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Guidance Note for operators on the EU organic testing procedure within the UK

September 2012

Llywodraeth Cymru
Welsh Government

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Department of the Environment
www.doeni.gov.uk

The Scottish Government

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Department for Environment Food and Rural Affairs

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Contents

Principles applicable to the testing procedure....1

A Testing....1

B. Taking samples and testing of livestock....3

Taking samples....3

Querying the results of sampling and analysis....4

C. Substantiated suspicion....5

Products certified by the Control Body that carried out the testing....5

Where the operator has a suspicion that a product is not in compliance with the EU Organic Regulations....6

D. Action to be taken where an irregularity or infringement is found....8

Principles applicable to the testing procedure

The fundamental premise of the EU organic regime is that there is mutuality and equivalence of Control Bodies, EU standards and EU systems. This is enshrined in **Article 34(1) of Regulation 834/2007**, which requires Control Bodies in one Member State to recognise the EU organic status of a product certified in another Member State. It follows that the requirements of **Article 34(1)** apply equally between Control Bodies within a Member State and, therefore, the EU organic status of a product certified by one Control Body must be respected and recognised by another Control Body.

In further support of this, Article 28(4) of Council Regulation (EC) 834/2007 provides that if an operator complies with the EU Organic Regulations and pays a reasonable fee towards control expenses is entitled to be covered by the organic control system. An operator who has been certified by one Control Body should have access to certification across the EU organic regime. Therefore, Control Bodies that fail to recognise the EU organic status of a product already certified by another Control Body (either in the UK or in another Member State) may be in breach of Article 28(4).

Operators should be aware that, in accordance with this approach, where a product has been certified as EU organic and its physical characteristics are unchanged, the operator's Control Body should not test the product nor require such testing to assess its EU organic integrity unless the operator or the operator's Control Body has a suspicion that the product may contain a prohibited substance. There are no restrictions on testing products that have not been previously certified as EU organic or where the product has been physically changed or where it is to look at compliance against a Control Body's own additional standards.

A Testing

1. We understand that operators are required to undertake checks and self-risk assessments of their products as part of their normal business pattern. These include:

- Raw material testing for quality, spoilage, contamination
- Micro e.g. pathogen testing
- Chemistry testing relating to spoilage or quality issues e.g. FFA testing
- Antibiotics
- Preservative agents
- Shelf life testing/ monitoring

- Temperature monitoring/ abuse testing
- Physical e.g. metal detection, x-ray
- Allergenic testing
- Sensory e.g. quality testing
- Visual checking
- Review of specifications (product changes, ingredient changes and source of ingredient e.g. seasonal variations in ingredient sourcing (may source from Europe and then China))
- Pesticide residue analysis
- GM analysis

2. Operators may also use supplier questionnaires/annual supplier audits when supplying a product to major retailers to obtain information as part of their normal business pattern.

- Pesticide residue analysis
- GMO
- Wax and growth regulator
- Fumigants
- Soil-sterilants

3. Testing frequencies will depend on the nature of the product (e.g. frozen, fresh, previously frozen, pre-cooked chilled, ambient, dehydrated, water activity) and risk of contamination (high, medium or low) as well as the target group it is aimed at e.g. babies.

4. Operators also have to identify possible points within their systems where contamination might occur or where there are potential risks to organic management requirements. This should include:

- Identifying critical control points;
- Identifying areas where possible human error could affect the organic product;
- Reviewing the effectiveness of their systems such as cleaning, separation, storage, labelling, etc – including sampling and testing;

- Where external risks of contamination are identified reviewing their systems to minimise the risk to their products.

B. Taking samples and testing of livestock

Taking samples

5. Paragraphs 9 to 14 of the Guidance Note for Control Bodies provide guidance on the taking of samples of an organic product for the purposes of testing. An operator must ensure that, should their Control Body wish to take samples of one of their products for the purposes of testing, the following traceability information is readily available:

- Batch number assigned by the operator and, if applicable, the suppliers' product reference for the raw materials (or in the case of livestock, the individual animal identifier such as ear tag, slap mark or other specific identifier);
- Details of the supplier (name and contact details i.e. address, telephone number and e-mail address);
- The delivery documents (i.e. the documents accompanying the product when it was delivered to the operator);
- The time and date of when the product or animal was delivered to the operator;
- Details of the supplier (name and contact details i.e. address, telephone number and e-mail address) and copies of the delivery documents.

