indicating the likelihood of substantially increased imports,
- (IV) whether imports of the subject merchandise are entering at prices that are likely to have a significant depressing or suppressing effect on domestic prices, and are likely to increase demand for further imports,
- (V) inventories of the subject merchandise,

¹ Section 771(7)(F)(ii) of the Act (19 U.S.C. § 1677(7)(F)(ii)) provides that "The Commission shall consider {these factors} . . . as a whole in making a determination of whether further dumped or subsidized imports are imminent and whether material injury by reason of imports would occur unless an order is issued or a suspension agreement is accepted under this title. The presence or absence of any factor which the Commission is required to consider . . . shall not necessarily give decisive guidance with respect to the determination. Such a determination may not be made on the basis of mere conjecture or supposition."

- (VI) the potential for product-shifting if production facilities in the foreign country, which can be used to produce the subject merchandise, are currently being used to produce other products,
- (VII) in any investigation under this title which involves imports of both a raw agricultural product (within the meaning of paragraph (4)(E)(iv)) and any product processed from such raw agricultural product, the likelihood that there will be increased imports, by reason of product shifting, if there is an affirmative determination by the Commission under section 705(b)(1) or 735(b)(1) with respect to either the raw agricultural product or the processed agricultural product (but not both),
- (VIII) the actual and potential negative effects on the existing development and production efforts of the domestic industry, including efforts to develop a derivative or more advanced version of the domestic like product, and
- (IX) any other demonstrable adverse trends that indicate the probability that there is likely to be material injury by reason of imports (or sale for importation) of the subject merchandise (whether or not it is actually being imported at the time).²

Information on the nature of the alleged subsidies was presented earlier in this report; information on the volume and pricing of imports of the subject merchandise is presented in Parts IV and V; and information on the effects of imports of the subject merchandise on U.S. producers' existing development and production efforts is presented in Part VI. Information on inventories of the subject merchandise; foreign producers' operations, including the potential for "product-shifting;" any other threat indicators, if applicable; and any dumping in third-country markets, follows. Also presented in this section of the report is information obtained for consideration by the Commission on nonsubject countries.

² Section 771(7)(F)(iii) of the Act (19 U.S.C. § 1677(7)(F)(iii)) further provides that, in antidumping investigations, ". . . the Commission shall consider whether dumping in the markets of foreign countries (as evidenced by dumping findings or antidumping remedies in other WTO member markets against the same class or kind of merchandise manufactured or exported by the same party as under investigation) suggests a threat of material injury to the domestic industry."

Subject countries

The Commission issued foreign producers' or exporters' questionnaires to 45 firms believed to produce and/or export HECs from Brazil, China, India, and Vietnam.³ Usable responses to the Commission's questionnaire were received from 14 firms in total.

Table VII-1 presents the number of producers/exporters in each subject country that responded to the Commission's questionnaire, their exports to the United States as a share of U.S. imports by each subject country in 2023, and their estimated share of total production of HECs in each subject country during 2023.

Table VII-1
HECs: Number of responding producers/exporters, approximate share of production, and exports to the United States as a share of U.S. imports, by subject foreign industry, 2023

Subject foreign industry	Number of responding firms	Approximate share of production (percent)	Exports as a share of U.S. imports from subject country (percent)
Brazil	2	***	***
China	6	***	***
India	5	***	***
Vietnam	1	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: "Approximate share of production" reflects the responding firms' estimates of their production as a share of total country production of mattresses in 2023. Since not all firms have perfect knowledge of the industry in their home market, different firms might use different denominators in estimating their firm's share of the total requested. For countries in which more than one firm responded, the average denominator for reasonably reported estimates is used in the share presented. Approximate shares are rounded to the nearest whole number.

Note: "Exports as a share of U.S. imports" reflects a comparison of export data reported by firms in response to the Commission's foreign producer/exporter questionnaire with official Commerce import statistics using HTS statistical reporting numbers 9602.00.1040 and 9602.00.5010, accessed November 14, 2024, adjusted to add in in-scope HECs imported under other HTS numbers as reported by U.S. importers in Commission questionnaires.

Note: ***. *** foreign producer question, section II-10.

³ These firms were identified through a review of information submitted in the petition and presented in third-party sources.

Table VII-2 presents information on the HECs operations of the responding producers in Brazil, China, India and Vietnam and table VII-3 presents summary information on responding resellers of subject HECs. Table VII-4 presents summary data on foreign producers by source. Only two subject producers, *** exported more than 50 percent of production to the U.S. market. The average for all subject producers was 16.3 percent. *** was the leading producer and exporter among the subject sources, accounting for just over half of total subject production.

Table VII-2
HECs: Summary data on responding subject foreign producers in 2023, by firm

Subject foreign industry: producer	Production (million units)	Share of reported production (percent)	Exports to the United States (million units)	Share of reported exports to the United States (percent)	Total shipments (million units)	Share of firm's total shipments exported to the United States (percent)
Brazil: ACG Brazil	***	***	***	***	***	***
Brazil: Genix	***	***	***	***	***	***
China: Chongqing	***	***	***	***	***	***
China: Hebei	***	***	***	***	***	***
China: Shandong	***	***	***	***	***	***
China: Suzhou	***	***	***	***	***	***
China: Xinchang	***	***	***	***	***	***
China: Zhejiang	***	***	***	***	***	***
India: ACG Associated	***	***	***	***	***	***
India: ACG Universal	***	***	***	***	***	***
India: Capsugel	***	***	***	***	***	***
India: Custom Capsules	***	***	***	***	***	***
India: Health Caps	***	***	***	***	***	***
Vietnam: Suheung	***	***	***	***	***	***
All individual producers	244,966	100.0	39,137	100.0	240,681	16.3
All individual producers except Brazil	***	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Shares and ratios shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Table VII-3

HECs: Summary data for subject resellers in 2023

Subject foreign industry: reseller	Resales exported to the United States (million units)	Share of resales exported to the United States (percent)
India: Custom Capsules	***	***
All individual resellers	***	100.0

Source: Compiled from data submitted in response to Commission questionnaires.

Table VII-4

HECs: Summary data on subject foreign industries in 2023, by source

Subject foreign industry	Production (million units)	Share of reported production (percent)	Exports to the United States (million units)	Share of reported exports to the United States (percent)	Total shipments (million units)	Share of firm's total shipments exported to the United States (percent)
Brazil	***	***	***	***	***	***
China	***	***	***	***	***	***
India	***	***	***	***	***	***
Vietnam	***	***	***	***	***	***
All subject foreign industries	244,966	100.0	39,137	100.0	240,681	16.3
All subject foreign industries except	***	***	***	***	***	***
Brazil	***	***	***		***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Table VII-5 presents events in the subject countries' industries since January 1, 2021.

Table VII-5
HECs: Important industry events in the subject foreign industry since January 1, 2021

Item	Firm and Event
Plant opening	ACG: Invested approximately US\$100 million to construct Asia's largest manufacturing plant and research & development center. India. December 2021.
Plant opening	Merck: Opened a US\$21 million distribution center. Brazil. February 28, 2024.
Expansion	Capsugel: Announced US\$96.7 million investment across 8 global sites, to increase annual production by 30 billion capsules. China and India. March 11, 2021
Expansion	ACG: Installed 12 new HEC machines in the Dahanu plant, increasing production capacity from 10.40 billion in 2021 to 19.36 billion in 2023. India. 2021.
Expansion	ACG: Announced approximately US\$100 million investment to increase production capacity. Brazil. October 1, 2024.
Expansion	Suheung: Announced plans to expand the Long Thanh factory, making it Suheung's largest capsule plant. Vietnam. May 31, 2022.
Acquisition	Roquette: Acquired Qualicaps. Brazil. October 24, 2023.
Acquisition	Kumar Organics: Kumar Organics: Acquired Fortcaps Healthcare. India. November 9, 2023.
Acquisition	Brenntag: Acquired PIC Quimica e Farmaceutica and PharmaSpecial Especialidades Quimicas e Famaceceuticas, Brazil. August 2024.

Sources: Pharmaceutical Technology, "ACG to Set Up," November 26, 2021, ACG to Set Up Vast
Capsule Manufacturing Plant in Asia; ChemManager, "Merck Opens New," February 28, 2024, Merck
Opens New €20 Million Distribution Center in Brazil | CHEManager; Happi, "Lonza Expands," March 11,
2021, Lonza Expands Its Capsule Manufacturing Capacity | Capsugel; Rodrigues, "Pharmaceutical
multinational ACG announces R\$100," October 1, 2024,
https://en.clickpetroleoegas.com.br/multinacional-farmaceutica-acg-anuncia-investimento-de-r-100milhoes-em-fabrica-no-brasil-a-expectativa-e-expandir-sua-capacidade-de-producao-no-

pais/#google_vignette; The Korea Economic Daily, "Korea Top Capsule Maker," May 31, 2022, https://www.kedglobal.com/korean-smes/newsView/ked202205310006; ContractPharma, "Roquette Completes Acquisition," October 24, 2023, https://www.contractpharma.com/contents/view_breakingnews/2023-10-24/roquette-completes-acquisition-of-qualicaps/; Happi, "Kumar Organic Products Acquires," November 9, 2023; Kumar Organic Products Acquires Fortcaps Healthcare | Happi; ChemManager, "Brenntag Acquires," August 21, 2024, Brenntag Acquires Two Brazilian Specialty Distributors | CHEManager.

