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from: Secretary-General of the European Commission,
signed by Mr Jordi AYET PUIGARNAU, Director

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to: Mr Javier SOLANA, Secretary-General/High Representative

Subject: Commission Staff Working Document - Comparative analysis between the
control provisions laid down in the proposal for a new Council Regulation on
organic production (COM/2005/671) and the inspection system laid down in
Council Regulation (EEC) No 2092/91

Delegations will find attached Commission document - SEC(2006) 1108.

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 1. 9.2006
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COMMISSION STAFF WORKING DOCUMENT

Comparative analysis between the control provisions laid down in the proposal for a new Council Regulation on organic production (COM/2005/671) and the inspection system laid down in Council Regulation (EEC) No 2092/91

{COM(2005) 671 final}

COMMISSION STAFF WORKING DOCUMENT

Comparative analysis between the control provisions laid down in the proposal for a new Council Regulation on organic production (COM/2005/671) and the inspection system laid down in Council Regulation (EEC) No 2092/91

The proposal for a new Regulation on organic production COM/2005/671 (referred to as 'the proposal' in this document) requires Member States to include controls on organic operators in line with Regulation (EC) No 882/2004 of the EP and of the Council on official food and feed controls (referred to as 'OFFC' in this document). In fact, the scope of OFFC covers controls on organic production.

The Commission is of the opinion that the OFFC represents an important reinforcement of the food/feed controls at EC level. The control methodology in OFFC is modern and includes risk-based action. OFFC requires Member States to integrate all controls on food and feed into control planning. Distribution of responsibilities as regards reporting and transparency at the different levels (Member States, competent authorities and Commission) are clearly laid down in the OFFC.

Notwithstanding the fact that organic production is solidly embedded in the OFFC framework, the Commission with its proposal does not intend to dismantle the current control system laid down in Council Regulation (EEC) No 2092/91. In fact, the current rules are tailor-made and have been developed based on experience in operating the organic regulation.

However, the Commission is of the opinion that in terms of structure, the current organic rules are compatible with OFFC. In this regard, the annex to this document explains how the current provisions on controls laid down in Articles 8 and 9 of Regulation are reflected in the proposal in connection with OFFC.

ANNEX

1. According to **Article 9(1) of Regulation (EEC) No 2092/91**, *Member States shall set up an inspection system.*

The proposal provides that Member States shall, in accordance with OFFC, set up a system of controls (cf. Article 22(1) of the proposal).

The term 'inspection' in the EN version of Regulation (EEC) No 2092/91 has been replaced by 'controls' in the proposal, in order to be in line with OFFC language. This change however should not represent a problem. Actually, the term 'control' has been used up until now in several language versions of Regulation (EEC) No 2092/91 (cf. amongst others DE, ES, FR, IT, PT, NL versions of Regulation (EEC) No 2092/91) without creating any confusion. Moreover, the term 'control' covers the term 'inspection'.

Member States will in any case continue being responsible for setting up a system which ensures the respect of the organic production rules.

2. According to **Article 9(1) of Regulation (EEC) No 2092/91**, *the inspection system set by Member States shall be operated by one or more designated inspection authorities and/or by approved private bodies.*

The three possible cases occur in practice, i.e., there are Member States who have designated inspection authorities, Member States who have approved private (inspection) bodies and finally, in a few cases, Member States who have at the same time designated inspection authorities and have approved private (inspection) bodies.

The proposal however follows the approach of OFFC, i.e., the Member States shall designate the competent authority responsible for the organisation of the official controls (cf. Article 22(3) of the proposal). It has to be pointed out, that according to OFFC, 'competent authority' means not only the central authority of a Member State competent for the organisation of official controls, but also any other authority to which that competence has been conferred (cf. Article 2(4) of OFFC).

It has been questioned whether this change would imply the exclusion of private bodies from control tasks. This is certainly not the case. In fact, the proposal, also in accordance with OFFC, foresees that the competent authority may delegate certain control tasks to one or more 'control bodies' (cf. Article 22(4) of the proposal). (Article 2(5) of OFFC defines a 'control body' as an independent third party to which the competent authority has delegated certain control tasks).

