



Brussels, XXX  
[...] (2012) XXX draft

**COMMISSION IMPLEMENTING REGULATION (EU) No .../..**

**of XXX**

**amending Regulation (EC) No 889/2008 as regards the control system for organic  
production**

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**amending Regulation (EC) No 889/2008 as regards the control system for organic production**

THE EUROPEAN COMMISSION,

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

Having regard to 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<sup>1</sup>, and in particular Article 33(2) and (3) and Article 38(c) and (d) thereof,

Whereas:

- (1) According to Article 28(1) of Regulation (EC) No 834/2007, operators who produce, prepare, store, place on the market, import or export products produced in compliance with the production rules laid down in that Regulation must submit their undertaking to the control system referred to in Article 27 of that Regulation. Detailed rules for the application of that control system are laid down in Title IV of 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<sup>2</sup>.
- (2) Under that control system the operators must notify their undertaking to the competent authority, including information on the relevant control body, and sign a declaration that they perform according to the organic rules, including the acceptance of enforcement of measures in case of infringements and irregularities.
- (3) Article 30(2) of Regulation (EC) No 834/2007 provides for the communication of information related to irregularities or infringements affecting the organic status of a product. To enhance efficiency, operators should inform their control authorities or control bodies of any irregularity or infringement affecting the organic status of their product including organic products they receive from other operators.
- (4) In the light of the experience gained with the implementation of the control system and in the interest of the organic sector, it is appropriate to establish a minimum number of samples to be taken and analysed by control authorities or control bodies every year on the basis of the general evaluation of the risk of non-compliance with the organic production rules. Where the control authorities or control bodies has suspicion that products not authorised for organic production are used, they should take and analyse samples of the products concerned. In such cases no minimum number of samples should apply.
- (5) In the light of the experience gained with the implementation of the control system and in the interest of the organic sector, it is appropriate to provide for the transmission of

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<sup>1</sup> OJ L 189, 20.7.2007, p. 1.

<sup>2</sup> OJ L 250, 18.9.2008, p. 1.

the relevant information in cases where the operator or the subcontractors of that operator are checked by different control authorities or control bodies or where operators or their subcontractors change their control authority or control body. Adequate exchange of information and transmission of the control files of those operators should be possible in order to manage the control system, while observing the requirements of the protection of personal data as laid down in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>3</sup>. Operators should accept the transmission and exchange of their data and all information relating to their activities under the control system.

- (6) In order to ensure the uniform application of the control system and to avoid ambiguities, a definition of the term 'control file' should be included in Regulation (EC) No 889/2008.
- (7) Electronic certification is referred to in Article 29(3) of Regulation (EC) No 834/2007 in relation to the form of the documentary evidence. It is appropriate to clarify that in case of electronic certification, the signature of the documentary evidence is not required if the authenticity of the documentary evidence is otherwise shown by a tamper-proof electronic method.
- (8) The experience has shown that clarification is needed as regards the exchange of information between Member States in cases where a Member State finds irregularities or infringements concerning compliance of the products imported in accordance with Article 33(2) and (3) of Regulation (EC) No 834/2007 or Article 19 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<sup>4</sup>.
- (9) In addition, it is appropriate to clarify the procedure relating to the exchange of information between Member States in cases of irregularities or infringements, taking into account the best practices established since 2009.
- (10) In order to ensure the coherence with Article 33(1) of Commission Regulation (EU) No 65/2011 of 27 January 2011 laying down detailed rules for the implementation of Council Regulation (EC) No 1698/2005, as regards the implementation of control procedures as well as cross-compliance in respect of rural development support measures<sup>5</sup>, it is important to clarify that Member States should ensure that sufficient information on the controls carried out is received by the paying agency where controls are not carried out by the paying agency.
- (11) In accordance with Article 44(1)(a) of Regulation (EC) No 882/2004 Member States are required to indicate in their annual report any amendment to their multi-annual national control plan to take account of, inter alia, new legislation. The Commission should have the necessary data and information on the supervision carried out by competent authorities of the Member States in relation to organic production. Therefore, Member States should be required to amend their national control plan in order to cover that supervision and to indicate those amendments and the relevant organic data in the annual report referred to in Article 44 of Regulation (EC) No

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<sup>3</sup> OJ L 281, 23.11.1995, p. 31.