Changes in operations

Subject producers were asked to report any change in the character of their operations or organization relating to the production of HECs since 2021. Ten of 14 producers indicated in their questionnaires that they had experienced such changes. Tables VII-6 and VII-7 present the changes identified by these producers. Eight subject producers reported expansions.

Table VII-6 HECs: Count of reported changes in operations since January 1, 2021, by change and subject foreign industry

Count in number of firms reporting

Item	Brazil	China	India	Vietnam	Subject producers	Subject producers except Brazil
Plant openings	***	1	1	***	3	***
Plant closings	***	0	0	***	0	***
Prolonged shutdowns	***	0	0	***	1	***
Production curtailments	***	1	0	***	1	***
Relocations	***	0	0	***	0	***
Expansions	***	2	4	***	8	***
Acquisitions	***	0	0	***	1	***
Consolidations	***	0	0	***	0	***
Weather-related or force majeure events	***	0	0	***	0	***
Other		0	1		1	
Any change	***	3	4	***	10	***

Source: Compiled from data submitted in response to Commission questionnaires.

Table VII-7

HECs: Reported changes in operations in the subject countries since January 1, 2021, by change, subject industry, and firm

	Subject foreign industry: firm name and accompanying narrative response regarding
Item	changes in operations
Plant	***
openings	
Plant	***
openings	
Plant	***
openings	
Prolonged	***
shutdowns	
Production	***
curtailments	
Expansions	***
Expansions	**
Expansions	***

Table VII-7 Continued

HECs: Reported changes in operations in the subject countries since January 1, 2021, by change, subject industry, and firm

_	Subject foreign industry: firm name and accompanying narrative response regarding
Item	changes in operations
Expansions	**
Expansions	**
Acquisitions	**
Other	***

Source: Compiled from data submitted in response to Commission questionnaires.

Table VII-8 presents anticipated changes in operations identified by subject producers. Three producers anticipate adding HECs capacity.

Table VII-8

HECs: Reported anticipated changes in operations in the subject countries since January 1, 2021, by subject foreign country and firm

Subject foreign industry: producer	Narrative regarding anticipated changes in operations
***	***
***	***
***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Installed and practical overall capacity

Table VII-9 presents data on subject producers' installed capacity, practical overall capacity, and practical HECs capacity and production on the same equipment. As no foreign producer reported out-of-scope production on the same equipment and capacity used to produce HECs, practical overall and practical HECs production, capacity, and capacity utilization were the same throughout the period for which data were collected. During 2021-23, installed overall capacity increased 11.5 percent and was 6.9 percent higher in interim 2024 compared to

interim 2023. Capacity utilization was lower in 2023 than in 2021 but higher in interim 2024 compared to interim 2023

Table VII-9
HECs: Subject producers' installed and practical capacity and production on the same equipment as in-scope production, by period

Capacity and utilization in 1,000 units; utilization in percent

Item	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
Installed overall	Capacity	276,897	301,516	308,671	152,017	162,503
Installed overall	Production	235,885	252,431	244,966	118,580	130,817
Installed overall	Utilization	85.2	83.7	79.4	78.0	80.5
Practical overall	Capacity	245,171	267,754	271,940	134,902	143,015
Practical overall	Production	235,885	252,431	244,966	118,580	130,817
Practical overall	Utilization	96.2	94.3	90.1	87.9	91.5
Practical HECs	Capacity	245,171	267,754	271,940	134,902	143,015
Practical HECs	Production	235,885	252,431	244,966	118,580	130,817
Practical HECs	Utilization	96.2	94.3	90.1	87.9	91.5

Source: Compiled from data submitted in response to Commission questionnaires.

Constraints on capacity

Table VII-10 presents subject producers' reported production and capacity constraints since January 1, 2021.

Table VII-10 HECs: Subject producers' reported constraints to practical overall capacity since January 1, 2021, by constraint and firm

by constraint and inin	Subject foreign industry: firm name and narrative response on constraints
Item	to practical overall capacity
Production bottlenecks	***
Fuel or energy	***
Storage capacity	***
Logistics/transportation	***
Other constraints	***

Source: Compiled from data submitted in response to Commission questionnaires.

Operations on HECs

Table VII-11 presents subject producers' reported production of gelatin and non-gelatin HECs.

Table VII-11
HECs: Production by product type in the subject foreign industries

Count in number of firms reporting

Subject foreign industry	Gelatin	Non-gelatin
Brazil	***	***
China	4	5
India	4	4
Vietnam	***	***
Subject foreign firms	11	10

Source: Compiled from data submitted in response to Commission questionnaires.

Aggregate HECs operations in the subject foreign industry

Table VII-12 presents information on the HECs operations of the responding producers/exporters (aggregate data for all subject foreign industries). Table VII-13 presents information on the HECs operations of responding producers/exports excluding Brazil. During 2021-23, foreign producers' production and capacity increased and were higher in interim 2024 compared to interim 2023. Foreign producers project production and capacity to increase in 2024 and again in 2025. Subject producers' exports to the United States were highest in 2022 and overall increased during 2021-23. Subject producers' exports to the United States were higher in interim 2024 compared to interim 2023. Subject foreign producers project exports to the United States to increase from 2023 to 2024 then decrease slightly from 2024 to 2025 and remain close to the levels seen in 2021 through 2023. home markets accounted for the majority of shipments throughout the POI and are projected to do so in 2024 and 2025.

Table VII-12 HECs: Data on industry in the subject foreign industry, by item and period

Quantity in million units

on units			Jan-Jun	Jan-Jun	Projection	Projection
2021	2022	2023	2023	2024	2024	2025
245,171	267,754	271,940	134,902	143,015	286,715	306,341
235,885	252,431	244,966	118,580	130,817	267,044	288,012
13,084	16,278	19,765	19,099	19,389	18,875	19,130
12,646	13,388	14,805	6,938	6,261	11,804	11,836
130.077	134.011	137.585	68.871	72.235	148.975	160,353
142,723	147,400	152,390	75,808	78,496	160,778	172,190
38,952	42,616	39,137	16,645	24,649	50,104	49,015
51,969	59,103	49,155	22,855	27,726	57,007	66,231
90,920	101,718	88,291	39,501	52,375	107,111	115,246
233,644	249,118	240,681	115,309	130,871	267,889	287,436
***	***	***	***	***	***	***
***	***	***	***	***	***	***
	2021 245,171 235,885 13,084 12,646 130,077 142,723 38,952 51,969 90,920 233,644	2021 2022 245,171 267,754 235,885 252,431 13,084 16,278 12,646 13,388 130,077 134,011 142,723 147,400 38,952 42,616 51,969 59,103 90,920 101,718 233,644 249,118 ***	2021 2022 2023 245,171 267,754 271,940 235,885 252,431 244,966 13,084 16,278 19,765 12,646 13,388 14,805 130,077 134,011 137,585 142,723 147,400 152,390 38,952 42,616 39,137 51,969 59,103 49,155 90,920 101,718 88,291 233,644 249,118 240,681	2021 2022 2023 Jan-Jun 2023 245,171 267,754 271,940 134,902 235,885 252,431 244,966 118,580 13,084 16,278 19,765 19,099 12,646 13,388 14,805 6,938 130,077 134,011 137,585 68,871 142,723 147,400 152,390 75,808 38,952 42,616 39,137 16,645 51,969 59,103 49,155 22,855 90,920 101,718 88,291 39,501 233,644 249,118 240,681 115,309	2021 2022 2023 Jan-Jun 2024 Jan-Jun 2024 245,171 267,754 271,940 134,902 143,015 235,885 252,431 244,966 118,580 130,817 13,084 16,278 19,765 19,099 19,389 12,646 13,388 14,805 6,938 6,261 130,077 134,011 137,585 68,871 72,235 142,723 147,400 152,390 75,808 78,496 38,952 42,616 39,137 16,645 24,649 51,969 59,103 49,155 22,855 27,726 90,920 101,718 88,291 39,501 52,375 233,644 249,118 240,681 115,309 130,871	2021 2022 2023 Jan-Jun 2023 Jan-Jun 2024 Projection 2024 245,171 267,754 271,940 134,902 143,015 286,715 235,885 252,431 244,966 118,580 130,817 267,044 13,084 16,278 19,765 19,099 19,389 18,875 12,646 13,388 14,805 6,938 6,261 11,804 130,077 134,011 137,585 68,871 72,235 148,975 142,723 147,400 152,390 75,808 78,496 160,778 38,952 42,616 39,137 16,645 24,649 50,104 51,969 59,103 49,155 22,855 27,726 57,007 90,920 101,718 88,291 39,501 52,375 107,111 233,644 249,118 240,681 115,309 130,871 267,889

