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bio.inspecta requirements on additional official control on products originating from certain third countries

Following the adoption of Commission Delegated Regulation (EU) 2025/2651, which amends Article 8 of Delegated Regulation (EU) 2021/1698, the criteria for identifying "high-risk" products and countries have been broadened to allow a more comprehensive risk-based approach. For the year 2025, additional control and reporting measures were implemented in compliance with DG AGRI guidance, as specified in Section 1.1 of the ARES letter. As no such list has been issued for 2026, bio. inspecta has carried out a documented risk assessment using data extracted from the Organic Farming Information System (OFIS), accompanied by the evaluation of established and suspected cases as well as major or critical non-compliance impacting the integrity of organic and in-conversion products. This assessment has identified certain imported products-country combinations have been classified as high-risk, for which additional control and reporting measures have been established and implemented for 2026.

This approach ensures consistency with the amended regulatory framework and maintains the integrity of organic certification.
Bio.inspecta established the guidelines according to its own based Risk-Assessment, taking into account:

- The art. 9.2 of REG 2021/1698
- The Guidelines of 2025
- This enclosed draft of list of High-Risk Products/Countries

(1) Commission Delegated Regulation (EU) 2021/1698 with procedural requirements for the recognition of organic control authorities and control bodies, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202502651

(2) Commission Implementing Regulation (EU) 2021/1378 of 19 August 2021 laying down certain rules concerning the certificate issued to operators, groups of operators and exporters in third countries involved in the imports of organic and in-conversion products into the Union and establishing the list of recognised control authorities and control bodies in accordance with Regulation (EU) 2018/848 of the European Parliament and of the Council: http://data.europa.eu/eli/reg_impl/2021/1378/2025-10-25

(3) Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007OJ L 150, 14.6.2018, p. 1, ELI: http://data.europa.eu/eli/reg/2018/848/oj.

(4) The frequency of physical controls must depend on the likelihood of non-compliances as laid down in Article 45(5) of Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) 834/2007 and Article 6 of Commission Delegated Regulation (EU) 2021/2306 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with rules on the official controls in respect of consignments of organic products and in- conversion products intended for import into the Union and on the certificate of inspection, OJ L 461, 27.12.2021, p. 13, http://data.europa.eu/eli/reg_del/2021/2306/2024-12-02.

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1. SCOPE OF THE ADDITIONAL CONTROL MEASURES FOR HIGH -RISK ORGANIC PRODUCTS AND COUNTRIES

1.1. Concerned products

Following criteria stated in the EU reg 2025/2651 of 16 October 2025, the art. 9.2 of REG 2021/1698, the Guidelines of 2025 and the draft of list of High-Risk Products/Countries for Year 2027 were considered by bio. inspecta to categorize the list of high-risk third countries and high-risk products for 2026.
bio.inspecta undertake the requirements mentioned on the previously issued ARES letter. "The reassessment of the risk of occurrence of non-compliances has led to the conclusion that additional control measures should be applied. This means that from 1 May 2026 until 31 December 2026 at least the following additional control measures as regards products originating in and imported directly from one of the countries below or via another third country are necessary to ensure compliance of products with Article 45 of Regulation (EU) No 2018/848.

These control measures are without prejudice to the basic obligations to carry out a minimum percentage of additional controls and take a minimum number of samples based on a risk assessment.

(5) https://eur-lex.europa.eu/eli/reg/1987/2658/oj/eng

(6) Commission Delegated Regulation (EU) 2021/2306 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with rules on the official controls in respect of consignments of organic products and in-conversion products intended for import into the Union and on the certificate of inspection, OJ L 461, 27.12.2021, p. 13, ELI: http://data.europa.eu/eli/reg_del/2021/2306/oj.

(7) Article 21(5) of Commission Delegated Regulation (EU) 2021/1698

(8) Commission Delegated Regulation (EU) 2025/2651 of 16 October 2025 amending Delegated Regulation (EU) 2021/1698 as regards certain criteria for the establishment of the list of high-risk third countries and high-risk products. http://data.europa.eu/eli/reg_del/2025/2651/oj

(9) COMMISSION REGULATION (EU) No 691/2013

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bio.inspecta ensure that these additional control measures should be applied exclusively to the following products and the operators producing, preparing, trading, storing or exporting organic food and feed with the following CN-codes.