It has been argued that the proposal would have for effect that some of the current 'inspection authorities' dependent on the competent authorities but not being part of them would be excluded from control tasks. Moreover, it has been argued that these 'inspection authorities' can, in certain cases, not be considered as 'control bodies' as they are not an independent third party as required by OFFC (cf. Article 2(5) of OFFC). The Commission in its proposal had no intention to exclude any of the current 'inspection authorities' from performing control tasks. In this regard, and for the sake of avoiding confusion, the Commission accepts that the text could provide more explicitly that the competent authority may confer powers on other public

authorities to carry out the task of performing controls. Accreditation of the latter authority would not be compulsory.

3. According to **Article 9(2) of Regulation (EEC) No 2092/91**, *Member States shall adopt the measures necessary to ensure that an operator who complies with the provisions of the Regulation and pays his contribution to inspection expenses has access to the inspection system.*

The proposal reflects this provision in Article 23(3).

4. According to **Article 9(3) of Regulation (EEC) No 2092/91**, *the inspection system shall comprise at least the application of the precautionary and inspection measures specified in Annex III.*

The proposal does not lay down detailed rules for any of its chapters, including controls. However, the intention is to maintain the current technical standards in the implementing rules to be laid down in the future. This applies also for the chapter on 'controls' with some exceptions resulting from the European Action Plan, e.g. to better develop the "risk-based approach", as also set out in OFFC Article 16, and "cross-inspections".

5. According to **Article 9(4) of Regulation (EEC) No 2092/91**, *Member States shall designate an authority responsible for the approval and supervision of private bodies operating the inspection system.*

As mentioned above, the proposal provides that competent authorities delegate control tasks to control bodies, where the provisions laid down in OFFC are respected. Supervision of control bodies is also ensured under OFFC (cf. Article 5(3) of OFFC).

6. According to **Article 9(5) of Regulation (EEC) No 2092/91**, *for the approval of a private inspection body, the following shall be taken into account:*
 - (a) *the standard inspection procedure to be followed, containing a detailed description of the inspection measures and precautions which the body undertakes to impose on operators subject to its inspection;*
 - (b) *the penalties which the body intends to apply where irregularities and/or infringements are found;*
 - (c) *the availability of appropriate resources in the form of qualified staff, administrative and technical facilities, inspection experience and reliability;*
 - (d) *the objectivity of the inspection body vis-à-vis the operators subject to its inspection.*

Furthermore, according to **Article 9(11) of the Regulation**, *private inspection bodies must satisfy the requirements laid down in the conditions of standard EN 45011.* Article 22(4) of the proposal also foresees the fulfilment of the requirements in standard EN 45011.

As regards the provisions under Article 9(5)(a), (c) and (d) of Regulation (EEC) No 2092/91, they are covered by the requirements of standard EN 45011. Moreover,

the provisions under Article 9(5)(c) and (d) are also required by OFFC (cf. Article 5(2) of OFFC).

As regards the 'penalties' foreseen under Article 9(5) (b) of Regulation (EEC) No 2092/91, it has to be pointed out that standard EN 45011 foresees the suspension or withdrawal (partially or total) of certification of compliance. However, according to OFFC, it is only up to the competent authority to take action in case of non-compliance (cf. Article 5(1) third subparagraph and Article 54 of OFFC), thus control bodies themselves are not entitled to impose sanctions.

The Commission accepts that the proposal should be amended in order to take into account the requirements set out in EN 45011.

7. According to **Article 9(6) of Regulation (EEC) No 2092/91**, *after an inspection body has been approved, the competent authority shall:*
- (a) *ensure that the inspections carried out by the inspection body are objective;*
 - (b) *verify the effectiveness of its inspections;*
 - (c) *take cognizance of any irregularities and/or infringements found and penalties applied;*
 - (d) *withdraw approval of the inspection body where it fails to satisfy the requirements referred to in (a) and (b) or no longer fulfils the criteria indicated in paragraph 5 or fails to satisfy the requirements laid down in paragraphs 7, 8, 9 and 11.*

Objectivity and supervision are *conditio sine qua non* of standard EN 45011. Moreover, under OFFC, the competent authorities are also responsible for the supervision of the control bodies to whom control tasks have been delegated. Withdrawal of such delegations is also provided for in OFFC, where the control bodies fail to carry out their tasks properly (cf. Article 5(3) of OFFC). Finally, according to OFFC, control bodies shall communicate the results of the controls carried out to the competent authority on a regular basis and whenever the competent authority so requests. If the results of the controls indicate non-compliance, the control body shall immediately inform the competent authority (cf. Article 5(2)(e) of OFFC). In any case an efficient and effective coordination between the delegating competent authority and the control body has to be ensured (cf. Article 5(2)(f) of OFFC).