Table VII-12 Continued

HECs: Data on industry in the subject foreign industry, by period

Ratio and share in percent

Ratio and share i	n percent					B 1 41	D 1 41
Item	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	Projection 2024	Projection 2025
Capacity							
utilization ratio	96.2	94.3	90.1	87.9	91.5	93.1	94.0
Inventory ratio							
to production	5.5	6.4	8.1	8.1	7.4	7.1	6.6
Inventory ratio							
to total							
shipments	5.6	6.5	8.2	8.3	7.4	7.0	6.7
Internal							
consumption							
share	5.4	5.4	6.2	6.0	4.8	4.4	4.1
Commercial							
home market							
shipments	55.7	50.0	57.0	50.7	55.0	55.0	55.0
share	55.7	53.8	57.2	59.7	55.2	55.6	55.8
Home market							
shipments	64.4	50.0	62.2	65.7	60.0	60.0	50.0
share	61.1	59.2	63.3	65.7	60.0	60.0	59.9
Exports to the United States							
share	16.7	17.1	16.3	14.4	18.8	18.7	17.1
Exports to all	10.7	17.1	10.3	14.4	10.0	10.1	17.1
other markets							
share	22.2	23.7	20.4	19.8	21.2	21.3	23.0
Export	22.2	20.1	20.4	19.0	21.2	21.0	25.0
shipments							
share	38.9	40.8	36.7	34.3	40.0	40.0	40.1
Total	00.0	10.0	00.1	0 1.0	10.0	10.0	10.1
shipments							
share	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Share of total							
exports to the							
United States							
exported by							
producers	***	***	***	***	***	***	***
Share of total							
exports to the							
United States							
exported by							
resellers	***	***	***	***	***	***	***
Adjusted share							
of total							
shipments							
exported to the	والمعادمات	444	4.4.4	alle aller de	المراجعة	alle alle of	المراجع
United States	***	***	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Shares and ratios shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Table VII-13 HECs: Data on industry in the subject foreign industry except Brazil, by item and period

Quantity in million units

Quantity in million	Trainte			Jan-Jun	Jan-Jun	Projectio	Projectio
Item	2021	2022	2023	2023	2024	n 2024	n 2025
Capacity	***	***	***	***	***	***	***
Production	***	***	***	***	***	***	***
End-of-period inventories	***	***	***	***	***	***	***
Internal consumption	***	***	***	***	***	***	***
Commercial home market							
shipments	***	***	***	***	***	***	***
Home market shipments	***	***	***	***	***	***	***
Exports to the United States	***	***	***	***	***	***	***
Exports to all other markets	***	***	***	***	***	***	***
Export shipments	***	***	***	***	***	***	***
Total shipments	***	***	***	***	***	***	***
Resales exported to the United							
States	***	***	***	***	***	***	***
Total exports to the United States	***	***	***	***	***	***	***

Table VII-13 Continued

HECs: Data on industry in the subject foreign industry except Brazil, by period

Ratio and share in percent

Item	Ratio and share i	n percent			1	lan lan	Dusiastics	Duning the state
Capacity utilization ratio utilization ratio to production linventory ratio to production linventory ratio to total shipments linternal consumption share """ "" "" "" "" "" "" "" "" "" "" "" "	14	0004	0000	0000				
Unitization ratio		2021	2022	2023	2023	2024	2024	2025
Inventory ratio to production		***	***	4.4.4	4.4.4.	de de de		4.4.4.
Inventory ratio to total shipments		***	***	***	***	***	***	***
Inventory ratio to total shipments								
to total shipments		***	***	***	***	***	***	***
Shipments Ship								
Internal								
consumption share *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** ****		***	***	***	***	***	***	***
share **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** <t< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></t<>								
Share Shar	consumption							
Nome market Shipments Share Sh	share	***	***	***	***	***	***	***
shipments share *** *** *** *** *** *** *** *** *** **	Commercial							
share **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** **** <t< td=""><td>home market</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></t<>	home market							
Share	shipments							
shipments *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *	share	***	***	***	***	***	***	***
share *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** </td <td>Home market</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td>	Home market							
Exports to the United States share	shipments							
United States share		***	***	***	***	***	***	***
United States share	Exports to the							
Exports to all other markets share								
Exports to all other markets share	share	***	***	***	***	***	***	***
other markets share								
Export shipments share								
Export shipments share	share	***	***	***	***	***	***	***
shipments *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *								
share *** *** *** *** *** *** Total shipments share 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 <td< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></td<>								
Total shipments share 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 Share of total exports to the United States exported by producers *** *** *** *** *** *** *** *** *** *		***	***	***	***	***	***	***
shipments share 100.0 100.0 100.0 100.0 100.0 100.0 100.0 Share of total exports to the United States exported by producers *** *** *** *** *** *** *** Share of total exports to the United States exported by resellers *** *** *** *** *** *** *** Adjusted share of total shipments exported to the								
share 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 100.0 <th< td=""><td>shipments</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></th<>	shipments							
Share of total exports to the United States exported by producers *** *** *** *** *** *** *** Share of total exports to the United States exported by resellers *** *** *** *** *** *** *** Adjusted share of total shipments exported to the		100.0	100.0	100.0	100.0	100.0	100.0	100.0
exports to the United States exported by producers *** *** *** *** *** *** *** Share of total exports to the United States exported by resellers *** *** *** *** *** *** *** Adjusted share of total shipments exported to the								
United States exported by producers *** *** *** *** *** *** *** *** Share of total exports to the United States exported by resellers *** *** *** *** *** *** *** *** Adjusted share of total shipments exported to the								
exported by producers *** *** *** *** *** *** *** *** *** *								
producers *** *** *** *** *** *** *** *** *** *								
Share of total exports to the United States exported by resellers *** *** *** *** *** *** Adjusted share of total shipments exported to the		***	***	***	***	***	***	***
exports to the United States exported by resellers *** *** *** *** *** *** *** *** Adjusted share of total shipments exported to the								
United States exported by resellers *** *** *** *** *** *** *** Adjusted share of total shipments exported to the								
exported by resellers *** *** *** *** *** *** *** *** *** *								
resellers *** *** *** *** *** *** *** *** *** *								
Adjusted share of total shipments exported to the		***	***	***	***	***	***	***
of total shipments exported to the								
shipments exported to the								
exported to the								
	United States	***	***	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Shares and ratios shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Practical HECs capacity and production by subject foreign industry

Table VII-14 presents information on subject producers' production, capacity, and capacity utilization by subject country.

Table VII-14

HECs: Subject producers' output: Practical capacity, by source and period

Practical capacity

Quantity in million units

Subject foreign industry	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	Projection 2024	Projection 2025
Brazil	***	***	***	***	***	***	***
China	***	***	***	***	***	***	***
India	***	***	***	***	***	***	***
Vietnam	***	***	***	***	***	***	***
All subject foreign industries	245,171	267,754	271,940	134,902	143,015	286,715	306,341
All subject foreign industries except Brazil	***	***	***	***	***	***	***

Table continued.

Table VII-14 Continued

HECs: Subject producers' output: Production, by source and period

Production

Quantity in million units

Subject foreign industry	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	Projection 2024	Projection 2025
Brazil	***	***	***	***	***	***	***
China	***	***	***	***	***	***	***
India	***	***	***	***	***	***	***
Vietnam	***	***	***	***	***	***	***
All subject foreign industries	235,885	252,431	244,966	118,580	130,817	267,044	288,012
All subject foreign industries except							
Brazil	***	***	***	***	***	***	***

Table continued.

Table VII-14 Continued

HECs: Subject producers' output: Capacity utilization, by source and period

Capacity utilization

Ratios in percent

Subject foreign industry	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	Projection 2024	Projection 2025
Brazil	***	***	***	***	***	***	***
China	***	***	***	***	***	***	***
India	***	***	***	***	***	***	***
Vietnam	***	***	***	***	***	***	***
All subject foreign industries	96.2	94.3	90.1	87.9	91.5	93.1	94.0
All subject foreign industries except Brazil	***	***	***	***	***	***	***

Table continued.

Note: Capacity utilization ratio represents the ratio of the subject producer's production to its production capacity.

Table VII-14 Continued

HECs: Subject producers' output: Share of production, by source and period

Share of production

Share in percent

Subject foreign industry	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	Projection 2024	Projection 2025
Brazil	***	***	***	***	***	***	***
China	***	***	***	***	***	***	***
India	***	***	***	***	***	***	***
Vietnam	***	***	***	***	***	***	***
All subject							
foreign							
industries	100.0	100.0	100.0	100.0	100.0	100.0	100.0

Table VII-14 Continued

HECs: Subject producers' output: Share of production excluding Brazil, by source and period

Share of production

Share in percent

Subject foreign industry	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	Projection 2024	Projection 2025
China	***	***	***	***	***	***	***
India	***	***	***	***	***	***	***
Vietnam	***	***	***	***	***	***	***
All subject							
foreign							
industries							
except Brazil	100.0	100.0	100.0	100.0	100.0	100.0	100.0

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Shares and ratios shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

HECs exports, by subject country

Table VII-15 presents information on subject producers' (and resellers) exports of HECs by subject country. Overall, during 2021-23, exports to the United States by foreign producers in Brazil, India, and Vietnam increased while exports to the United States by foreign producers in China decreased. Exports to the United States by foreign producers in each subject country were higher in interim 2024 compared to interim 2023. Foreign producers in China and India project exports to the United States to increase from 2023 to 2025 while foreign producers in Brazil and Vietnam project exports to the United States to decrease from 2023 to 2025.

Table VII-15

HECs: Subject producers' (and resellers') exports: Exports to the United States, by source and period

Exports to the United States

Quantity in million units

Subject foreign industry	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	Projection 2024	Projection 2025
Brazil	***	***	***	***	***	***	***
China	***	***	***	***	***	***	***
India	***	***	***	***	***	***	***
Vietnam	***	***	***	***	***	***	***
All subject							
foreign	20.052	40.646	20 127	16 645	24.640	50 104	40.045
industries	38,952	42,616	39,137	16,645	24,649	50,104	49,015
All subject							
foreign							
industries							
except Brazil	***	***	***	***	***	***	***

Table continued.