<sup>4</sup> OJ L 334, 12.12.2008, p. 25.

<sup>5</sup> OJ L 25, 28.1.2011, p. 8.

882/2004. Member States should be allowed to present those organic data as a separate chapter in the national control plan and in the annual report.

- (12) In addition to obligations relating to controls set out in Regulation (EC) No 882/2004, Title V of Regulation (EC) No 834/2007 and Regulation (EC) No 889/2008 set out more specific provisions on the controls in the organic sector. In case the competent authority delegates control tasks to control bodies, which are private entities, Regulation (EC) No 889/2008 sets out more detailed requirements and obligations each control body has to fulfil.
- (13) The experience has shown that the specific provisions on controls of organic production need to be more detailed, particularly in order to strengthen the supervision of competent authorities over the control bodies that have been delegated control tasks.
- (14) Competent authorities of the Member States should have documented procedures for delegating tasks to control bodies and supervising them in order to ensure that the regulatory requirements are respected.
- (15) The exchange of information within Member States, among Member States, and between Member States and the Commission relating to the supervision carried out by competent authorities should be improved.
- (16) Regulation (EC) No 889/2008 should therefore be amended accordingly.

(17) For the efficiency of the control arrangements, the additional elements, as added by this Regulation, which are to be covered by the undertaking included in the declaration to be signed by the operator as referred to in Article 63(2) of Regulation (EC) No 889/2008, should also apply to operators who signed that declaration before the date of application entry into force of this Regulation.

(18) In order to ensure the smooth transition from the current control system ~~to~~ and the amended system, this Regulation should apply from 1 January 2014.

~~(17)~~(19) The measures provided for in this Regulation are in accordance with the opinion of the regulatory Committee on organic production,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

#### *Article 1*

#### *Amendment of Regulation (EC) No 889/2008*

Regulation (EC) No 889/2008 is amended as follows:

- (1) In Article 2, the following point (s) is added:

"(s) "control file" means all the information and documents transmitted, for the purposes of the control system, to the competent authorities of the Member State or to control authorities and control bodies by an operator subject to the control system as referred to in Article 28 of Regulation (EC) No 834/2007, including all the information and documents relating to that operator or the activities of that operator held by competent authorities, control authorities and control bodies, with the exception of information or documents that have no bearing on the operation of the control system."

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(2) In the first subparagraph of Article 63(2), the following points (d) to (h) are added:

- "(d) to accept, in cases where the operator and/or the subcontractors of that operator are checked by different control authorities or control bodies in accordance with the control system set up by Member State concerned, the exchange of information between those authorities or bodies;
- (e) to accept, in cases where the operator and/or the subcontractors of that operator change their control authority or control body, the transmission of their control files to the subsequent control authority or control body;
- (f) to accept, in cases where the operator withdraws from the control system, to inform without delay the relevant competent authority and control authority or control body;
- (g) to accept, in cases where the operator withdraws from the control system, that the control file is kept for a period of at least five years;
- (h) to send the competent authority an undertaking to inform the relevant control authority or authorities or control body or bodies without delay of any irregularity or infringement affecting the organic status of their product or organic products received from other operators or subcontractors."

(3) In Article 65, paragraph 2 is replaced by the following:

"2. The control authority or control body shall take and analyse samples for detecting of products not authorised for organic production, for checking production techniques not in conformity with the organic production rules or for detecting possible contamination by products not authorised for organic production. The number of samples to be taken and analysed by the control authority or control body every year shall correspond to at least 540% of the number of operators under its control. As regards pesticide residues, that minimum threshold shall take into account the number of samples to be taken and analysed within the framework of the coordinated multiannual control programme of the Union provided for in Article 29 of Regulation (EC) No 396/2005 of the European Parliament and of the Council[\*]

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The selection of the operators where samples have to be taken shall be based on the general evaluation of the risk of non-compliance with the organic production rules. This general evaluation shall take into account all stages of production, preparation and distribution.

