

COMMISSION REGULATION (EC) No 2491/2001
of 19 December 2001
amending Council Regulation (EEC) No 2092/91 on organic production of agricultural products and
indications referring thereto on agricultural products and foodstuffs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs ⁽¹⁾, as last amended by Commission Regulation (EC) No 436/2001 ⁽²⁾, and in particular Article 13, second indent thereof,

Whereas:

- (1) Organic production of agricultural products has developed significantly in recent years. In many cases organic production is not anymore limited to local productions and local trade but, on the contrary, involves very often several operators and operations, such as import, transport, storage and packaging.
- (2) Annex III to Regulation (EEC) No 2092/91 lays down minimum inspection requirements and precautionary measures under the inspection scheme referred to in Articles 8 and 9 of that Regulation.
- (3) Annex III already comprises provisions for the main operators and different stages involved in the organic production of agricultural products. However, in order to ensure the traceability of organic agricultural products throughout the different stages of the trade chain, and

finally the compliance of these products with the provisions laid down in Regulation (EEC) No 2092/91 in the light of recent developments, it is necessary to adapt the provisions set out in Annex III.

- (4) It is necessary that Member States complete the measures set out in Annex III to ensure that consumers are given guarantees that the products have been produced in accordance with Regulation (EEC) No 2092/91.
- (5) Regulation (EEC) No 2092/91 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Committee referred to in Article 14 of Regulation (EEC) No 2092/91,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EEC) No 2092/91 is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 60th day following its publication in the *Official Journal of the European Communities*.

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

Done at Brussels, 19 December 2001.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 198, 22.7.1991, p. 1.

⁽²⁾ OJ L 63, 3.3.2001, p. 16.

ANNEX

'ANNEX III

MINIMUM INSPECTION REQUIREMENTS AND PRECAUTIONARY MEASURES UNDER THE INSPECTION SCHEME REFERRED TO IN ARTICLES 8 AND 9

GENERAL PROVISIONS

1. Minimum inspection requirements

The inspection requirements of this Annex shall apply without prejudice of the measures adopted by the Member States necessary to ensure traceability of the products, as referred to in Article 9(12)(a) and (c), during the entire production chain, and to ensure that the provisions of this Regulation are satisfied.

2. Implementation

The operators already in activity at the date mentioned in Article 2 of Regulation (EC) No 2491/2001 shall also be subject to the provisions referred to in point 3 and to the initial inspection provisions foreseen in sections A, B, C and D of the specific provisions of this Annex.

3. Initial inspection

When the inspection arrangements are first implemented, the operator responsible must draw up:

- a full description of the unit and/or premises and/or activity,
- all the practical measures to be taken at the level of the unit and/or premises and/or activity to ensure compliance with this Regulation, and in particular with the requirements in this Annex.

The description and practical measures concerned must be contained in a declaration, signed by the responsible operator.

In addition, this declaration must include an undertaking by the operator:

- to perform the operations in accordance with Articles 5, 6, 6a and, where relevant, Article 11,
- to accept, in the event of infringement or irregularities, the enforcement of the measures referred to in Article 9(9) and, where relevant, in Article 10(3), and
- to accept to inform in writing the buyers of the product in order to ensure that the indications referring to the organic production method are removed from this production.

This declaration must be verified by the inspection body or authority that issues a report identifying the possible deficiencies and non-compliances with the provisions of this Regulation. The operator must countersign this report and take the necessary corrective measures.

4. Communications

The operator responsible must notify any change in the description or of the practical measures referred to in point 3 and in the initial inspection provisions foreseen in sections A, B, C and D of the specific provisions of this Annex to the inspection body or authority in due time.

5. Inspection visits

The inspection body or authority must make a full physical inspection, at least once a year, of the production/preparation units or other premises. The inspection body or authority may take samples for testing of products not authorised under this Regulation or for checking production techniques not in conformity with this Regulation. Samples may also be taken and analysed for detecting possible contamination by unauthorised products. However, such analysis must be carried out where the use of unauthorised products is suspected. An inspection report must be drawn up after each visit, countersigned by the responsible person of the unit or his representative.

Moreover, the inspection body or authority shall carry out random inspection visits, announced or not. The visits shall cover in particular those holdings or situations where specific risk or exchange of products from organic production with other products may exist.