Table VII-15 Continued

HECs: Subject producers' (and resellers') exports: Share of total shipments exported to the United States, by source and period

Share of total shipments exported to the United States

Share in percent

Subject foreign industry	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	Projection 2024	Projection 2025
Brazil	***	***	***	***	***	***	***
China	***	***	***	***	***	***	***
India	***	***	***	***	***	***	***
Vietnam	***	***	***	***	***	***	***
All subject foreign industries	16.7	17.1	16.3	14.4	18.8	18.7	17.1
All subject foreign industries except Brazil	***	***	***	***	***	***	***

Table VII-15 Continued

HECs: Subject producers' (and resellers') exports: Exports to all destination markets, by source and period

Total exports

Quantity in million units

Subject foreign	2024	2022	2022	Jan-Jun	Jan-Jun	Projection	Projection
industry	2021	2022	2023	2023	2024	2024	2025
Brazil	***	***	***	***	***	***	***
China	***	***	***	***	***	***	***
India	***	***	***	***	***	***	***
Vietnam	***	***	***	***	***	***	***
All subject							
foreign industries	90,920	101,718	88,291	39,501	52,375	107,111	115,246
All subject							
foreign industries							
except Brazil	***	***	***	***	***	***	***

Table continued.

Table VII-15 Continued

HECs: Subject producers' (and resellers') exports: Share of total shipments exported to all destination markets, by source and period

Share of total shipments exported

Share in percent

Subject foreign				Jan-Jun	Jan-Jun	Projection	Projection
industry	2021	2022	2023	2023	2024	2024	2025
Brazil	***	***	***	***	***	***	***
China	***	***	***	***	***	***	***
India	***	***	***	***	***	***	***
Vietnam	***	***	***	***	***	***	***
All subject							
foreign							
industries	38.9	40.8	36.7	34.3	40.0	40.0	40.1
All subject							
foreign							
industries							
except Brazil	***	***	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

HECs inventories, by subject foreign industry

Table VII-16 presents foreign industries ending inventories during 2021-23, both interim periods and 2024-25 projections. Combine foreign producers' inventories were higher in 2023 than in 2021 and are projected to be at similar levels in 2025. The ratio of inventories were higher in 2023 than in 2021 but projected to be lower in 2025.

Table VII-16
HECs: Subject foreign industries' ending inventories: Ending inventories, by subject foreign industry and period

Quantity in million units

Subject foreign industry	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	Projection 2024	Projection 2025
Brazil	***	***	***	***	***	***	***
China	***	***	***	***	***	***	***
India	***	***	***	***	***	***	***
Vietnam	***	***	***	***	***	***	***
All subject							
foreign							
industries	13,084	16,278	19,765	19,099	19,389	18,875	19,130
All subject							
foreign							
industries							
except Brazil	***	***	***	***	***	***	***

Table continued.

Table VII-16 Continued

HECs: Subject foreign industries' ending inventories: Ratio of ending inventories to total shipments exported, by subject foreign industry and period

Ratio in percent

Subject foreign industry	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	Projection 2024	Projection 2025
Brazil	***	***	***	***	***	***	***
China	***	***	***	***	***	***	***
India	***	***	***	***	***	***	***
Vietnam	***	***	***	***	***	***	***
All subject foreign							
industries	5.6	6.5	8.2	8.3	7.4	7.0	6.7
All subject foreign industries							
except Brazil	***	***	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Ratios shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Alternative products

The responding producers in Brazil, China, India, and Vietnam did not report any production of alternative products using the same equipment and/or labor as those used to produce HECs during the period of investigation.

Exports

Table VII-17 presents Global Trade Atlas ("GTA") data for exports of worked vegetable or mineral carving materials and articles, a category which includes HECs, from subject countries to the United States and to all destination markets. The table presents exports from subject exporters to the United States, global exports from subject exporters (exports to all destination markets), and shares of exports exported to the United States, by exporter and period. Exports to the United States collectively reported for the subject foreign industries under this category decreased 6.0 percent, by value, during 2021-23. Exports to all destination markets collectively reported for the subject foreign industries under this category increased by 5.9 percent, by value, during 2021-23.

Table VII-17
Worked vegetable or mineral carving materials and articles: Global exports from subject exporters: Exports to the United States, by exporter and period

Value in \$1,000

Exporter	Measure	2021	2022	2023
Brazil	Value	3,298	1,896	4,133
China	Value	72,844	81,129	59,360
India	Value	58,167	70,956	66,981
Vietnam	Value	36,327	42,805	29,875
Subject exporters	Value	170,636	196,785	160,349
Subject exporters except Brazil	Value	167,338	194,889	156,216

Table continued.

Table VII-17 Continued

Worked vegetable or mineral carving materials and articles: Global exports from subject exporters: Exports to all destination markets, by exporter and period

Value in \$1.000

Value III \$ 1,000				
Exporter	Measure	2021	2022	2023
Brazil	Value	10,007	9,157	10,472
China	Value	192,317	220,881	211,563
India	Value	141,309	174,787	148,217
Vietnam	Value	60,379	68,857	57,475
Subject exporters	Value	404,012	473,682	427,726
Subject exporters except Brazil	Value	394,005	464,525	417,254

Table VII-17 Continued

Worked vegetable or mineral carving materials and articles: Global exports from subject exporters: Share of exports exported to the United States, by exporter and period

Shares in percent

Exporter	Measure	2021	2022	2023
Brazil	Share	33.0	20.7	39.5
China	Share	37.9	36.7	28.1
India	Share	41.2	40.6	45.2
Vietnam	Share	60.2	62.2	52.0
Subject exporters	Share	42.2	41.5	37.5
Subject exporters except Brazil	Share	42.5	42.0	37.4

Source: Official exports statistics and official global imports statistics from Vietnam (constructed exports) under HS subheading 9602.00 as reported by various national statistical authorities in the Global Trade Atlas Suite database, accessed November 20, 2024.

Note: Shares represent the shares of value exported to the United States out of all destination markets. Shares shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

U.S. inventories of imported merchandise

Table VII-18 presents data on U.S. importers' reported inventories of HECs. Inventories from subject sources were highest in 2022 and overall increased by 95.8 percent during 2021-23. Inventories from subject sources were 9.2 percent higher in interim 2024 compared to interim 2023. Overall, during 2021-23, inventories increased from each subject country. U.S. importers reported lower inventories from China and India in interim 2024 compared to interim 2023 while inventories from Brazil and Vietnam were higher in interim 2024 compared to interim 2023. During 2021-23, inventories from nonsubject sources were highest in 2022 and overall increased by 112.6 percent. Inventories from nonsubject sources were 10.2 percent lower in interim 2024 compared to interim 2023.

Table VII-18 HECs: U.S. importers' inventories and their ratio to select items, by source and period

Quantity in 1,000 units; ratio in percent

Quantity in 1,000 unit	.s, ratio iii pe	ercerit			Jan-Jun	Jan-Jun
Measure	Source	2021	2022	2023	2023	2024
Inventories quantity	Brazil	***	***	***	***	***
Ratio to imports	Brazil	***	***	***	***	***
Ratio to U.S.						
shipments of						
imports	Brazil	***	***	***	***	***
Ratio to total						
shipments of	D''	***	***	***	***	***
imports	Brazil	***	***	***	***	
Inventories quantity	China					***
Ratio to imports	China	***	***	***	***	***
Ratio to U.S.						
shipments of	Ola iva	***	***	***	***	***
imports Ratio to total	China					
shipments of						
imports	China	***	***	***	***	***
Inventories quantity	India	***	***	***	***	***
Ratio to imports	India	***	***	***	***	***
Ratio to U.S.						
shipments of						
imports	India	***	***	***	***	***
Ratio to total						
shipments of						
imports	India	***	***	***	***	***
Inventories quantity	Vietnam	***	***	***	***	***
Ratio to imports	Vietnam	***	***	***	***	***
Ratio to U.S.						
shipments of	,,, ,	***	***	***	***	***
imports	Vietnam	***	***	***	***	***
Ratio to total						
shipments of	Vietnam	***	***	***	***	***
imports	vietnam					

Table VII-18 Continued HECs: U.S. importers' inventories and their ratio to select items, by source and period

Quantity in 1,000 units; ratio in percent

Qualitity III 1,000	units; ratio in percent				Jan-Jun	Jan-Jun
Measure	Source	2021	2022	2023	2023	2024
Inventories						
quantity	Subject sources	7,844,629	17,798,096	15,356,746	14,637,987	15,980,538
Ratio to imports	Subject sources	***	***	***	***	***
Ratio to U.S.						
shipments of						
imports	Subject sources	***	***	***	***	***
Ratio to total						
shipments of						
imports	Subject sources	***	***	***	***	***
Inventories	Subject sources					
quantity	less Brazil	***	***	***	***	***
	Subject sources					
Ratio to imports	less Brazil	***	***	***	***	***
Ratio to U.S.						
shipments of	Subject sources		***	data	to both	datab
imports	less Brazil	***	***	***	***	***
Ratio to total						
shipments of	Subject sources	***	***	***	***	***
imports	less Brazil	***	***	***	***	***
Inventories	NI.	0.055.070	45 004 400	44.575.000	44 700 047	40.040.000
quantity	Nonsubject sources	6,855,876	15,234,436	14,575,098	14,709,217	13,210,866
Ratio to imports	Nonsubject sources	***	***	***	***	***
Ratio to U.S.						
shipments of		***	***	***	***	***
imports	Nonsubject sources	^^^	^^^	^^^	^^^	***
Ratio to total						
shipments of	Niamandala at a anna a	***	***	***	***	***
imports	Nonsubject sources					
Inventories	Nonsubject sources	***	***	***	***	***
quantity	plus Brazil					
Datia ta imparta	Nonsubject sources	***	***	***	***	***
Ratio to imports Ratio to U.S.	plus Brazil					
shipments of	Nonsubject sources					
imports	plus Brazil	***	***	***	***	***
Ratio to total	pius Diazii					
shipments of	Nonsubject sources					
imports	plus Brazil	***	***	***	***	***
Inventories	pius biazii					
quantity	All import sources	14,700,505	33,032,532	29,931,844	29,347,204	29,191,404
Ratio to imports	All import sources	***	***	***	***	***
Ratio to Imports	All lillhort sources					
shipments of						
imports	All import sources	***	***	***	***	***
Ratio to total	7 til lilipoit 30uloe3					
shipments of						
imports	All import sources	***	***	***	***	***
porto	, ai import sources					

Source: Compiled from data submitted in response to Commission questionnaires.