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The control authority or control body shall take and analyse samples in each case where the use of products not authorised for organic production is suspected. In such cases no minimum number of samples to be taken and analysed shall apply."

\*OJ L 70, 16.3.2005, p. 1."

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(4) In Article 68(1), the following subparagraph is added :

<sup>[1]</sup> OJ L 70, 16.3.2005, p. 1.

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"In case of electronic certification as referred to in Article 29(3) of Regulation (EC) No 834/2007, the signature in box 8 of the documentary evidence shall not be required if the authenticity of the documentary evidence is otherwise shown by a tamper-proof electronic method. "

- (5) Articles 92 and 92a are replaced by the following:

*"Article 92*

*Exchange of information between control authorities, control bodies and competent authorities*

1. Where the operator and/or the subcontractors of that operator are checked by different control authorities or control bodies, the control authorities or control bodies shall exchange the relevant information on the operations under their control.

2. Where operators and/or their subcontractors change their control authority or control body, the change shall be notified without delay to the competent authority by both control authorities or control bodies.

The previous control authority or control body shall hand over the control file of the operator concerned and the reports referred to in the second subparagraph of Article 63(2) to the subsequent control authority or control body.

The new control authority or control body shall ensure that non-conformities noted in the report of the previous control contractor have been or are being addressed by the operator.

3. Where the operator withdraws from the control system, the control authority or control body of that operator shall, without delay, inform the competent authority.

4. Where a control authority or control body finds irregularities or infringements relating to the application of this Regulation **and affecting the organic status of** ~~with regard to a products~~, it shall without delay inform the competent authority of the Member State which designated or approved it in accordance with Article 27 of Regulation (EC) No 834/2007.

In case of irregularities or infringements found with regard to products under the control of other control authorities or control bodies, it shall also inform those authorities or bodies without delay.

5. Member States shall take the appropriate measures and establish documented procedures to enable exchange of information between all control authorities they have designated and/or all control bodies they have approved in accordance with Article 27 of Regulation (EC) No 834/2007, including procedures for the exchange of information for the purpose of verifying documentary evidence referred to in Article 29(1) of that Regulation.
6. Member States shall take the appropriate measures and establish documented procedures in order to ensure that the results of checks are communicated to the paying agency in accordance with Article 33(1) of Commission Regulation (EU) No 65/2011(\*).

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## *Article 92a*

### *Exchange of information between different Member States and the Commission*

1. Where a Member State finds irregularities or infringements relating to the application of this Regulation with regard to a product coming from another Member State and bearing indications as referred to in Title IV of Regulation (EC) No 834/2007 and in Title III and/or Annex XI of this Regulation, it shall notify the Member State which designated the control authority or approved the control body, the other Member States and the Commission without delay via the system referred to in Article 94(1) of this Regulation.
2. Where a Member State finds irregularities or infringements as regards compliance of the products imported in accordance with Article 33(2) or (3) of Regulation (EC) No 834/2007 with the requirements laid down in that Regulation or Regulation (EC) No 1235/2008, it shall notify the other Member States and the Commission without delay via the system referred to in Article 94(1) of this Regulation.
3. Where a Member State finds irregularities or infringements as regards compliance of the products imported in accordance with Article 19 of Regulation (EC) No 1235/2008 with the requirements laid down in that Regulation and Regulation (EC) No 834/2007, it shall notify the Member State which issued the authorisation, the other Member States and the Commission without delay via the system referred to in Article 94(1) of this Regulation. The notification shall be sent to the other Member States and to the Commission in case the irregularity or infringement is found on products for which the Member State itself issued the authorisation referred to in Article 19 of Regulation (EC) No 1235/2008.
4. The Member State which receives a notification relating to non-compliant products in accordance with paragraphs 1 or 3 or the Member State which issued the authorisation referred to in Article 19 of Regulation (EC) No 1235/2008 for a product for which an irregularity or infringement was found, shall investigate the origin of the irregularities or infringements. It shall take appropriate action immediately.  
  