6. Documentary accounts

Stock and financial records must be kept in the unit or premises, to enable the operator and the inspection body or authority to trace:

- the supplier and, where different, the seller, or the exporter of the products,
- the nature and the quantities of agricultural products as referred to in Article 1 delivered to the unit and, where relevant, of all materials bought and the use of such materials,
- the nature, the quantities and the consignees and, where different, the buyers of any products as referred to in Article 1, which have left the unit or the first consignee's premises or storage facilities,
- any other information required by the inspection body or authority for the purpose of proper inspection.

The data in the accounts must be documented with appropriate justification documents.

The accounts must demonstrate the balance between the input and the output.

7. Packaging and transport of products to other production/preparation units or premises

The operators shall ensure that products as referred to in Article 1 may be transported to other units, including wholesalers and retailers, only in appropriate packaging, containers or vehicles closed in such a manner that substitution of the content cannot be achieved without manipulation or damage of the seal and provided with a label stating, without prejudice to any other indications required by law:

- (a) the name and address of the operator and, where different, of the owner or seller of the product;
- (b) the name of the product, including a reference to the organic production method, in accordance with Article 5;
- (c) the name and/or the code number of the inspection body or authority to which the operator is subject; and
- (d) where relevant, the lot identification mark according to a marking system either approved at national level or agreed with the inspection body or authority and which permits to link the lot with the accounts referred to in point 6.

The information under (a), (b), (c) and (d) can also be presented on an accompanying document, if such document can be undeniably linked with the packaging, container or vehicle of the product. This accompanying document shall include information on the supplier and/or the transporter.

However, the closing of packaging, containers or vehicles is not required where:

- transportation is direct between a producer and another operator who are both subject to the inspection system referred to in Article 9, and
- the products are accompanied by a document giving the information required under the previous subparagraph, and
- the inspection body or authority of both the expediting and the receiving operators have been informed of such transport operations and have agreed thereto. Such agreement might be provided for one or more transport operation(s).

8. Storage of products

For the storage of products, areas must be managed in order to ensure identification of lots and to avoid any mixing with or contamination by products and/or substances not in compliance with this Regulation.

9. Products suspected not to satisfy the requirements of the Regulation

Where an operator considers or suspects that a product which he has produced, prepared, imported or been delivered from another operator, is not in compliance with this Regulation, he shall initiate procedures either to withdraw from this product any reference to the organic production method or to separate and identify the product. He only may put it into processing or packaging or on the market after elimination of that doubt, unless it is placed on the market without indication referring to the organic production method. In case of such doubt, the operator shall immediately inform the inspection body or authority. The inspection body or authority may require that the product cannot be placed on the market with indications referring to the organic production method until it is satisfied, by the information received from the operator or from other sources, that the doubt has been eliminated.

Where an inspection body or authority has a substantiated suspicion that an operator intends to place on the market a product not in compliance with this Regulation but bearing a reference to the organic production method, this inspection body or authority can require that the operator may provisionally not market the product with this reference. This decision shall be supplemented by the obligation to withdraw from this product any reference to the organic production method if the inspection body or authority is sure that the product does not fulfil the requirements of this Regulation. However if the suspicion is not confirmed, the above decision shall be cancelled not later than a time period after having been taken. The inspection body or authority shall define this time period. The operator shall cooperate fully with the inspection body or authority in resolving the suspicion.

10. Access to facilities

The operator must give the inspection body or authority, for inspection purposes, access to all parts of the unit and all premises, as well as to the accounts and relevant supporting documents. He must provide the inspection body or authority with any information deemed necessary for the purposes of the inspection.

When requested by the inspection body or authority, the operator shall submit the results of its own voluntary inspection and sampling programmes.

In addition, importers and first consignees must submit any import authorisations under Article 11(6) and certificates of inspection for import from third countries.

11. Exchange of information

Where the operator and his subcontractors are inspected by different inspection bodies or authorities, the declaration referred to in point 3 must include an agreement by the operator on his behalf and that of his subcontractors, that the different inspection bodies or authorities can exchange information on the operations under their inspection and on the way this exchange of information can be implemented.

SPECIFIC PROVISIONS

A. Production of plants, plant products, livestock and/or livestock products

This section applies to any unit involved in production as defined in Article 4(2) of products referred to in Article 1(1)(a) for its own account or for account of a third party.

Production must take place in a unit of which the production premises, land parcels, pasturage, open-air exercise areas, open air runs, livestock buildings, and, where applicable, the premises for the storage of crops, crop products, livestock products, raw materials and inputs, are clearly separate from those of any other unit not producing in accordance with the rules laid down in this Regulation.