6. The operator, or a suitable representative of the operator, should be on hand while the samples are taken to answer any questions or provide any additional information regarding traceability. The operator should also be present when the sample is bagged and sealed and it should be signed and dated by both the operator and the person taking the sample.

7. Organic operators should be aware that under paragraph 9 of the Control Bodies Guidance Note, Control Bodies are required to take a minimum of three samples of a product for the purposes of testing: one sample for testing, the second to be kept by the operator and the third to be kept by the Control Body.

8. Paragraph 14 of the Control Bodies Guidance Note provides guidance on the procedure for testing livestock for the use of prohibited substances in feed or the over-use of chemically-synthesised allopathic veterinary medicinal products or antibiotics. An operator must ensure that all feed records, veterinary records and any relevant further documentation are on hand where the Control Body wishes to undertake tests on

livestock. The operator, or a suitable representative of the operator, should be on hand while the inspections take place to answer any questions or provide any additional information regarding traceability.

Querying the results of sampling and analysis

9. In accordance with Articles 11(5) and 11(6) of Regulation 882/2004[1], operators may query the results of any testing that is carried out and ask for a supplementary expert opinion. The Control Body must undertake further analysis of the product, including the analysis of another available sample. This is without prejudice to Defra's obligation to take prompt action in case of emergency (Article 11(5) of Regulation 882/2004). The operator may arrange for further analysis of the product himself if he chooses but the analysis would need to comply with the requirements set down in Regulation 882/2004.

10. The procedure for operators querying the results of any testing is:

- the organic operator should inform their organic Control Body of a wish to query the result no later than 48 hours after being notified of the outcome;
- within 14 days of being informed, the Control Body acknowledges the query and provides a summary of how it will undertake further analysis of the product, including use of a supplementary expert opinion, and the likely timescales;
- the Control Body informs the operator of the outcome of this further analysis within 24 hours of receiving the results.

11. The cost of this further analysis may be recovered from the operator where the same or similar results are obtained.

[1] Regulation (EC) No. 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Article 27(1) of Council Regulation 834/2007 requires the organic control system in a Member State to comply with the requirements of Regulation 882/2004.

C. Substantiated suspicion

Products certified by the Control Body that carried out the testing

12. Once the Control Body has obtained the results of permissible testing, it will need to consider whether the levels of prohibited substance in the organic product are consistent with the EU Organic Regulations or require further investigation.

13. Where the Control Body considers that a product requires further investigation, it may have a substantiated suspicion that the product does not comply with the organic Regulations (this is set out in detail in paragraphs 18 to 31 of the Guidance Note for Control Bodies). If this is the case, the Control Body will follow the procedure set out in Article 91(2) of Regulation 889/2008 and this will impact on operators as follows**:**

- The Control Body will inform the operator of the test results. The operator will be given time to query the results if he wishes;
- The operator may be forbidden from marketing the product as EU organic for a defined period set by the Control Body. Before the Control Body does this, the operator will be given time to comment on the matter;
- The operator will be obliged to withdraw any reference to the organic production method where the Control Body is sure that the product does not fulfil the requirements of organic production.

14. The Control Body will investigate the cause of the presence of the prohibited substance in the product in order to determine whether the product is in compliance with the EU organic production rules. Such investigative actions can include:

- Checking whether the level of prohibited substance is consistent with actual use of the product;
- Doing spot checks on operators further up the supply chain to ascertain whether their procedures are consistent with organic production;
- Checking whether any other products might have been affected by the prohibited substance;
- Asking the operator to give a possible explanation for the levels of prohibited substance.