It shall inform the Member State which sent the notification, the other Member States and the Commission of the result of the investigation and of the action taken by replying to the original notification via the system referred to in Article 94(1). The reply shall be sent within 30 calendar days from the date of the original notification.
5. The Member State which sent the original notification may ask the replying Member State for additional information, if needed. In any case, after receiving a reply or additional information from a notified Member State, the Member State which sent the original notification shall make the necessary entries and updates in the system referred to in Article 94(1).

## *Article 92b*

### *Publication of information*

Member States shall make available to the public, in an appropriate manner including publication on the Internet, the updated lists referred to in Article 28(5) of Regulation

(EC) No 834/2007 containing updated documentary evidence related to each operator, as provided for in Article 29(1) of that Regulation and using the model set out in Annex XII to this Regulation. The Member States shall duly observe the requirements of the protection of personal data as laid down in Directive 95/46/EC of the European Parliament and of the Council(\*\*).

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(\*) OJ L 25, 28.1.2011, p. 8.

(\*\*) OJ L 281, 23.11.1995, p. 31."

(6) In Title IV, the following Chapter 9 is added:

#### *"CHAPTER 9*

##### *Supervision by competent authorities*

##### *Article 92c*

##### *Supervisory activities relating to control bodies*

1. The supervisory activities by competent authorities delegating control tasks to control bodies in accordance with Article 27(4)(b) of Regulation (EC) No 834/2007 shall focus on the evaluation of the operational performance of those control bodies, taking into account the results of the work of the national accreditation body as referred to in Article 2(11) of Regulation (EC) No 765/2008 of the European Parliament and of the Council (\*).

Those supervisory activities shall include an assessment of the internal procedures of the control bodies for the controls, the management and examination of control files in the light of the obligations established by Regulation (EC) No 834/2007 and the verification of handling of non-conformities and **the handling of appeals and** complaints.

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2. The competent authorities shall require control bodies to submit documentation on their risk analysis procedure.

The risk analysis procedure shall be designed in such a way that:

- (a) the result of the risk analysis provides the basis for determining the intensity of the unannounced or announced annual inspections;
- (b) additional inspections of at least 10% of operators under contract in accordance with the risk category are performed;
- (c) **at least 1020%** of all inspections carried out in accordance with Article 65(1) and (4) of Regulation (EC) No 889/2008 are unannounced;
- (d) the selection of operators to be submitted to unannounced inspections is determined on the basis of the risk analysis and that **additional unannounced** inspections are planned according to the level of risk.

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3. Competent authorities delegating control tasks to control bodies shall verify that the staff of the control bodies has sufficient knowledge, including knowledge of the risk elements affecting the organic status of products, qualifications, training and experience with respect to organic production in



general and with the relevant Union rules in particular and that appropriate rules on rotation of inspectors are in force.

4. Competent authorities shall have documented procedures for the delegation of tasks to control bodies in accordance with Article 27(5) of Regulation (EC) 834/2007 and for the supervision in accordance with this Article, detailing the information to be submitted by control bodies.

#### *Article 92d*

##### *Catalogue of measures in case of irregularities and infringements*

Competent authorities shall adopt and communicate to control bodies that have been delegated control tasks a catalogue listing most common infringements and irregularities affecting the organic status of products and corresponding measures to be applied by control bodies in case of infringements or irregularities by operators under their control who are involved in organic production.