Processing, packaging and/or marketing may take place at the production unit, where these activities are limited to its own agricultural produce.

Quantities sold directly to the final consumer shall be accounted on a daily basis.

Storage, in the unit, of input products other than those permitted by Article 6(1)(b) and (c) and Article 6(3)(a), is prohibited.

On receipt of a product as referred to in Article 1, the operator shall check the closing of the packaging or container where it is required and the presence of the indications referred to in point 7 of the general provisions of this Annex. The result of this verification shall be explicitly mentioned in the documentary accounts referred to in point 6 of the general provisions.

A.1. Plants and plant products from farm production or collection

1. Initial inspection

The full description of the unit referred to under point 3 of the general provisions of this Annex must:

- be drawn up even where the producer limits his activity to the collection of wild plants,
- show the storage and production premises and land parcels and/or collection areas and, where applicable, premises where certain processing and/or packaging operations take place, and

- specify the date of the last application on the parcels and/or collection areas concerned of products, the use of which is not compatible with Article 6(1)(b).

In case of collection of wild plants, the practical measures referred to under point 3 of the general provisions of this Annex must include the guarantees given by third parties which the producer can provide to ensure that the provisions of Annex I, section A, point 4, are complied with.

2. Communications

Each year, before the date indicated by the inspection body or authority, the producer must notify the body or authority of its schedule of production of crop products, giving a breakdown by parcel.

3. Several production units run by the same operator

Where an operator runs several production units in the same area, the units producing crops or crop products not covered by Article 1, together with storage premises for input products (such as fertilisers, plant protection products, seed) must also be subject to the general inspection arrangements laid down in the general provisions of this Annex as well as to the specific inspections provisions as regards points 1, 2, 3, 4 and 6 of the general provisions.

The same variety as, or a variety that cannot be easily differentiated from those produced at the unit referred to in the second paragraph of section A, may not be produced at these units.

However, producers may derogate from the rule referred to in the last sentence of the preceding subparagraph:

- (a) in the case of the production of perennial crop products (edible fruit bearing trees, vines and hops) provided the following conditions are met:
 - 1. the production in question forms part of a conversion plan in respect of which the producer gives a firm undertaking and which provides for the beginning of the conversion of the last part of the area concerned to organic production in the shortest possible period which may not in any event exceed a maximum of five years,
 - 2. appropriate measures have been taken to ensure the permanent separation of the products obtained from each unit concerned,
 - 3. the inspection body or authority is notified of the harvest of each of the products concerned at least 48 hours in advance,
 - 4. immediately upon completion of the harvest, the producer informs the inspection body or authority of the exact quantities harvested on the units concerned together with any particular distinguishing features (such as quality, colour, average weight, etc.) and confirms that the measures taken to separate the products have been applied,
 - 5. the conversion plan and the measures referred to in point 1 and in point 3 of the general provisions have been approved by the inspection body or authority. This approval must be confirmed each year after the start of the conversion plan.
- (b) in the case of areas intended for agricultural research agreed by the Member States' competent authorities, provided that conditions 2, 3 and 4 and the relevant part of condition 5 referred to in (a) are met;
- (c) in the case of production of seed, vegetative propagating material and transplants, provided that conditions 2, 3 and 4 and the relevant part of condition 5 referred to in (a) are met;
- (d) in the case of grassland exclusively used for grazing.

A.2. Livestock and livestock products produced by animal husbandry

1. Initial inspection

When the inspection system applying specifically to livestock production is first implemented, the full description of the unit referred to under point 3 of the general provisions of this Annex must include:

- a full description of the livestock buildings, pasturage, open-air exercise areas, open-air runs, etc., and, where applicable, the premises for the storage, packaging and processing of livestock, livestock products, raw materials and inputs,
- a full description of the installations for the storage of livestock manure.

The practical measures referred to under point 3 of the general provisions of this Annex must include:

- plan for spreading manure agreed with the inspection body or authority, together with a full description of the areas given over to crop production,
- where appropriate, as regards the spreading of manure, the written arrangements with other holdings complying with the provisions of this Regulation,
- management plan for the organic-production livestock unit (e.g. management for feeding, reproduction, health, etc.).

2. Identification of livestock

The livestock must be identified permanently using techniques adapted to each species, individually in the case of large mammals and individually or by batch in the case of poultry and small mammals.

3. Livestock records

Livestock records must be compiled in the form of a register and kept available to the inspection authorities or bodies at all times at the address of the holding.