Country of origin	Product	CN code (s)	Taric subheadings	Percentage of consignments subject to checks and sampling in third country
Egypt	Basil	1211 90 86		10 %
Egypt	Peanuts	1202 41 00 1202 42 00		10 %
Egypt	Onions	0703 10 19		5 %
Egypt	Chamomile	1211 90 86		5 %
Türkiye	Strawberry	0811 10 90 2008 80 90 2007 99 33		30 %
Türkiye	Sultanas	0806 20 30		10 %
Türkiye	Pomegranates	ex0810 90 75 ex0811 90 95 ex2009 89 99		10 %
Türkiye	Lentils	0713 40 00		10 %
Türkiye	Chickpeas	0713 20 00		5 %

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1.2 Sampling percentage

For the products defined in section 1.1, bio.inspecta should carry out additional sampling for consignments applying the minimum sampling percentages as stipulated in the table above, for the products in the abovementioned list.

2. NATURE OF THE ADDITIONAL CONTROL MEASURES

2.1. Sampling and analysis for presence of non-authorised substances

For consignments of products sampled according to the percentages defined in section 1, bio.inspecta should take at least one representative sample of the consignment.

- Sampling methods and chain of custody- Sampling method should be followed as described in Commission Regulation (EU) No 691/2013 and Commission Directive 2002/63/EC. The sampling report with consignment identification (product name, operator details, lot number, COI number when available); seal and track samples need to be sent to the laboratory.
- Laboratories: The samples should be sent and analysed in an accredited and bio.inspecta approved labs competent for the analytes; methods must cover relevant for the presence of non-authorised substances, including ethylene oxide. Additionally, the appropriate specific analytical methods – including single-residue methods where relevant – should be applied to detect nonauthorized substances.
- Lab reports: The lab report should include information mentioned in the sampling report and contain the identification of the consignment: lot number and, when available, number of the certificate of inspection (COI).
- Timing and notification: Bio.inspecta should not issue the Certificate of Inspection (COI) before receiving and assessing analytical results. Upload sampling reports and results in TRACES as required by Article 5(2) of Commission Delegated Regulation (EU) 2021/2306. Immediately notify PM Residue and Sampling, including international@bio-inspecta.ch of positive findings.

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2.2 Controls

(a) Inspections: bio. inspecta should carry out at least 2 physical inspections per year of each operator listed as a high risk. One of these inspections should be unannounced.
(b) New crop cultivation operator: On a farm that is certified for the first time, bio.inspecta should carry out the first inspection of each parcel before cultivation measures on that parcel in order to be able to certify the product.
(c) Field sampling: bio. inspecta should take at least one field crop sample each year at each operator as defined in point (a). The sample should be taken from crops in the field, at the most appropriate and reasonable period to detect the potential use of non-authorised substances. The sample should be analysed as set out in point 2.1. For operators not growing crops, a relevant sample of incoming raw material, intermediate product or processed product should be taken.
(d) bio.inspecta should strictly verify the product flows and traceability of the product during the inspection and sampling of each operator. Additionally, Bio.inspecta should verify the quantities harvested and/or prepared, the means of storage and transport of the goods, including the possible application of non-authorised substances at these stages, book-keeping and all other relevant documents.
(e) bio.inspecta should issue the certificate of inspection before the shipment leaves the third country of origin or of export as per the requirements stated in Article 4 of Delegated Regulation (EU) 2021/2306.

- Before issuing the certificate of inspection, bio.inspecta should verify the following documents (in accordance with Article 3 of Delegated Regulation (EU) 2021/2306):
  - i) the traceability of the products and ingredients.
  - ii) that the volume of the products included in the consignment is in line with the mass balance checks of the respective operators according to the assessment carried out by bio.inspecta.
  - iii) the relevant transport documents and commercial documents (including invoices) of the products.

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bio.inspecta must send this traceability documentation to the control body of the importer concerned and to the Competent Authorities of the importing country. In case of a complex supply chain a transparent flow chart must be added to that documentation unequivocally presenting both the flow of the goods and the financial flow.
At least points a) and c) should also be applied to new and other operators who cultivate fields that are in conversion to organic farming.

3. Annual review and reporting

a) Annual report content: Include the list of operators under control in the affected countries and, for each operator (period 1 May - 31 Dec 2026 or applicable year), the inspections performed, sampling and analyses, non-compliances, corrective measures/sanctions, COIs signed, and follow up for operators that changed control body. For consignments subject to additional controls include COI references, sampling results indicating non authorised substances (if any), and follow up measures (downgrading, non-issuance of COI, corrective actions).

b) TRACES: Upload sampling reports and results in TRACES as required.

c) Review cadence: Certifiers reviews the high-risk list at the start of each year and after each relevant incident; update and document changes.

bio.inspecta must follow the above list of high-risk product/countries and procedures until the Commission issues a new ARES letter or releases a new delegating act.