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#### *Article 92e*

##### *Annual inspection of control bodies*

Competent authorities shall organise an annual inspection of the control bodies that have been delegated control tasks in accordance with Article 27(4)(b) of Regulation (EC) No 834/2007. For the purposes of the annual inspection, the competent authority shall take into account the results of the work of the national accreditation body as referred to in Article 2(11) of Regulation (EC) No 765/2008. During the annual inspection, the competent authority shall, in particular, verify:

- (a) the compliance with the control body's standard control procedure as submitted by the control body to the competent authority in accordance with Article 27(6)(a) of Regulation (EC) No 834/2007;
- (b) that the control body has a sufficient number of suitable qualified and experienced staff in accordance with Article 27(5)(b) of Regulation (EC) No 834/2007 and that training concerning risks affecting the organic status of products has been implemented;
- (c) that the control body has and follows documented procedures and templates for:
  - (i) the annual risk analysis in accordance with Article 27(3)(1) of Regulation (EC) No 834/2007;
  - (ii) preparing a risk-based sampling plan, conducting sampling and laboratory analysis;
  - (iii) information exchange with other control bodies and with the competent authority;
  - (iv) initial and follow-up controls of operators under their control;
  - (v) the application and follow-up to the catalogue of measures to be applied in case of infringements or irregularities;
  - (vi) observing the requirements of the protection of personal data for the operators under its control as laid down by the Member States where that competent authority operates and in accordance with

Directive 95/46/EC of the European Parliament and of the Council(\*\*).

#### *Article 92f*

##### *Organic data in the multi-annual national control plan and annual report*

Member States shall ensure that their multi-annual national control plans referred to in Article 41 of Regulation (EC) No 882/2004 cover the supervision of controls performed on the organic production in accordance with this Regulation and to include the specific data on that supervision, hereinafter referred to as "the organic data", in the annual report referred to in Article 44 of Regulation (EC) No 882/2004. The organic data shall cover the topics listed in Annex XIIIb to this Regulation.

The organic data shall be based on information on the controls performed by the control bodies and/or control authorities and on audits performed by the competent authority.

The data shall be presented according to the templates provided for in Annex XIIIc to this Regulation.

Member States may insert the organic data as an organic chapter of their national control plan and their annual report.

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OJ L 218, 13.8.2008, p. 30.

OJ L 281, 23.11.1995, p. 31."

- (7) Annexes XIIIb and XIIIc, the text of which is set out in the Annex to this Regulation, are inserted.

#### *Article 2* *Transitional provision*

Points (d) to (h) of the first subparagraph of Article 63(2) of Regulation (EC) No 889/2008 as added by point (2) of Article 1 of this Regulation shall also apply to operators who signed the declaration referred to in Article 63(2) of Regulation (EC) No 889/2008 before the date of application entry into force of this Regulation.

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#### *Article 3* *Entry into force and application*

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

It shall apply from 1 January 2014.

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This Regulation shall be binding in its entirety and directly applicable in the Member States.  
Done at Brussels,

*For the Commission*  
*The President*

<b><u>ANNEX</u></b>
---------------------

**“Annex XIIIb**

**Topics to be covered by the national competent authority in the organic data referred to in Article 92f**

1. Information on the competent authority for the organic production
  - which body is the competent authority
  - resources available to the competent authority
  - description of audits performed by the competent authority (how, by whom)
  - documented procedure of the competent authority
2. Description of the control system for organic production
  - system of control bodies and / or control authorities
  - registered operators covered by the control system – minimum annual inspection
  - how is the risk based approach applied
3. Information on control bodies / authorities
  - list of control bodies / authorities
  - tasks delegated to the control bodies / authorities
  - supervision of delegated control bodies (by whom and how)
  - coordination of activities in case of more than one control body / authority
  - training of staff performing the controls
  - announced / unannounced inspections

# Annex XIIIc

## Templates for the organic data referred to under Article 92f

Report on official controls in the organic sector

Country:

Year:

### 1) Information on controls of operators

Code number of control body or control authority	Number of registered operators						Number of annual visits						Number of additional risk based visits						Total number of visits					
	Agricultural Produce rs*	Aquaculture animal production units	Processors**	Importers	Exporters	Other operators***	Agricultural Produce rs*	Aquaculture animal production units	Processors**	Importers	Exporters	Other operators***	Agricultural Produce rs*	Aquaculture animal production units	Processors**	Importers	Exporters	Other operators***	Agricultural Produce rs*	Aquaculture animal production units	Processors**	Importers	Exporters	Other operators***
MS-BIO-01																								
MS-BIO-02																								
MS-BIO-...																								
Total																								

