



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Quality, Research & Innovation, Outreach  
The Director

Brussels  
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Dear Sir, Dear Madam,

Against the background of the large number of notifications of non-compliances opened in the Organic Farming Information System (OFIS) concerning 'organic' sesame seed exported from India to the EU and contaminated with ethylene oxide, stronger control and reporting measures are necessary. The Committee on Organic Production agreed on additional official controls to be implemented by the EU Member States' competent authorities regarding sesame seed imported from India, in accordance with the "Guidelines on additional official controls on products originating from India" agreed on 5 May 2021<sup>1</sup>.

Therefore, the present letter is addressed by the services of the Commission to the control bodies recognised as competent to carry out controls and issue certificates for the purpose of the export of sesame seed (falling under category D) from India. This letter is also sent to all other control bodies recognised in Annex IV of Commission Regulation (EC) No 1235/2008 for information purposes.

Bearing in mind that the on-going COVID-19 pandemic may hamper the implementation of the measures set out in section 2.1 of these guidelines, some flexibility should be granted. Sampling should nevertheless be carried out to the maximum extent possible and deviations from these guidelines shall be limited. In any case, sampling requirements in the guidelines should be carried out fully from 1 July 2021 onwards.

Although the requirements set out below concern only 'sesame seed', the Commission would like to alert control bodies that the contamination of other commodities with ethylene oxide - e.g. amaranth, ashwaganda, cumin seed, fenugreek seed, flax seed, ginger, guar gum, moringa, psyllium husk, quinoa, turmeric/curcuma, triphala – has recently been notified via a set of OFIS notifications that are limited in number but involve very high levels of contaminations. In accordance with Article 65(2) and (4) of Regulation (EC) No 889/2018, control bodies should duly consider this information in the general evaluation of the risk of non-compliance in order to select operators where samples have to be taken and/or to carry out random control visits, primarily unannounced. Moreover, the control authority or control body shall take and analyse samples in each case where the use of products or techniques not authorised for organic production is suspected. In such cases, no minimum number of samples to be taken and analysed shall apply.

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<sup>1</sup> See [https://ec.europa.eu/info/food-farming-fisheries/farming/organic-farming/trade\\_en](https://ec.europa.eu/info/food-farming-fisheries/farming/organic-farming/trade_en)

To the Control Bodies and Control Authorities recognised for the purpose of equivalence

## 1. SCOPE OF THE ADDITIONAL CONTROL MEASURES

The assessment of the risk of occurrence of non-compliances and infringements<sup>2</sup> has led to the conclusion that additional control measures should be applied. This means that, **until the end of the year 2021**, at least the following increased control measures as regards sesame seed originating from India and exported from India or from another third country are necessary to ensure the compliance of products with Regulation (EC) No 834/2007.

These additional control measures have to be applied exclusively to the following products and to the operators, preparing - in particular processing - storing, trading or exporting organic food and feed with the following CN-code<sup>3</sup> originating from India:

CN code 12074090 – sesame seed

## 2. NATURE OF THE ADDITIONAL CONTROL MEASURES

### 2.1. Sampling and analysing for presence of pesticide residues, including ethylene oxide

For all consignments<sup>4</sup> as defined in section 1 above, the control body should take at least one representative sample of each consignment. Sampling should be done **using the methods as described in Commission Regulation (EU) No 691/2013** on the sampling methods to be used for official control of feed<sup>5</sup> and Commission Directive 2002/63/EC establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin<sup>6</sup>. These samples should be analysed for the presence of pesticide residues by validated methods (including single-residue methods where relevant) **in accredited laboratories**. The scope of the analysis should cover all relevant pesticides including, **ethylene oxide (ETO)**, as defined by expert knowledge. The sampling report should contain the identification of the consignment: lot number and, when available, number of the certificate of inspection (COI)<sup>7</sup>. The control body should not issue the certificate of inspection before it has received and assessed the result of these analyses.

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<sup>2</sup> According to Article 27 (3) of Regulation (EC) No 834/2007 the nature and frequency of the controls shall be determined on the basis of an assessment of the risk of occurrence of irregularities and infringements as regards compliance with the requirements laid down in this Regulation. Article 92c of Regulation (EC) No 889/2008 lays down the requirements for the risk analysis; Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91, OJ L 189, 20.7.2007, p. 1–23.