15. In tandem with the levels of prohibited substance involved, the process should consider the seriousness of the incident. For example, if the contamination (even if

unavoidable) resulted from an operator's negligence or such incidents happened regularly due to a lack of care or precaution on the part of the operator, this might have a bearing on the Control Body's decision. Further details on the investigative process are included in Section D of the Guidance Note for Control Bodies.

16. Where such investigations are taking place, the operator must cooperate fully with the control body in resolving the suspicion. In particular, the operator should:

- Provide any information requested about the prohibited substance and its presence;
- Provide any records requested by the Control Body;
- Provide full details, if possible, of operators further up the supply chain;
- Provide any information or explanations requested promptly.

17. If, following investigation, the Control Body concludes that the presence of the prohibited substance results from practices that are consistent with organic production, the operator will be able to market the product as organic.

18. If, following investigation, the Control Body concludes that the presence of the prohibited substance results from practices that are inconsistent with organic production, the procedure outlined in Section D below will be followed.

Where the operator has a suspicion that a product is not in compliance with the EU Organic Regulations

19. In accordance with Article 91 (1) of Commission Regulation (EC) 889/2008,[2] an operator who considers or suspects that a product he has produced, prepared, imported or received from another operator, is not in compliance with organic production rules must inform his organic Control Body immediately. At the same time, the operator must either withdraw from the product any reference to the organic production system or separate and identify the product. Where an operator has undertaken either or both of these actions, the product must not be marketed as organic until testing and/or investigation eliminates any doubt that the product has been produced in compliance with the organic production rules.

20. Such a suspicion might arise from the operator's testing, routine or otherwise, of the product (for food safety, quality control, private standards, etc), a visual inspection of the product (which indicates that contamination might have occurred e.g. damaged packaging, inaccurate labelling) or reliable information received from another source e.g. a member of

[2] Commission Regulation (EC) No 889/2008 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.

the public. An operator might also be informed by its Control Body of a suspicion and agree to follow the procedure set out in Article 91(1) of Regulation 889/2008. The product may only be placed on the market as an organic product once the doubt about the organic integrity of the product has been eliminated.

21. Where the operator considers or suspects that a product he has produced, prepared, imported or received from another operator is not in compliance with the organic production rules, paragraphs 20 and 21 of the Guidance Note to Control Bodies provide details of his and the Control Body's responsibilities under the procedure set out in Article 91(1) of Commission Regulation (EC) 889/2008. The operator must:

- alert his Control Body immediately to the matter;
- the onus will be on the operator to investigate the matter further;
- keep his Control Body informed of progress with investigations;
- answer any questions/ follow any instructions from his Control Body on the matter;
- where the operator uses laboratory testing, the testing must be done to a standard that is acceptable to the Control Body e.g. an accredited laboratory and/ or an accredited test. If the testing is not done to the satisfaction of the Control Body, the findings may not be accepted as evidence that any doubt of the product's integrity has been eliminated;
- provide his Control Body with satisfactory evidence that the doubt has been eliminated before selling the product as organic;
- inform his Control Body if he is unable to provide satisfactory evidence that the doubt has been eliminated.

In such cases, the Control Body can:

- require that the product is not sold until it receives satisfactory information from either the operator or another source that the suspicion has been eliminated;

The Control Body should then:

- check any information provided by the operator or another source and confirm whether or not the suspicion has been eliminated;
- allow the product to be sold as organic if the suspicion has been eliminated;
- if the operator is unable to provide satisfactory evidence that the suspicion has been eliminated, the Control Body should, if necessary, implement the procedures outlined in Section D of this Guidance.

Although the onus is on the operator to provide evidence on the organic integrity of the product, the Control Body may assist the operator with investigations.

D. Action to be taken where an irregularity or infringement is found

22. Where, following investigation of the prohibited substance, a Control Body has concluded that the product has been produced in a way that is inconsistent with organic production methods, the Control Body must 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 violated requirement and the nature and circumstances of the irregularity or infringement. This is covered by paragraphs 32 to 35 of the Control Bodies Guidance Note.

23. Where the infringement is severe or its effect is prolonged, the operator associated with this may be prohibited from marketing their organic products for a period agreed by Defra.