

Brussels, 17 October 2025
(OR. en)

14173/25

AGRI 503
DELECT 155

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	16 October 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2025) 6855 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 16.10.2025 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

Delegations will find attached document C(2025) 6855 final.

Encl.: C(2025) 6855 final



EUROPEAN
COMMISSION

Brussels, 16.10.2025
C(2025) 6855 final

COMMISSION DELEGATED REGULATION (EU) .../...

of 16.10.2025

**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**

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Commission Delegated Regulation (EU) 2021/1698 lays down provisions dealing with controls on operators in third countries carried out by control authorities and control bodies recognised pursuant to Article 46(1) of Regulation (EU) 2018/848 and establishes the rules on the verification of the consignments intended for import into the Union to be carried out by those control authorities and control bodies.

Pursuant to Article 8 of Delegated Regulation (EU) 2021/1698, high-risk products originating from third countries are to be listed in an implementing act adopted in accordance with Article 46(8) of Regulation (EU) 2018/848 on the basis of a selection made after major, critical or repetitive cases of non-compliance affecting the integrity of organic or in-conversion products or their production.

The list of high-risk products may therefore be established only on the basis of established non-compliances, that is to say, cases of non-compliance affecting the integrity of organic or in-conversion products at any stage of production, preparation and distribution.

Article 46(8) of Regulation (EU) 2018/848 provides that the Commission may adopt implementing acts to ensure the application of the measures to be taken in relation to cases of both established and suspected non-compliance.

Many suspected cases of non-compliance affecting the integrity of organic or in-conversion products never become established. The reason is that the control authority or control body carrying out an investigation in the third country concerned upon notification by a Member State in the Organic Farming Information System (OFIS) cannot substantiate the cases due to a lack of sufficient information on the source or the cause of the contamination, but where suspicion nevertheless persists.

It is therefore appropriate that the high-risk products and the third countries in which they originate should be listed on the basis of a selection made after both established and suspected major, critical or repetitive cases of non-compliance that affect the integrity of organic or in-conversion products or production.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The draft delegated act was discussed thoroughly with the Group of Experts on Organic Production as well as with the main organisations representing accreditation and control authorities and control bodies active in the import of organic products from third countries. It was transmitted to the European Parliament and to the Council when convening the meeting of the Group of Experts in Organic production. Following a four weeks' public consultation - from 13 June to 11 July 2025 - carried out through the Feedback Mechanism¹, the Commission analysed the 12 comments received. Most feedback objected to the necessary change proposed, which provides for considering not only established non-compliances to the EU organic rules but also suspected ones in the criteria for the establishment of the list of high-risk products and high-risk third countries.

WTO partners were notified for feedback from 28 July to 26 September 2025.

¹ [High-risk organic and in-conversion products – import checks \(amendment\)](#)

The Commission decided to not to modify the initial act given that many suspected cases of non-compliance affecting the integrity of organic or in-conversion products never qualified as established because the investigation performed usually does not gather sufficient evidence to conclude to an established non-compliance.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This act amends Delegated Regulation (EU) 2021/1698 as regards the basis for the establishment of the list of high-risk products referred to in its Article 8.

COMMISSION DELEGATED REGULATION (EU) .../...

of 16.10.2025

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

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 834/2007², and in particular Article 46(7), point (b)(ii), thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2021/1698³ lays down provisions dealing with controls on operators in third countries carried out by control authorities and control bodies recognised pursuant to Article 46(1) of Regulation (EU) 2018/848 and establishes the rules on the verification of the consignments intended for import into the Union to be carried out by those control authorities and control bodies.
- (2) Pursuant to Article 8 of Delegated Regulation (EU) 2021/1698, high-risk products originating from third countries are to be listed in an implementing act adopted in accordance with Article 46(8) of Regulation (EU) 2018/848 on the basis of a selection made after major, critical or repetitive cases of non-compliance affecting the integrity of organic or in-conversion products or their production.
- (3) The list of high-risk products may therefore currently be established only on the basis of established cases of non-compliance affecting the integrity of organic or in-conversion products at any stage of production, preparation and distribution.
- (4) Article 46(8) of Regulation (EU) 2018/848 provides that the Commission may adopt implementing acts to ensure the application of the measures to be taken in relation to cases of both established and suspected non-compliance.
- (5) A specific organic or in-conversion product and its third country of origin should be inserted in the list of high-risk products where this product has been involved in major, critical or repetitive cases of non-compliance with Regulation (EU) 2018/848 and that those cases have been established by the control authority or the control body as non-compliances affecting the integrity of the product. Article 22(3) of Delegated Regulation (EU) 2021/1698 lays down criteria for the classification of a non-compliance as major, critical or repetitive non-compliance.

² OJ L 150, 14.6.2018, p. 1, ELI: <http://data.europa.eu/eli/reg/2018/848/oj>.

³ Commission Delegated Regulation (EU) 2021/1698 of 13 July 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with procedural requirements for the recognition of control authorities and control bodies that are competent to carry out controls on operators and groups of operators certified organic and on organic products in third countries and with rules on their supervision and the controls and other actions to be performed by those control authorities and control bodies (OJ L 336, 23.9.2021, p. 7, ELI: http://data.europa.eu/eli/reg_del/2021/1698/oj).

- (6) Many suspected cases of non-compliance affecting the integrity of organic or in-conversion products never become established. The reason is that the control authority or control body carrying out an investigation in the third country concerned upon notification by a Member State in the Organic Farming Information System (OFIS) cannot substantiate the cases due to a lack of sufficient information on the source or the cause of the contamination, but where suspicion nevertheless persists.
- (7) It is therefore appropriate that the high-risk products and the third countries in which they originate should be listed on the basis of a selection made after both established and suspected major, critical or repetitive cases of non-compliance that affect the integrity of organic or in-conversion products or production.
- (8) Delegated Regulation (EU) 2021/1698 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Delegated Regulation (EU) 2021/1698

Article 8 of Delegated Regulation (EU) 2021/1698 is replaced by the following:

‘Article 8

List of high-risk third countries and high-risk products

High-risk products and the third countries in which they originate shall be listed together with the shares of consignments of those products to be subject to identity and physical checks and sampling by control authorities and control bodies in third countries, in an implementing act adopted in accordance with Article 46(8) of Regulation (EU) 2018/848 on the basis of a selection made after major, critical or repetitive non-compliances affecting the integrity of organic or in-conversion products or production, or the suspicion thereof.

The shares referred to in the first paragraph can be lower than 100 % and may, for the same product, be different for controls by control authorities and control bodies in third countries.’

Article 2

Entry into force and application

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16.10.2025

*For the Commission
The President
Ursula VON DER LEYEN*