U.S. importers' outstanding orders

The Commission requested importers to indicate whether they imported or arranged for the importation of HECs from Brazil, China, India, and Vietnam after June 30, 2024. Their reported data are presented in table VII-19. Thirteen of 18 importers reported arranged imports from subject sources and four of 18 importers reported arranged imports from nonsubject sources. Arranged imports from subject sources accounted for a large majority of arranged imports during the period for which data were collected.

Table VII-19 HECs: U.S. importers' arranged imports, by source and period

Quantity in 1,000 units; shares in percent

·	Magazira		Oct-Dec	Jan-Mar	Apr-Jun	Total
Source	Measure	Jul-Sep 2024	2024	2025	2025	Total
Brazil	Quantity	***	***	***	***	***
China	Quantity	***	***	***	***	***
India	Quantity	***	***	***	***	***
Vietnam	Quantity	***	***	***	***	***
Subject sources	Quantity	***	***	***	***	***
Subject sources						
less Brazil	Quantity	***	***	***	***	***
Nonsubject						
sources	Quantity	***	***	***	***	***
Nonsubject						
sources plus						
Brazil	Quantity	***	***	***	***	***
All import						
sources	Quantity	17,874,420	17,285,736	8,466,985	3,913,341	47,540,482
Brazil	Share	***	***	***	***	***
China	Share	***	***	***	***	***
India	Share	***	***	***	***	***
Vietnam	Share	***	***	***	***	***
Subject sources	Share	***	***	***	***	***
Subject sources						
less Brazil	Share	***	***	***	***	***
Nonsubject						
sources	Share	***	***	***	***	***
Nonsubject						
sources plus						
Brazil	Share	***	***	***	***	***
All import						
sources	Share	100.0	100.0	100.0	100.0	100.0

Source: Compiled from data submitted in response to Commission questionnaires.

Note: Shares shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---".

Third-country trade actions

In November 2021, Brazil initiated an antidumping investigation on imports of empty hard gelatin capsules (HS 9602.00.10) from Mexico and the United States.⁴

In May 2023, a definitive antidumping duty was imposed on imports of the subject good from Mexico and the United States. The rate of duty on imports from Mexico ranges from US\$0.67 per thousand to US\$1.67 per thousand depending on the company. The rate of duty on imports from the United States ranges from US\$.12 per thousand to US\$2.13 per thousand depending on the company.⁵

Information on nonsubject countries

Table VII-20 presents global export data for hard empty capsules, including in-scope hard empty capsules as well as out-of-scope hard empty capsules. The largest non-subject global exporter was Belgium, representing 51.4 percent of global export values in 2023, with exports of more than \$252.7 billion. The next four leading non-subject exporters, which accounted for a combined 21.4 percent of global export value in 2023, were the United States, Mexico, Croatia, and South Korea. Exports from non-subject countries, combined, represented about 55.3 percent of total global export values in 2023.

⁴ World Trade Organization, Semi-annual report under article 16.4 of the Agreement, Brazil, March 18, 2022, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/G/ADP/N364BRA.pdf.

⁵ Official Diary of the Union, GECEX RESOLUTION NO. 470, MAY 9, 2023, May 10, 2023, RESOLUÇÃO GECEX № 470, DE 9 DE MAIO DE 2023 - RESOLUÇÃO GECEX № 470, DE 9 DE MAIO DE 2023 - DOU - Imprensa Nacional.

Table VII-20 Worked vegetable or mineral carving materials and articles: Global exports, by reporting country and period

Value in 1,000 dollars; Share in percent

Exporting country	Measure	2021	2022	2023
United States	Value	91,087	93,338	99,987
Brazil	Value	10,007	9,157	10,472
China	Value	192,317	220,881	211,563
India	Value	141,309	174,787	148,217
Vietnam	Value	60,379	68,857	57,475
Subject exporters	Value	404,012	473,682	427,726
Subject exporters except Brazil	Value	394,005	464,525	417,254
Belgium	Value	237,568	216,914	252,657
Mexico	Value	62,036	69,368	82,091
Croatia	Value	29,656	32,922	38,554
South Korea	Value	47,658	45,909	32,355
Canada	Value	28,874	31,156	30,810
Romania	Value	23,231	21,660	29,667
All other exporters	Value	196,093	219,281	186,284
Nonsubject exporters	Value	625,117	637,211	652,417
Nonsubject exporters plus Brazil	Value	635,123	646,368	662,889
All reporting exporters	Value	1,120,216	1,204,230	1,180,131
United States	Share of value	8.1	7.8	8.5
Brazil	Share of value	0.9	0.8	0.9
China	Share of value	17.2	18.3	17.9
India	Share of value	12.6	14.5	12.6
Vietnam	Share of value	5.4	5.7	4.9
Subject exporters	Share of value	36.1	39.3	36.2
Subject exporters except Brazil	Share of value	35.2	38.6	35.4
Belgium	Share of value	21.2	18.0	21.4
Mexico	Share of value	5.5	5.8	7.0
Croatia	Share of value	2.6	2.7	3.3
South Korea	Share of value	4.3	3.8	2.7
Canada	Share of value	2.6	2.6	2.6
Romania	Share of value	2.1	1.8	2.5
All other exporters	Share of value	17.5	18.2	15.8
Nonsubject exporters	Share of value	55.8	52.9	55.3
Nonsubject exporters plus Brazil	Share of value	56.7	53.7	56.2
All reporting exporters	Share of value	100.0	100.0	100.0

Notes continued.

Table VII-20 Continued

Worked vegetable or mineral carving materials and articles: Global exports, by reporting country and period

Source: Official exports statistics under HS subheading 9602.00 as reported by various national statistical authorities in the Global Trade Atlas Suite database, accessed November 19, 2024.

Note: Shares shown as "0.0" represent values greater than zero, but less than "0.05" percent. Zeroes, null values, and undefined calculations are suppressed and shown as "---". The United States is shown at the top followed by the countries under investigation, all remaining top exporting countries in descending order of 2023 data.

APPENDIX A FEDERAL REGISTER NOTICES

The Commission makes available notices relevant to its investigations and reviews on its website, www.usitc.gov. In addition, the following tabulation presents, in chronological order, Federal Register notices issued by the Commission and Commerce during the current proceeding.

Citation	Title	Link	
	Hard Empty Capsules From Brazil,		
	China, India, and Vietnam; Institution		
89 FR 86370,	of Antidumping and Countervailing Duty Investigations and Scheduling of	https://www.govinfo.gov/content/pkg/FR-	
October 30, 2024	Preliminary Phase Investigations	2024-10-30/pdf/2024-25161.pdf	
	Hard Empty Capsules From Brazil, the		
	People's Republic of China, India, and		
89 FR 91680,	the Socialist Republic of Vietnam:		
November 20,	Initiation of Countervailing Duty	https://www.govinfo.gov/content/pkg/FR-	
2024	Investigations	2024-11-20/pdf/2024-27008.pdf	
	Hard Empty Capsules From Brazil, the		
	People's Republic of China, India, and		
89 FR 91684,	the Socialist Republic of Vietnam:		
November 20,	Initiation of Less-Than-Fair-Value	https://www.govinfo.gov/content/pkg/FR-	
2024	Investigations	2024-11-20/pdf/2024-27009.pdf	

APPENDIX B LIST OF STAFF CONFERENCE WITNESSES

CALENDAR OF PUBLIC PRELIMINARY CONFERENCE

Those listed below appeared as witnesses at the United States International Trade Commission's preliminary conference:

Subject: Hard Empty Capsules from Brazil, China, India, and Vietnam

Inv. Nos.: 701-TA-742-745 and 731-TA-1720-1723 (Preliminary)

Date and Time: November 14, 2024 - 9:30 a.m.

Sessions were held in connection with these preliminary phase investigations in the Main Hearing Room (Room 101), 500 E Street, SW., Washington, DC.

OPENING REMARKS:

In Support of Imposition (**Shawn M. Higgins**, Sidley Austin LLP)
In Opposition to Imposition (**Lizbeth R. Levinson**, Fox Rothschild LLP)

In Support of the Imposition of the

Antidumping and Countervailing Duty Orders:

Sidley Austin LLP Washington, DC on behalf of

Lonza Greenwood LLC ("Lonza")

Michael Goetter, Vice President and Regional Business Unit Head, Americas (Capsules and Health Ingredients), Lonza Group Ltd.