Code number of control body or control authority or Name of Competent Authority	Number of registered operators						Number of samples analysed						Number of samples indicating breach of Regulation (EC) No 834/2007 and No 1235/2008					
	Agricultural Produce rs*	Aquaculture animal production units	Processors**	Importers	Exporters	Other operators***	Agricultural Produce rs*	Aquaculture animal production units	Processors**	Importers	Exporters	Other operators***	Agricultural Produce rs*	Aquaculture animal production units	Processors**	Importers	Exporters	Other operators***
MS-BIO-01																		
MS-BIO-02																		
MS-BIO-...																		

[illegible][illegible]

(1) Only irregularities which affect the organic status of products and/or have resulted in a penalty (including ordinary remark) being applied are included.

(2) Where an irregularity is found as regards compliance with the requirements laid down in this Regulation, the control authority or control body shall ensure that no reference to the organic production method is made in the labelling and advertising of the entire lot or production run affected by this irregularity, where this would be proportionate to the relevance of the requirement that has been violated and to the nature and particular circumstances of the irregular activities (as referred to in first subparagraph of Article 30(1) of Council Regulation (EC) No 834/2007).

(3) Where a severe infringement or an infringement with prolonged effect is found, the control authority or control body shall prohibit the operator concerned from marketing products which refer to the organic production method in the labelling and advertising for a period to be agreed with the competent authority of the Member State (as referred to in second subparagraph of Article 30(1) of Council Regulation (EC) No 834/2007).

\*Agricultural producers include agricultural producers only, producers that are also processors, producers that are also importers, other mixed producers not elsewhere classified (n.e.c.).

\*\*Processors include processors only, processors that are also importers, other mixed processors n.e.c.

\*\*\*Other operators include traders (wholesalers, retailers), other operators n.e.c.

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## 2) Information on supervision and audits

Code number of control body or control authority	Number of registered operators						Document review and office audit (4) (Number of operator files checked)						Number of review audits (5)						Number witness audits (6)					
	Agricultural Produce rs*	Aquaculture animal production units	Processors **	Importers	Exporters	Other operators***	Agricultural Produce rs*	Aquaculture animal production units	Processors **	Importers	Exporters	Other operators***	Agricultural Produce rs*	Aquaculture animal production units	Processors **	Importers	Exporters	Other operators***	Agricultural Produce rs*	Aquaculture animal production units	Processors **	Importers	Exporters	Other operators***
MS-BIO-01																								
MS-BIO-02																								
MS-BIO-...																								
Total																								

(4) Document review of the relevant general documents describing the structure, functioning and quality management of the control body. Office audit of the control body, including checking of operator files and verification of handling of non-conformities and complaints, including the minimum control frequency, the use of risk based approach, unannounced and follow-up visits, the sampling policy and the exchange of information with other control bodies and control authorities.

(5) Review audit: inspection of an operator by the competent authority to verify compliance with the operating procedures of the control body and to verify its effectiveness.

(6) Witness audit: observation by the competent authority of an inspection by an inspector of the control body.

\* All producers : includes "Producers only", "Mixed producers/processors", "Mixed producers/importers", "Mixed producers/processors/importers"

\*\* All processors : includes "Processors only", "Mixed producers/processors", "Mixed processors/importers", "Mixed producers/processors/importers"

\*\*\* All importers : includes "Importers only", "Mixed producers/importers", "Mixed processors/importers", "Mixed producers/processors/importers"

3) Conclusions on the control system for the organic production

Code number of control body or control authority		Withdrawal of the approval			Actions taken to ensure effective operation of the control system for the organic production (enforcement)
		Yes/No	From (date)	To (date)	
MS-BIO-01					
MS-BIO-02					
MS-BIO-...					

Statement of overall performance of the control system for the organic production: