VDC Position - Ensuring a Legally Operable and Proportionate EU Import Pathway for Carmine (E 120) and Shellac (E 904)

Position on the application of EU border-control and third-country listing requirements from 1 October 2026

For Consideration by European Commission, Directorate-General for Health and Food Safety (DG SANTE)

Date 3 August 2026

Position in brief

VDC supports effective traceability, official controls and equivalent third-country guarantees. We highly appreciate the proactive initiative launched by DG SANTE to gather data from trade bodies concerning non-EU countries exporting animal-derived food additives. In response, VDC and its members submitted the requested detailed mapping of trade flows on 29 April 2026, highlighting critical supply chains including Carmine (E 120) from Peru and Shellac (E 904) from countries such as India, Thailand, China, the USA, the UK, Japan, Myanmar, Indonesia, Vietnam, and Laos.

The issue is not whether E 120 and E 904 should be controlled, but whether Union law provides a complete and practically usable route for their entry after 1 October 2026. Unless a suitable listing route is established in time, there is a serious risk that established imports of Carmine from Peru and Shellack will no longer have legally operable pathway into the Union.

Requested Commission Action

1. **Create the permanent legal route:** Amend Article 22 of Implementing Regulation (EU) 2021/405 so that insect-derived highly refined products can be linked to an appropriate third country list and assess Peru for E 120 and India for E 904 based on the required official guarantees.

2. **Clarify uniform implementation:** Provide Member States and Border Control Posts (BCP) with a common interpretation of the rules applicable before and from 1 October 2026, including the treatment of consignments during any legislative transition.

3. **Prevent a regulatory interruption and disruption to trade and supply chains:** Adopt a legally sound transitional measure if the permanent amendment and the relevant country listings cannot be completed before 1 October 2026.

4. **Clarify and reassess the necessity of documentary requirements:** The current legal framework requires a Common Health Entry Document (CHED-P). It is however not yet clear if there is a need for an additional official certificate. Given the degree of processing of the animal-based raw materials, the question arises as to whether a private declaration would not suffice, rather than equating these highly processed products with other products of animal origin. Both stakeholders and enforcement authorities urgently require this clarity well in advance of the 1 October deadline, as past experience demonstrates that post-deadline guidance creates severe operational and legal disruption.

Therefore, we kindly request an opportunity to present our scientific data and discuss these regulatory drafting proposals in a brief technical meeting (via videoconference) at your earliest convenience.

1. **Executive summary**

Commission Delegated Regulation (EU) 2025/1449 expressly brought food additives of animal origin within Section XVI of Annex III to Regulation (EC) No 853/2004 and permitted insects as raw materials for highly refined products. Recital 10 explains that the manufacturing of such additives eliminates the relevant animal- and public-health risks that the highly refined products regime is designed to address.

Commission Implementing Regulation (EU) 2026/551, which applies from 1 October 2026, places relevant animal-origin products under ex 1301 and ex 3203 00 within the list of goods subject to official controls at Border Control Posts. This includes Shellac used as food additive E 904 and animal-origin colouring matter such as Carmine/cochineal used in food or feed production.

The corresponding third-country listing mechanism is not yet complete. Article 22 of Implementing Regulation (EU) 2021/405 currently provides entry routes for highly refined products derived from ungulates, fishery products and poultry, but not for highly refined products derived from insects. The resulting mismatch creates a serious risk that compliant consignments cannot be authorised for entry after 1 October 2026 unless the Commission completes the legal framework in time.

VDC therefore calls for a targeted and product-specific solution. The Union should preserve effective official controls while ensuring that the legal route, country listings and documentary requirements are coherent, proportionate and operational before the new Border Control Post listing applies.

2. **The regulatory chain and the point of discontinuity**

EU measure	Effect	Relevance to the gap
Delegated Regulation (EU) 2025/1449	Adds food additives of animal origin to Section XVI of Annex III to Regulation (EC) No 853/2004 and permits insects as raw materials for highly refined products.	Confirms the hygiene-law status of insect-derived animal-origin food additives as highly refined products.
Implementing Regulation (EU) 2026/551	From 1 October 2026, brings relevant animal-origin products under ex 1301 and ex 3203 00 within the list of goods subject to official controls at Border Control Posts.	E 904 and E 120 will require a legally operable route through the EU entry-control system.
Article 22 of Implementing Regulation (EU) 2021/405	Provides listing routes for highly refined products derived from ungulates, fishery products and poultry.	It does not presently provide a corresponding route for highly refined products derived from insects.

Core Regulatory Issue

EU hygiene legislation now recognizes insect-derived animal-origin food additives as highly refined products, and EU border-control legislation will require the relevant consignments to be presented at Border Control Posts. The missing element is a matching third-country listing route for this product category.

3. Regulatory Context

The 2025 amendment to Regulation (EC) No 853/2004 is an important clarification: food additives of animal origin authorised under Regulation (EC) No 1333/2008 are expressly included among highly refined products, and insects are expressly permitted as raw materials. VDC supports this product- and process-based treatment.

The 2026 amendment to Implementing Regulation (EU) 2021/632 serves a different purpose. It identifies goods that must be presented for official controls at Border Control Posts. That inclusion does not by itself create the third-country authorisation route required under the separate listing legislation.

With the adoption of Commission Implementing Regulation (EU) 2026/551, amending Implementing Regulation (EU) 2021/632, E 120 (under CN code ex 3203 00) and E 904 (under CN code ex 1301) will be subject to mandatory presentation at EU Border Control Posts (BCPs) as of 1 October 2026, pursuant to Article 2 of Regulation (EU) 2026/551. However, due to an irreconcilable gap in the intersecting third-country listing framework under Commission Implementing Regulation (EU) 2021/405, there is a serious risk that consignments of E 120 and E 904 will no longer have **a legally operable pathway** for entry into the Union **from 1 October 2026**.

VDC members have also reported divergent approaches at certain points of entry in advance of the application date. These cases should be documented and addressed through prompt Commission guidance so that the current rules are applied consistently until 30 September 2026 and the new rules are applied consistently thereafter.

4. Economic Relevance

The likely impact extends beyond the value of the imported additives. A disruption may require reformulation, laboratory and shelf-life validation, adaptation of processing parameters, revised specifications, customer approval, label changes and re-registration in third-country export markets. Those steps can take substantially longer than ordinary procurement changes, representing a disproportionate amount of effort for two additives that have been used safely in foods for many years. It surely cannot be the intention of the regulatory framework to de facto remove additives from the EU market that are long-established and fully approved under the EU Food Additives Regulation (EU) No 231/2012.

The consequences are also product specific. Carmine disruption would affect colour systems in selected formulations, as synthetic alternatives (E 122, E 124, E 129) are strictly restricted or entirely prohibited in many applications, while natural alternatives (such as red beet or anthocyanins) fail to match its technical performance. As a result, numerous food products would either change fundamentally or disappear from the market altogether. Furthermore, EU exporters would face a severe competitive disadvantage on the global market if Carmine can no longer be used in their formulations.

Shellac disruption would similarly affect coating and glazing systems. Treating both products as if the only alternative were a synthetic dye understates the distinct technical functions of E 904 and E 120 and drastically weakens the economic analysis.

Overall, the economic impact on the European food industry would be massive: the reported import value of USD 83.1 million for Carmine represents approximately 280 tonnes of 50% Carmine, capable of coloring up to 2.8 million tonnes of finished food with an estimated consumer market value of at least €12 to €15 billion. Peruvian export figures supplied to VDC indicate exports to EU destinations with a reported FOB value of approximately USD 83.1 million in 2025 and USD 41.7 million in January to June 2026 (PROMPERÚ, 2026).

Conclusion

Swift administrative and legislative alignment is required to ensure legal certainty, prevent avoidable disruptions to established Union food manufacturing supply chains, and avoid unintentionally denying EU market access to two additives that are fully approved under EU legislation and have been safely used in Europe across numerous products for many years. A comprehensive technical and legal dossier supporting this request is structured in Annexes I through V to this paper.

Association of Firms engaged in
Wholesale and Foreign Trade in Drugs and Chemicals (VDC)

German Bundestag Lobby Register No.: R002395
EU Transparency Register No.: 660181152464-81
Address: Sonninstrasse 28, 20097 Hamburg, Germany
Phone: +49 (0)40 23 60 16 13
Email: vdc@wga-hh.de
www.v-c-d.org

ANNEX I: Detailed Legal Analysis

1. Scope of Border Controls Under Regulation (EU) 2026/551

Commission Implementing Regulation (EU) 2026/551 updates the list of goods subject to official controls at BCPs under Implementing Regulation (EU) 2021/632. By capturing tariff lines ex 3203 00 and ex 1301, the regulation establishes that from 1 October 2026, consignments must undergo mandatory presentation at an EU Border Control Post, 100% documentary checks, identity checks, and risk-based physical checks. Under basic Union control frequencies for highly refined products, physical checks are set at a baseline of 1%.

2. Transitional Provisions Prior to 1 October 2026

Pursuant to Article 2 of Regulation (EU) 2026/551, the requirement for BCP presentation applies strictly from 1 October 2026. Recital 5 explicitly states that this deferred application is designed to provide operators and competent authorities adequate time to adapt. Unilateral implementation or rejection of consignments by local BCPs prior to 1 October 2026 represents a misinterpretation of the transitional timeline set by the Union legislator.

ANNEX II: Proposed Legislative Textual Amendments

Proposal 1: Amendment to Commission Implementing Regulation (EU) 2021/405

Objective: Expand the scope of Article 22 to include highly refined products derived from insects and insert an explicit third-country list authorizing Peru and India for these specific additive categories.

1. The introductory phrase of Article 22 of Implementing Regulation (EU) 2021/405 is replaced by the following:

"Consignments of specified highly refined products referred to in Section XVI, Point 1 of Annex III to Regulation (EC) No 853/2004 derived from ungulates, poultry, aquaculture products, or insects, intended for human consumption, shall only be authorized for the entry into the Union if they originate from the following third countries or regions thereof:"

2. Point (d) is added to Article 22 of Implementing Regulation (EU) 2021/405:

"(d) for highly refined products derived from insects: from the third countries listed in Annex XIVa."

3. A new Annex XIVa is inserted in Implementing Regulation (EU) 2021/405:

"ANNEX XIVa

List of third countries or regions thereof authorized for the entry into the Union of highly refined products derived from insects referred to in Article 22(d)

<table>
<tr><th>ISO Code</th><th>Third Country</th><th>Remarks</th></tr>
<tr><td>PE</td><td>Peru</td><td>Highly refined food additives (E 120 Carmine)</td></tr>
<tr><td>IN</td><td>India</td><td rowspan="11">Highly refined food additives (E 904 Shellac)</td></tr>
<tr><td>TH</td><td>Thailand</td></tr>
<tr><td>CN</td><td>China</td></tr>
<tr><td>US</td><td>USA</td></tr>
<tr><td>GB</td><td>UK</td></tr>
<tr><td>JP</td><td>Japan</td></tr>
<tr><td>MM</td><td>Myanmar</td></tr>
<tr><td>ID</td><td>Indonesia</td></tr>
<tr><td>VN</td><td>Vietnam</td></tr>
<tr><td>LA</td><td>Laos</td></tr>
</table>

Proposal 2: Clarification Under Commission Delegated Regulation (EU) 2022/2292

Objective: Provide legal clarity confirming that highly refined food additives under HS positions 1301 and 3203 are not subject to official third-country health certificates.

Article 21 of Delegated Regulation (EU) 2022/2292 is amended by adding the following paragraph:

"Consignments of food additives classified as highly refined products in accordance with Section XVI of Annex III to Regulation (EC) No 853/2004 falling under CN codes ex 1301 and ex 3203 00 shall be exempt from the requirement to present an official certificate. Compliance shall be demonstrated through commercial documentation confirming that the product meets the purity criteria established under Commission Regulation (EU) No 231/2012."

ANNEX III: Reports of Divergent Application Prior to 1 October 2026

VDC members have reported instances of divergent interpretation by certain local Member State BCP authorities during the pre-October 2026 period.

- **Reported Issues:** Local requests for official health certificates or mandatory CHED-P filings for Carmine and Shellac consignments prior to the statutory applicability date of 1 October 2026 set by Regulation (EU) 2026/551.
- **Requested Action:** We respectfully request DG SANTE to issue an administrative clarification to Member State competent authorities, confirming that existing import procedures remain applicable until 30 September 2026 to ensure uniform enforcement across all EU entry points.

ANNEX IV: Technical and Scientific Dossiers

Part A: Carmine (E 120)

1. **Safety Re-evaluation:** Re-evaluated by EFSA in 2015 (EFSA Journal 2015;13(11):4288). EFSA established an ADI of 2.5 mg/kg bw/day and confirmed safety for authorized food additive uses.
2. **Risk Profile:** As recognized in Recital 10 of Commission Delegated Regulation (EU) 2025/1449, validated multi-stage refining processes (acid/alkali extraction, precipitation, and thermal treatment) substantially reduce animal- and public-health risk profiles.
3. **Technological Functionality:** E 120 provides exceptional heat, light, and pH stability. Under Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives, authorized synthetic dyes are subject to strict maximum numerical limits and cannot serve as direct functional substitutes in heat-processed meat, confectionery, and dairy applications.

Part B: Shellac (E 904)

1. **Safety Re-evaluation:** Re-evaluated by EFSA in 2024 (EFSA Journal 2024, 22(8), e8897). EFSA confirmed safety for food additive uses as a glazing agent, establishing specific recommendations for raw material purity and chemical specifications.
2. **Origin and Processing:** Shellac is a natural resinous secretion derived from *Kerria lacca*. Industrial processing involves multi-stage dewaxing, purification, and bleaching to achieve standardized purity criteria under Commission Regulation (EU) No 231/2012.
3. **Technological Functionality:** E 904 serves as a surface glazing agent and protective barrier coating (providing moisture regulation and surface protection) for confectionery, citrus fruit surface treatment, and food supplements. It performs distinct physical functions separate from food colorants and is not readily substitutable in specialized coating applications.