Such records, which are to provide a full description of the herd or flock management system, must contain the following information:

- by species, as regards livestock arriving at the holding: origin and date of arrival, conversion period, identification mark and veterinary record,
- as regards livestock leaving the holding: age, number of heads, weight in case of slaughter, identification mark and destination,
- details of any animals lost and reasons,
- as regards feed: type, including feed supplements, proportions of various ingredients of rations and periods of access to free-range areas, periods of transhumance where restrictions apply,
- as regards disease prevention and treatment and veterinary care: date of treatment, diagnosis, type of treatment product, method of treatment and practitioner's prescription for veterinary care with reasons and withdrawal periods applying before livestock products can be marketed.

4. Several production units run by the same operator

Where a producer, in accordance with points 1.6 of section B and 1.3 of section C of Annex I manages several production units, the units which produce livestock or livestock products not covered by Article 1 must also be subject to the inspection system as regards point 1 of this subsection on livestock and livestock products and as regards the provisions on livestock management, livestock records and the principles governing storage of animal husbandry products used.

A derogation with regard to the requirement of different involved species in point 1.6 of Annex I, part B, may be granted to holdings carrying out agricultural research by the inspection body or authority in agreement with the competent authority of the Member State, where the following conditions are met:

- appropriate measures, agreed with the inspection body or authority have been taken in order to guarantee the permanent separation between livestock, livestock products, manure and feedingstuffs of each of the units,
- the producer informs the inspection body or authority in advance of any delivery or selling of the livestock or livestock products,
- the operator informs the inspection body or authority of the exact quantities produced in the units together with all characteristics permitting the identification of the products and confirms that the measures taken to separate the products have been applied.

5. Other requirements

By way of a derogation from those rules, the storage of allopathic veterinary medicinal products and antibiotics is permitted on holdings provided that they have been prescribed by a veterinarian in connection with treatment as referred to in Annex I, that they are stored in a supervised location and that they are entered in the farm register.

B. Units for preparation of plant and livestock products and foodstuffs composed of plant and livestock products

This section applies to any unit involved in the preparation, as defined in Article 4(3), of products referred to in Article 1(1), for its own account or for account of a third party, and including in particular also:

- units involved in packaging and/or re-packaging of such products,
- units involved in labelling and/or re-labelling of such products.

1. Initial inspection

The full description of the unit referred to under point 3 of the general provisions of this Annex must show the facilities used for the reception, the processing, packaging, labelling and storage of agricultural products before and after the operations concerning them, as well as the procedures for the transport of the products.

2. Documentary accounts

The documentary accounts referred to in point 6 of the general provisions shall include the verification referred to in point 5 of this subsection.

3. Preparation units handling also products not from organic production

Where products not referred to in Article 1 are also prepared, packaged or stored in the preparation unit concerned:

- the unit must have areas separated by place or time within the premises for the storage of products as referred to in Article 1, before and after the operations,
- operations must be carried out continuously until the complete run has been dealt with, separated by place or time from similar operations performed on products not covered by Article 1,
- if such operations are not carried out at regular times or on a fixed day, they must be announced in advance, with a deadline agreed on with the inspection body or authority,
- every measure must be taken to ensure identification of lots and to avoid mixtures or exchanges with products not obtained in accordance with the rules laid down in this Regulation,
- operations on products in accordance with the rules laid down in this Regulation must be carried out only after cleaning of the production equipment. The effectiveness of the cleaning measures must be checked and recorded.

4. Packaging and transport of products to preparation units

Milk, eggs and egg-products from organic farming shall be collected independently from products not produced in accordance with this Regulation. By derogation, and subject to the prior approval by the inspection body or authority, simultaneous collection may occur, where appropriate measures are taken to prevent any possible mixture or exchange with products not produced in accordance with this Regulation and to ensure the identification of the products produced in accordance with the provisions of this Regulation. The operator keeps the information relating to collection days, hours, circuit and date and time of reception of the products available to the inspection body or authority.

5. Reception of products from other units

On receipt of a product as referred to in Article 1, the operator shall check the closing of the packaging or container where it is required and the presence of the indications referred to in point 7 of the general provisions of this Annex. The operator shall crosscheck the information on the label referred to in point 7 of the general provisions with the information on the accompanying documents. The result of these verifications shall be explicitly mentioned in the documentary accounts referred to in point 6 of the general provisions.

C. Imports of plants, plant products, livestock, livestock products and foodstuffs composed of plant products and/or livestock products from third countries

This section applies to any operator involved, as importer and/or as first consignee, in the import and/or reception, for its own account or for account of another operator, of products referred to in Article 1(1). For the purpose of this section:

- the importer shall mean the natural or legal person within the European Community who presents a consignment for release for free circulation into the European Community, either on its own, or through a representative,
- the first consignee shall mean the natural or legal person referred to in Article 11(3)(a) to whom the consignment is delivered and who will receive it for further preparation and/or marketing.

1. Initial inspection

Importers

- The full description of the unit referred to under point 3 of the general provisions of this Annex must include the importer's premises and of his import activities, indicating the points of entry of the products into the Community and any other facilities the importer intends to use for the storage of the imported products pending their delivery to the first consignee,
- In addition, the declaration referred to under point 3 of the general provisions must include an undertaking by the importer to ensure that any facilities that the importer will use for storage of products are submitted to inspection, to be carried out either by the inspection body or authority or, when these storage facilities are situated in another Member State or region, by an inspection body or authority approved for inspection in that Member State or region.

First consignee

- The full description of the unit referred to under point 3 of the general provisions must show the facilities used for the reception and storage. Where other activities, like processing, packaging, labelling and storage of agricultural products before and after the operations concerning them, as well the transport of the products, take place, the relevant provisions under section B shall apply.

When the importer and the first consignee are the same legal person and operating in one single unit, the reports referred to in point 3 of the general provisions can be formalised within one single report.

2. Documentary accounts

When the importer and the first consignee are not operating in one single unit, both of them must keep stock and financial records.

On request of the inspection body or authority, any details on the transport arrangements from the exporter in the third country to the first consignee and, from the first consignee's premises or storage facilities to the consignees within the Community must be provided.

3. Information on imported consignments

The importer shall, at the latest by the time that the certificate is submitted to the relevant Member State's authority in accordance with Article 4 point 1 of Commission Regulation (EC) No 1788/2001 of 7 September 2001 laying down detailed rules for implementing the provisions concerning the certificate of inspection for imports from third countries under Article 11 of Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs⁽¹⁾, inform the inspection body or authority of each consignment to be imported into the Community, giving:

- the name and address of the first consignee,
- any details this body or authority may require, such as a copy of the inspection certificate for the importation of products from organic farming. On the request of the inspection body or authority of the importer, the latter must pass the information to the inspection body or authority of the first consignee.

4. Importers and first consignees handling also products not from organic production

When imported products referred to in Article 1 are stored in storage facilities where also other agricultural products or foodstuffs are stored:

- the products as referred to in Article 1 must be kept separate from the other agricultural products and/or foodstuffs,
- every measure must be taken to ensure identification of consignments and to avoid mixtures or exchanges with products not obtained in accordance with the rules laid down in this Regulation.

⁽¹⁾ OJ L 243, 13.9.2001, p. 3.

5. Inspection visits

The inspection body or authority shall inspect the stock and financial records mentioned in section C, point 2 and the certificates referred to in Article 11(1)(b) and Article 11(3) and established by Regulation (EC) No 1788/2001.

Where the importer performs the import operations by different units or premises, he must make available on request, the reports foreseen under point 3 and 5 of the general provisions of this Annex for each of these facilities.

6. Reception of products from a third country

Products as referred to in Article 1 shall be imported from a third country in appropriate packaging or containers, closed in a manner preventing substitution of the content and provided with identification of the exporter and with any other marks and numbers serving to identify the lot with the certificate of inspection for import from third countries.

On receipt of a product as referred to in Article 1, imported from a third country, the first consignee shall check the closing of the packaging or container and the correspondence of the identification of the consignment with the certificate referred to in Regulation (EC) No 1788/2001. The result of this verification shall be explicitly mentioned in the accounts referred to in section C, point 2.

D. Units involved in the production, preparation or import of products referred to in Article 1(1) and which have contracted out to third parties in part or in total the actual operations concerned**Initial inspection**

With regard to the operations, which are contracted out to third parties, the full description referred to in point 3 of the general provisions shall include:

- a list of the subcontractors with a description of their activities and the inspection bodies or authorities to which they are subject; these subcontractors must have agreed to have their holding being subject to the inspection regime of Article 9, in accordance with the relevant sections of Annex III,
 - all the practical measures, including *inter alia* an appropriate system of documentary accounts, to be taken at the level of the unit to ensure that the products the operator places on the market can be traced to their suppliers, and, where different, their sellers, as well as to their consignees and, where different, their buyers.'
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