Frank Romanski, Executive Director of Strategic Programs for Capsules and Health Ingredients, Lonza Group Ltd.

Ty James Corallo, Director, Head of Finance Operations, Capsules & Health Ingredients, Lonza Group Ltd.

Emilee Terry, Director, Associate General Counsel, Lonza Group Ltd.

In Support of the Imposition of the

Antidumping and Countervailing Duty Orders (continued):

Gabriel McCutcheon, Vice President, Greenwood Site Head, Lonza Greenwood LLC

Simon A.B. Schropp, Managing Economist, Sidley Austin LLP

Kornel Mahlstein, International Economist, Sidley Austin LLP

Shawn M. Higgins)
Rajib Pal)
Heather Hedges) – OF COUNSEL
Lauren Shapiro)
Allison V. Reading)

In Opposition to the Imposition of the <u>Antidumping and Countervailing Duty Orders:</u>

Fox Rothschild LLP Washington, DC on behalf of

Associated Capsules Group ("ACG") Torpac Inc. Custom Capsules Private Limited

Karan Singh, Director, ACG

Parag Shah, Chief Financial Officer, ACG

Raj Tahil, President, Torpac Inc.

Lizbeth R. Levinson)
) – OF COUNSEL
Brittney R. Powell)

Interested Party

Huangshan Capsule Inc. Ontario, CA

Michel Zhang, General Manager and Owner, Huangshan Capsule Inc.

REBUTTAL/CLOSING REMARKS:

In Support of Imposition (Rajib Pal, Sidley Austin LLP)
In Opposition to Imposition (Brittney R. Powell, Fox Rothschild LLP)

APPENDIX C

SUMMARY DATA

Table C-1

HECs: Summary data concerning the U.S. market, by item and period

Quantity=1,000 units; Value=1,000 dollars; Unit values, unit labor costs, and unit expenses=dollars per 1,000 units; Period changes=percent--exceptions noted

			Reported data		 			changes	
II .		Calendar year	0000	Jan-			mparison ye		Jan-Jun
Item	2021	2022	2023	2023	2024	2021-23	2021-22	2022-23	2023-24
U.S. consumption quantity:									
Amount	***	***	***	***	***	***	***	***	^ ***
Producers' share (fn1)	***	***	***	***	***	* ***	* ***	***	***
Importers' share (fr1):						*	•	•	•
	***	***	***	***	***	***	***	A ***	^ ***
Brazil	***	***	***	***	***	***	* ***	***	A ***
ChinaIndia	***	***	***	***	***	▲ ▲***	▲ ▲ ***	▲ ▲ ***	* ***
	***	***	***	***	***	* ***	A ***	▲ ***	↓ ***
Vietnam	***	***	***	***	***	▲ ▲***	▲ ▲ ***	▲ ▲ ***	▲ ▲ ***
Subject sources	***	***	***	***	***	▲ ▲ ***	▲ ▲ ***	▲ ***	▲ ▲ ***
Subject sources less Brazil	***	***	***	***	***	▲ ▼***	▲ ▼***	▲ ▼***	▲ ▲ ***
Nonsubject sources	***	***	***	***	***	▼***	* ***	***	▲ ***
Nonsubject sources plus Brazil	***	***	***	***	***				A ~~~
All import sources	***	***	***	***	***	***	***	***	A ***
U.S. consumption value:									
Amount	***	***	***	***	***	***	***	***	***
Producers' share (fn1)	***	***	***	***	***	****	▲ ***	* ***	▼***
Importers' share (fn1):						•	_	•	•
Brazil	***	***	***	***	***	***	***	A ***	***
China	***	***	***	***	***	***	▲ ***	▲ ***	_ ▲***
India	***	***	***	***	***	* ***	_ ***	_ ▲***	_ ***
Vietnam	***	***	***	***	***	▲ ***	▲ ***	▲ ***	Ā***
Subject sources	***	***	***	***	***	* ***	- - ***	_ ▲***	_ ***
Subject sources less Brazil	***	***	***	***	***	▲ ***	▲ ***	▲ ***	Ā***
Nonsubject sources	***	***	***	***	***	* ***	* ***	* ***	▲ ***
Nonsubject sources plus Brazil	***	***	***	***	***	* ***	* ***	* ***	▲ ***
All import sources	***	***	***	***	***	▼ ▲ ***	▼ ***	↓ ***	▲ ***
U.S. importers' U.S. shipments of imports from Brazil: Quantity	***	***	***	***	***	****	V ***	A ***	A ***
Value	***	***	***	***	***	***	***	▲ ***	▲ ***
Unit value						***	▲***	***	▼***
Ending inventory quantity	***	***	***	***	***	▲ ***	▲ ***		▲ ***
							_	▲ ***	_
China:									
China: Quantity	***	***	***	***	***	***	^ ***	A ***	***
China: Quantity Value	***	***	***	***	***	***	▲ *** ▲ ***	▲ *** ▲ ***	≜ ***
China: Quantity Value Unit value	***	***	***	***	***	▲ *** ▼***	A *** A ***	▲ *** ▲ *** ▼ ***	▲*** ▲*** ▼***
China: QuantityValueUnit value. Ending inventory quantity	***	***	***	***	***	***	▲ *** ▲ ***	▲ *** ▲ ***	≜ ***
China: Quantity Value Unit value Ending inventory quantity India:	*** *** ***	*** *** ***	*** *** ***	*** *** ***	*** *** ***	▲ *** ▼ *** ▲ ***	▲*** ▲*** ▲***	▲ *** ▲ *** ▼ ***	▲ *** ▲ *** ▼ ***
China: QuantityValueUnit value. Ending inventory quantity	*** *** ***	*** *** ***	*** *** ***	*** *** ***	*** *** ***	▲ *** ▼ *** ▲ ***	▲ *** ▲ *** ▲ *** ▲ ***	▲ *** ▲ *** ▼ ***	▲ *** ▲ *** ▼ ***
China: Quantity Value Unit value Ending inventory quantity India: Quantity Value	*** *** *** ***	*** *** *** ***	*** *** *** ***	*** *** *** ***	*** *** *** ***	▲ *** ▼ *** ▲ *** ▲ ***	▲ *** ▲ *** ▲ *** ▲ ***	▲ ***	▲ *** ▲ *** ▼ *** ▲ ***
China: Quantity Value Unit value Ending inventory quantity India: Quantity	*** *** *** *** ***	*** *** *** ***	*** *** *** ***	*** *** *** *** *** ***	*** *** *** *** ***	A *** A *** A *** A ***	*** *** *** *** *** ***	A *** A *** V *** A *** A *** A ***	A *** V *** V *** A *** A ***
China: Quantity Value Unit value Ending inventory quantity India: Quantity Value	*** *** *** ***	*** *** *** ***	*** *** *** ***	*** *** *** ***	*** *** *** ***	▲ *** ▼ *** ▲ *** ▲ ***	▲ *** ▲ *** ▲ *** ▲ ***	▲ ***	▲ *** ▲ *** ▼ ***
China: Quantity Value Unit value Ending inventory quantity India: Quantity Value Unit value	*** *** *** *** *** ***	*** *** *** *** ***	*** *** *** *** ***	*** *** *** *** *** ***	*** *** *** *** ***	▲ ***	A ***	A *** A *** V *** A *** A *** A *** A ***	A*** *** *** A*** A*** *** ***
China: Quantity. Value Unit value. Ending inventory quantity India: Quantity Value Unit value. Ending inventory quantity	*** *** *** *** *** ***	*** *** *** *** *** ***	*** *** *** *** *** ***	*** *** *** *** *** ***	*** *** *** *** ***	▲ ***	A ***	A ***	A *** V *** A *** A *** V *** A ***
China: Quantity Value Unit value Ending inventory quantity India: Quantity Value Unit value Ending inventory quantity Vietnam:	*** *** *** *** *** ***	*** *** *** *** *** ***	*** *** *** *** *** ***	*** *** *** *** *** ***	*** *** *** *** *** *** ***	_ ***	A ***	A *** V *** A *** V *** A *** A *** A *** A ***	A *** A *** V *** A *** A *** A *** A *** A ***
China: Quantity Value Unit value Ending inventory quantity India: Quantity Value Unit value Ending inventory quantity Vietnam: Quantity Quantity	*** *** *** *** *** *** ***	*** *** *** *** *** *** ***	*** *** *** *** *** *** ***	*** *** *** *** *** *** ***	*** *** *** *** *** *** ***	_ ***	A ***	A *** V *** A *** V *** A *** V *** V ***	A *** V *** A *** A *** V *** A *** V *** A ***
China: Quantity Value Unit value Ending inventory quantity India: Quantity Value Unit value Ending inventory quantity Vietnam: Quantity. Value Value Vietnam: Quantity.	*** *** *** *** *** ***	*** *** *** *** *** ***	*** *** *** *** *** ***	*** *** *** *** *** ***	*** *** *** *** *** *** ***	_ ***	A ***	A *** V *** A *** V *** A *** A *** A *** A ***	A *** A *** A *** A *** A *** A ***
China: Quantity	*** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** *** ***	A ***	A ****	A ****
China: Quantity. Value Unit value Ending inventory quantity India: Quantity. Value Unit value Ending inventory quantity Vietnam: Quantity. Value Unit value Ending inventory quantity Unit value Unit value Unit value. Ending inventory quantity	*** *** *** *** *** *** ***	*** *** *** *** *** *** ***	*** *** *** *** *** *** ***	*** *** *** *** *** *** ***	*** *** *** *** *** *** ***	_ ***	A *** A ***	A ***	A
China: Quantity	*** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** ***	A ***	A *** V *** V *** A *** A *** A *** A *** A ***	A ****
China: Quantity Value Unit value Ending inventory quantity India: Quantity Value Unit value Ending inventory quantity Vietnam: Quantity Value Unit value Ending inventory quantity Vietnam: Quantity Value Unit value Ending inventory quantity Subject sources: Quantity	*** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** *** ***	A ***	A ****	A ****
China: Quantity. Value Unit value Ending inventory quantity India: Quantity. Value Unit value. Ending inventory quantity Vietnam: Quantity. Value Unit value Ending inventory quantity Vietnam: Quantity. Value Unit value. Ending inventory quantity Subject sources: Quantity. Value Quantity. Value	*** *** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** ***	A ***	A *** V *** V *** A *** A *** A *** A *** A ***	A **** A *** A ** A
China: Quantity. Value Unit value Ending inventory quantity India: Quantity. Value Unit value Ending inventory quantity Vietnam: Quantity. Value Unit value Ending inventory quantity Vietnam: Quantity. Value Unit value. Ending inventory quantity Subject sources: Quantity. Value Unit value. Ending inventory quantity Unit value. Ending inventory quantity	*** *** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** *** ***	▲*** ✓ ***	*** *** *** *** *** *** *** *** *** *** *** *** *** ***	A ***	A**** A**** A**** A**** A**** A**** A**** A**** A****
China: Quantity. Value Unit value Ending inventory quantity India: Quantity. Value Unit value Ending inventory quantity Vietnam: Quantity Value Unit value Ending inventory quantity Value Unit value Ending inventory quantity Subject sources: Quantity Value Unit value Unit value Ending inventory quantity Subject sources: Quantity Value Unit value Unit value	*** *** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** *** ***	**** *** *** *** *** *** *** *** *** *** *** *** *** *** *** ***	*** *** *** *** *** *** *** *** *** *** *** *** *** ***	**** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** ** *** *** *** *** *** *** *** *** *** *** *** *** ** *** *** *** *** *** *** *** *** *** *** *** *** ** *** *** *** *** *** *** *** *** *** *** *** *** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** **	A**** A**** A**** A**** A**** A**** A**** A****
China: Quantity. Value Unit value guantity. Value Unit value. Ending inventory quantity. Value. Unit value. Ending inventory quantity. Vietnam: Quantity. Value Unit value. Ending inventory quantity. Vietnam: Quantity. Value Unit value. Ending inventory quantity. Subject sources: Quantity. Value Unit value. Ending inventory quantity. Subject sources less Brazil:	*** *** *** *** *** *** *** *** *** 7,844,629	*** *** *** *** *** *** *** *** 17,798,096	*** *** *** *** *** *** *** *** 15,356,746	*** *** *** *** *** *** *** *** *** 14,637,987	*** *** *** *** *** *** *** *** *** 15,980,538	**** *** *** *** *** *** *** *** *** *** *** *** *** *** *** ***	A ***	**** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** ** *** *** *** *** *** *** *** *** *** *** *** *** ** *** *** *** *** *** *** *** *** *** *** *** *** ** *** *** *** *** *** *** *** *** *** *** *** *** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** **	A**** A**** A**** A**** A**** A**** A**** A**** A****
China: Quantity. Value Unit value. Ending inventory quantity India: Quantity. Value Unit value. Ending inventory quantity Vietnam: Quantity. Value Unit value. Ending inventory quantity Value Unit value. Ending inventory quantity Subject sources: Quantity. Value Unit value. Ending inventory quantity Subject sources less Brazil: Quantity Quantity Subject sources less Brazil:	*** *** *** *** *** *** *** *** *** 7,844,629	*** *** *** *** *** *** *** *** *** 17,798,096 ***	*** *** *** *** *** *** *** *** 15,356,746	*** *** *** *** *** *** *** *** *** 14,637,987 ***	*** *** *** *** *** *** *** *** 15,980,538	▲*** ✓ ***	*** *** *** *** *** *** *** *** *** *** *** *** *** *** ***	**** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** *** ** *** *** *** *** *** *** *** *** *** *** *** *** ** *** *** *** *** *** *** *** *** *** *** *** *** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** ** **	A ****

Table C-1 Continued HECs: Summary data concerning the U.S. market, by item and period

Quantity=1,000 units; Value=1,000 dollars; Unit values, unit labor costs, and unit expenses=dollars per 1,000 units; Period changes=percent-exceptions noted

-		Calendar year	Reported data	Jan-	lun		Period omparison year		Jan-Jui
Item	2021	2022	2023	2023	2024	2021-23	2021-22	2022-23	2023-2
10: 1 1110 1: 1 1: 1	0 "								
J.S. importers' U.S. shipments of imports from	m: Continued								
Nonsubject sources:	***	***	***	***	***	***	***	***	. *
Quantity	***	***	***	***	***	▼***	* ***	* ***	*
Value	***	***	***	***	***				_ *
Unit value						A ***	A ***	***	▼*
Ending inventory quantity	6,855,876	15,234,436	14,575,098	14,709,217	13,210,866	▲ 112.6	▲ 122.2	▼ (4.3)	▼ (10.
Nonsubject sources plus Brazil:									
Quantity	***	***	***	***	***	▼***	***	***	▲*
Value	***	***	***	***	***	***	***	***	▲*
Unit value	***	***	***	***	***	***	▲ ***	***	▼*
Ending inventory quantity	***	***	***	***	***	▲ ***	***	***	▼*
All import sources:									
Quantity	78,994,367	70,530,016	75,373,343	35,315,290	43,682,150	▼ (4.6)	▼ (10.7)	▲ 6.9	▲23
Value	372,232	348,021	343,767	166,770	191,376	▼ (7.6)	▼ (6.5)	▼ (1.2)	▲ 14
Unit value	\$4.71	\$4.93	\$4.56	\$4.72	\$4.38	▼(3.2)	▲ 4.7	▼ (7.6)	▼(7
Ending inventory quantity	14,700,505	33,032,532	29,931,844	29,347,204	29,191,404	▲ 103.6	▲ 124.7	▼ (9.4)	▼ (0
J.S. producers':								` '	`
Practical capacity quantity	***	***	***	***	***	▼***	***	***	▼,
Production quantity	***	***	***	***	***	***	***	***	▼:
Capacity utilization (fn1)	***	***	***	***	***	***	* ***	▲ ***	▼:
U.S. shipments:						_	•	_	•
Quantity	***	***	***	***	***	▼ ***	***	***	_
•	***	***	***	***	***	* ***	* ***	* ***	÷
Value	***	***	***	***	***	▼	* ***	▼ ***	Ť
Unit value						A	A	A	•
Export shipments:	***	***	***	***	***	A ***	***	***	_
Quantity	***	***	***	***	***				
Value	***	***	***	***	***	***	***	***	•
Unit value						***	***	***	▼
Ending inventory quantity	***	***	***	***	***	▲ ***	***	***	•
Inventories/total shipments (fn1)	***	***	***	***	***	***	***	***	•
Production workers	***	***	***	***	***	***	▲ ***	***	▼
Hours worked (1,000s)	***	***	***	***	***	▲ ***	▲ ***	***	▼
Wages paid (\$1,000)	***	***	***	***	***	▲ ***	▲ ***	▲ ***	▼
Hourly wages (dollars per hour)	***	***	***	***	***	***	***	***	
Productivity (1,000 units per hour)	***	***	***	***	***	***	***	***	▼
Unit labor costs	***	***	***	***	***	***	***	***	A
Net sales:									
Quantity	***	***	***	***	***	▼***	***	***	▼:
Value	***	***	***	***	***	***	***	***	· ·
Unit value	***	***	***	***	***	_ ▲ ***	▲ ***	_ ▲***	, i
Cost of goods sold (COGS)	***	***	***	***	***	_ ▲ ***	_ _ ***	***	÷
	***	***	***	***	***	* ***	* ***	↓ ***	÷
Gross profit or (loss) (fn2)	***	***	***	***	***	▼	▼ ★ ***	▲ ▲***	Ť
SG&A expenses(f-2)	***	***	***	***	***	* ***	▲ ▼***	▲ ▲ ***	Ť
Operating income or (loss) (fn2)	***	***	***	***	***	***	***		¥
Net income or (loss) (fn2)	***	***	***	***	***			A ***	
Unit COGS	***	***	***	***	***	***	▲ ***	▲ ***	A
Unit SG&A expenses						▲ ***	***	▲ ***	A
Unit operating income or (loss) (fn2)	***	***	***	***	***	▼ ***	***	***	▼
Unit net income or (loss) (fn2)	***	***	***	***	***	▼***	***	▲***	•
COGS/sales (fn1)	***	***	***	***	***	▲ ***	▲ ***	***	•
Operating income or (loss)/sales (fn1)	***	***	***	***	***	▼***	***	***	▼
Net income or (loss)/sales (fn1)	***	***	***	***	***	***	***	***	▼
Capital expenditures	***	***	***	***	***	***	***	***	_
Research and development expenses	***	***	***	***	***	***	***	***	
Total assets	***	***	***	***	***	***	***	***	

Source: Compiled from data submitted in response to Commission questionnaires. 508-compliant tables for these data are contained in parts III, IV, VI, and VII of this report.