<sup>3</sup> See <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:111003>

<sup>4</sup> The definition of consignment is set out in Article 2(3) of Commission Regulation (EC) No 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries, OJ L 334, 12.12.2008, p. 25–52.

<sup>5</sup> Commission Regulation (EU) No 691/2013 of 19 July 2013 amending Regulation (EC) No 152/2009 as regards methods of sampling and analysis, OJ L 197, 20.7.2013, p. 1.

<sup>6</sup> Commission Directive **2002/63/EC** of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC, OJ L 187, 16/07/2002 p. 30-43.

<sup>7</sup> The certificate of inspection referred to in Article 33(1)(d) of Regulation (EC) No 834/2007 covering one consignment.

Particular attention should be paid by the control body to verifying that the analyses of the presence of pesticide residues are performed by a laboratory accredited under **ISO 17025** and that the pesticides tested, in particular ethylene oxide, are covered by the scope of the accreditation of this laboratory.

The sampling report of a consignment should be introduced into TRACES and accompany the certificate of inspection for that consignment.

## **2.2. Controls**

- a. The control body should carry out 2 physical inspections before 31 December 2021 of each operator involved in preparing, processing, storing, trading or exporting the organic products listed under section 1 above that it intends to certify. One of these inspections shall be unannounced.
- b. A relevant sample of incoming raw material, intermediate product or processed product should be taken.
- c. The control body should pay utmost attention to the verification of the product flows and traceability established by each operator as defined in section 1. It should also verify the quantities involved, the means of storage and transport of the goods, the possible presence of pesticides, including **ethylene oxide** and biocides.
- d. The control body should analyse in an in-depth manner the bookkeeping and financial documentation of each operator as defined in section 1, for which it intends to certify products.
- e. As stipulated in article 33(1) of Council Regulation (EC) No 834/2007, the certificate of inspection shall accompany the goods. Consequently, the control body shall issue the certificate of inspection before the shipment leaves the third country of origin or of export.
- f. At the time of issuing the certificate of inspection, the control body shall have documented the complete operator and product traceability. At simple request, the control body shall 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 shall be added to that documentation unequivocally presenting both the flow of the goods and the financial flow.

## **3. EXCHANGE OF INFORMATION**

In accordance with Article 92 of Commission Regulation (EC) No 889/2008<sup>8</sup>, where operators and/or their subcontractors change their control body, the new control body shall verify and ensure that non-conformities noted in the control file forwarded by the previous control body have been completely and effectively addressed by the operator.

The control bodies have to evaluate carefully the situation where a certification decision on such an operator has to be made. The services of the Commission will take all necessary supervisory actions to ensure that control bodies have done this effectively.

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<sup>8</sup> Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, O.J. L 250, 18.09.2008, p. 1.

**In case of suspension or withdrawal of an operator, the control body shall immediately update Traces accordingly as regards the profile of that operator.**

Any detection of pesticide residues, including ethylene oxide, from an incoming raw material shall be communicated along the communication chain, in particular to the relevant control body of the operator concerned as well as to the Indian competent authorities, i.e The Agricultural and Processed Food Products Export Development Authority (APEDA).

#### **4. REPORTING**

In accordance with Article 11(4) of Regulation (EC) No 1235/2008, the services of the Commission request the implementation of these recommendations to be documented and made available in a report. This report shall be included in the annual report referred to in Article 12 (1) (b) of Commission Regulation (EC) No 1235/2008 and include at least the following information:

1. The list of the operators under your control in India.
2. For each operator and for the period starting on 1 July 2021:
  - a. The inspections carried out, indicating the date of each inspection
  - b. The sampling and analyses carried out
  - c. The irregularities and infringements found
  - d. The corrective measures and/or sanctions applied
  - e. The certificates of inspection signed
  - f. For each operator that changed its control body, the corrective measures and/or sanctions applied if non-conformities were noted in the report of the previous control body.
3. As regards consignments subject to the additional official controls in accordance with this letter:
  - a. COI reference for imported consignments;
  - b. Overview of sampling analysis results that indicate the presence of pesticide residues, including ethylene oxide, if any;
  - c. Investigations and follow-up measures taken by the control body in case of pesticide residues, including ethylene oxide, found in the consignment, including the decision concerning the consignment, e.g. downgrading the consignment to conventional, not issuing a COI etc., as well as confirmation that the operator has taken corrective measures.
  - d. Certificate of the operators involved

Yours sincerely,



Nathalie SAUZE-VANDEVYVER

c.c.: List of Accreditation bodies