With regard to penalties, as mentioned above (cf. last paragraph of point 6) the Commission accepts that the proposal should be amended in order to take into account the requirements of standard EN 45011.

8. According to **Article 9(6a) of Regulation (EEC) No 2092/91**, *Member States shall issue a code number to each inspection body or authority approved or designated.*

This provision is reflected in the proposal. In fact, Article 22(7) of the proposal states that Member States shall attribute a code number to each body competent to carry out controls.

9. According to **Article 9(7)(a) of Regulation (EEC) No 2092/91**, *the inspection authority and the approved inspection bodies shall ensure that at least the inspection measures and precautions specified in Annex III are applied.*

As mentioned above (cf. point 4), implementing rules on controls shall be laid down later on in the future by comitology and there is no intention to deviate from the detailed provisions currently foreseen in Annex III.

10. According to **Article 9(7)(b) of Regulation (EEC) No 2092/91**, *the inspection authority and the approved inspection bodies shall not disclose information and data they obtain in their inspection activity to persons other than the person responsible for the undertaking concerned and the competent public authorities.*

This provision on confidentiality is ensured not only by standard EN 45011 but also by OFFC (cf. Article 7(2) of OFFC).

However, **Article 9(7)(b)** of Regulation (EEC) No 2092/91 also foresees that, *upon request duly justified by the necessity to guarantee that the products have been produced in accordance with the Regulation, they shall exchange with other inspection authorities or approved inspection bodies relevant information on the results of their inspection. They may also exchange the abovementioned information on their own initiative.*

This provision is reflected in Article 26 of the proposal.

11. According to **Article 9(8)(a) of Regulation (EEC) No 2092/91**, *approved inspection bodies shall give the competent authority, for inspection purposes, access to their offices and facilities, together with any information and assistance deemed necessary by the competent authority for the fulfilment of its obligations pursuant to this Regulation.*

This provision is reflected in Article 22(5) of the proposal.

12. According to **Article 9(8)(b) of Regulation (EEC) No 2092/91**, *approved inspection bodies shall send to the competent authority of the Member State by 31 January each year a list of operators subject to their inspection on 31 December of the previous year and present to the said authority a concise annual report.*

This provision is reflected in Article 22(8) of the proposal.

13. According to **Article 9(9) of Regulation (EEC) No 2092/91**, *the inspection authority and inspection bodies shall:*

- (a) *ensure that, where an irregularity is found regarding the implementation on organic labelling requirements, the indications referring to the organic production method are removed from the entire lot or production run affected by the irregularity concerned;*
- (b) *where a manifest infringement, or an infringement with prolonged effects is found, prohibit the operator concerned from marketing products with indications referring to the organic production method for a period to be agreed with the competent authority of the Member State.*

In this respect, the proposal corresponds to the provisions of OFFC which state that in case of identifying a non-compliance, the competent authority shall take action. (cf. Article 54(1) of OFFC). However, as mentioned above (cf. last paragraph of point 6) the Commission accepts that the proposal should be amended in order to take into account the requirements of standard EN 45011.

14. According to **Article 8(1) of Regulation (EEC) No 2092/91**, *any operator [in the organic sector] shall notify his activity to the competent authority and shall submit his undertaking to the inspection system referred to in Article 9. Member States may exempt certain categories of operators. Subcontractors shall also notify and submit their undertaking to the inspection system.*

This provision is reflected in the proposal, Article 23(1) (except for the content of the notifications, which was considered to be better placed in implementing rules). The same possibility for exemptions is reflected in Article 23(2). The provision on the subcontractors is not reflected in the proposal, as it was considered that they are already covered by "any operator" and the reference to subcontractors is therefore redundant.

15. According to **Article 8(2) of Regulation (EEC) No 2092/91**, *Member States shall designate an authority or body for the reception of notifications and may ask for any additional information from the operators when needed for efficient supervision.*

The provision on designation of the authority for notification is not reflected in the proposal as it was considered self-evident. The right to ask for more information is already covered by OFFC, Article 10(e).

16. According to **Article 8(3) of Regulation (EEC) No 2092/91**, *competent authorities shall ensure that an updated list containing the names and addresses of the operators subject to the inspection system is made available to interested parties.*

This provision is reflected in the proposal in a shorter version in Article 23(4), while Article 7 of the OFFC lays down more detailed rules on transparency and confidentiality.