Note.—Shares and ratios shown as "0.0" percent represent non-zero values less than "0.05" percent (if positive) and greater than "(0.05)" percent (if negative). Zeroes, null values, and undefined calculations are suppressed and shown as "---". Period changes preceded by a "▲" represent an increase, while period changes preceded by a "▼" represent a decrease.

fn1.--Reported data are in percent and period changes are in percentage points.

fn2.—Percent changes only calculated when both comparison values represent profits; The directional change in profitability provided when one or both comparison values represent a loss.

APPENDIX D

U.S. SHIPMENTS BY CHANNELS OF DISTRIBUTION AND PRODUCT TYPE

Table D-1 HECs: U.S. producers' and U.S. importers' U.S. shipments to distributors/retailers, by source and year

Source	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
U.S. producers	Quantity	***	***	***	***	***
Brazil	Quantity	***	***	***	***	***
China	Quantity	***	***	***	***	***
India	Quantity	***	***	***	***	***
Vietnam	Quantity	***	***	***	***	***
Subject sources	Quantity	***	***	***	***	***
Subject sources less Brazil	Quantity	***	***	***	***	***
Nonsubject sources	Quantity	***	***	***	***	***
Nonsubject sources plus Brazil	Quantity	***	***	***	***	***
All import sources	Quantity	***	***	***	***	***
All sources	Quantity	***	***	***	***	***
U.S. producers	Share	***	***	***	***	***
Brazil	Share	***	***	***	***	***
China	Share	***	***	***	***	***
India	Share	***	***	***	***	***
Vietnam	Share	***	***	***	***	***
Subject sources	Share	***	***	***	***	***
Subject sources less Brazil	Share	***	***	***	***	***
Nonsubject sources	Share	***	***	***	***	***
Nonsubject sources plus Brazil	Share	***	***	***	***	***
All import sources	Share	***	***	***	***	***
All sources	Share	100.0	100.0	100.0	100.0	100.0

Table D-1 Continued

HECs: U.S. producers' and U.S. importers' U.S. shipments to distributors/retailers, by source and year

Ratios represent the ratio to overall apparent U.S. consumption

Source	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
U.S. producers	Ratio	***	***	***	***	***
Brazil	Ratio	***	***	***	***	***
China	Ratio	***	***	***	***	***
India	Ratio	***	***	***	***	***
Vietnam	Ratio	***	***	***	***	***
Subject sources	Ratio	***	***	***	***	***
Subject sources less Brazil	Ratio	***	***	***	***	***
Nonsubject sources	Ratio	***	***	***	***	***
Nonsubject sources plus Brazil	Ratio	***	***	***	***	***
All import sources	Ratio	***	***	***	***	***
All sources	Ratio	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Table D-2 HECs: U.S. producers' and U.S. importers' U.S. shipments to pharmaceutical end users, by source and year

Source	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
U.S. producers	Quantity	***	***	***	***	***
Brazil	Quantity	***	***	***	***	***
China	Quantity	***	***	***	***	***
India	Quantity	***	***	***	***	***
Vietnam	Quantity	***	***	***	***	***
Subject						
sources	Quantity	***	***	***	***	***
Subject						
sources less						
Brazil	Quantity	***	***	***	***	***
Nonsubject	Oursetitu.	***	***	***	***	***
sources Nonsubject	Quantity					
sources plus						
Brazil	Quantity	***	***	***	***	***
All import	<u> </u>					
sources	Quantity	***	***	***	***	***
All sources	Quantity	***	***	***	***	***
U.S. producers	Share	***	***	***	***	***
Brazil	Share	***	***	***	***	***
China	Share	***	***	***	***	***
India	Share	***	***	***	***	***
Vietnam	Share	***	***	***	***	***
Subject						
sources	Share	***	***	***	***	***
Subject						
sources less						
Brazil	Share	***	***	***	***	***
Nonsubject	Cl	***	***	***	***	***
sources	Share	***			***	***
Nonsubject						
sources plus Brazil	Share	***	***	***	***	***
All import	Silait					
sources	Share	***	***	***	***	***
All sources	Share	100.0	100.0	100.0	100.0	100.0

Table D-2 Continued HECs: U.S. producers' and U.S. importers' U.S. shipments to pharmaceutical end users, by source and year

Ratios represent the ratio to overall apparent U.S. consumption

Source	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
U.S. producers	Ratio	***	***	***	***	***
Brazil	Ratio	***	***	***	***	***
China	Ratio	***	***	***	***	***
India	Ratio	***	***	***	***	***
Vietnam	Ratio	***	***	***	***	***
Subject sources	Ratio	***	***	***	***	***
Subject sources less Brazil	Ratio	***	***	***	***	***
Nonsubject sources	Ratio	***	***	***	***	***
Nonsubject sources plus Brazil	Ratio	***	***	***	***	***
All import sources	Ratio	***	***	***	***	***
All sources	Ratio	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Table D-3 HECs: U.S. producers' and U.S. importers' U.S. shipments to nutraceutical end users, by source and year

Source	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
U.S. producers	Quantity	***	***	***	***	***
Brazil	Quantity	***	***	***	***	***
China	Quantity	***	***	***	***	***
India	Quantity	***	***	***	***	***
Vietnam	Quantity	***	***	***	***	***
Subject	•					
sources	Quantity	***	***	***	***	***
Subject						
sources less	0 "	***	***	***	***	***
Brazil	Quantity	***	***	***	***	***
Nonsubject sources	Quantity	***	***	***	***	***
Nonsubject	Quantity					
sources plus						
Brazil	Quantity	***	***	***	***	***
All import	,					
sources	Quantity	***	***	***	***	***
All sources	Quantity	***	***	***	***	***
U.S. producers	Share	***	***	***	***	***
Brazil	Share	***	***	***	***	***
China	Share	***	***	***	***	***
India	Share	***	***	***	***	***
Vietnam	Share	***	***	***	***	***
Subject						
sources	Share	***	***	***	***	***
Subject						
sources less	Ob	***	***	***	***	***
Brazil	Share	***	***	***	***	***
Nonsubject sources	Share	***	***	***	***	***
Nonsubject	Jilait					
sources plus						
Brazil	Share	***	***	***	***	***
All import						
sources	Share	***	***	***	***	***
All sources	Share	100.0	100.0	100.0	100.0	100.0

Table D-3 Continued HECs: U.S. producers' and U.S. importers' U.S. shipments to nutraceutical end users, by source and year

Ratios represent the ratio to overall apparent U.S. consumption

Source	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
U.S. producers	Ratio	***	***	***	***	***
Brazil	Ratio	***	***	***	***	***
China	Ratio	***	***	***	***	***
India	Ratio	***	***	***	***	***
Vietnam	Ratio	***	***	***	***	***
Subject sources	Ratio	***	***	***	***	***
Subject sources less Brazil	Ratio	***	***	***	***	***
Nonsubject sources	Ratio	***	***	***	***	***
Nonsubject sources plus Brazil	Ratio	***	***	***	***	***
All import sources	Ratio	***	***	***	***	***
All sources	Ratio	***	***	***	***	***

Source: Compiled from data submitted in response to Commission questionnaires.

Table D-4 HECs: U.S. producers' and U.S. importers' U.S. shipments to all other users, by source and type, 2023

Source	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024
U.S. producers	Quantity	***	***	***	***	***
Brazil	Quantity	***	***	***	***	***
China	Quantity	***	***	***	***	***
India	Quantity	***	***	***	***	***
Vietnam	Quantity	***	***	***	***	***
Subject sources	Quantity	***	***	***	***	***
Subject sources less Brazil	Quantity	***	***	***	***	***
Nonsubject sources	Quantity	***	***	***	***	***
Nonsubject sources plus Brazil	Quantity	***	***	***	***	***
All import sources	Quantity	***	***	***	***	***
All sources	Quantity	***	***	***	***	***
U.S. producers	Share	***	***	***	***	***
Brazil	Share	***	***	***	***	***
China	Share	***	***	***	***	***
India	Share	***	***	***	***	***
Vietnam	Share	***	***	***	***	***
Subject sources	Share	***	***	***	***	***
Subject sources less Brazil	Share	***	***	***	***	***
Nonsubject sources	Share	***	***	***	***	***
Nonsubject sources plus Brazil	Share	***	***	***	***	***
All import sources	Share	***	***	***	***	***
All sources	Share	100.0	100.0	100.0	100.0	100.0

Table D-4 Continued

HECs: U.S. producers' and U.S. importers' U.S. shipments to all other users, by source and type, 2023

Ratios represent the ratio to overall apparent U.S. consumption

Source	Measure	2021	2022	2023	Jan-Jun 2023	Jan-Jun 2024	
U.S. producers	Ratio	***	***	***	***	***	
Brazil	Ratio	***	***	***	***	***	
China	Ratio	***	***	***	***	***	
India	Ratio	***	***	***	***	***	
Vietnam	Ratio	***	***	***	***	***	
Subject sources	Ratio	***	***	***	***	***	
Subject sources less Brazil	Ratio	***	***	***	***	***	
Nonsubject sources	Ratio	***	***	***	***	***	
Nonsubject sources plus Brazil	Ratio	***	***	***	***	***	
All import sources	Ratio	***	***	***	***	***	
All sources	Ratio	***	***	***	***	***	

Source: Compiled from data submitted in response to Commission questionnaires.