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Testing of Organic Products in the UK

Draft Guidance on the testing procedure for prohibited substances in organic products

September 2012

This document/publication is also available on our website at:

http://www.defra.gov.uk/consult/open/

Any enquiries regarding this document/publication should be sent to us at:

organic.standards@defra.gsi.gov.uk

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Section 1 - Background

What is the purpose of this consultation?

1.1 To seek your views on the draft Guidance for organic Control Bodies and organic operators on the testing of organic products for prohibited substances.

1.2 Organic food and feed production in the UK and in other EU Member States is strictly regulated. European legislation (Council Regulation 834/2007[1] and Commission Regulation 889/2008[2] ('the Regulations')) sets out organic production rules (including the substances and products which may be used) and the inspection system that must be in place to ensure this and these must comply with the requirements of Council Regulation 882/2004[3]. In the UK, Defra is the Competent Authority for ensuring that the organic sector complies with these Regulations, but it delegates the operation of the control requirements in the Regulations to a number of approved UK organic Control Bodies.

1.3 The Regulations provide a framework for the testing of organic products for substances that are not permitted in organic production, such as pesticides. However, they do not detail the procedures and processes Member States should follow, which has resulted in different approaches across the EU and within the UK. Defra, acting as the Competent Authority under the EU Organic Regulations, therefore proposes national guidance on how testing should be carried out in the UK. This includes guidance for the organic Control Bodies and guidance for organic operators, which will be set out in Guidance Notes.

How do I comment on these proposals?

1.4 We are seeking your views on the proposals described in Sections 2, 3 and 4 of this document. Specific questions have been highlighted throughout and are listed at **Annex A**. The consultation package also includes our draft Guidance Notes for organic Control Bodies and organic operators at **Annexes B** and **C** respectively.

How do I respond?

1.5 Please send your responses no later than 21 December 2012 by email to:

organic.standards@defra.gsi.gov.uk

[1] Council Regulation (EC) No 834/2007 on organic production and labelling of organic products ('Regulation 834/2007')

[2] Commission Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation 834/2007 ('Regulation 889/2008')

[3] Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ('Regulation 882/2004')

Or alternatively by post to:

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Please contact us if you wish for these documents to be made available in a different format (large print etc) and we will endeavour to accommodate your request.

Confidentiality

1.6 In line with Defra's policy of openness, at the end of the consultation period copies of the responses we receive may be published in a summary/analysis document. **If you do not consent to this, you must clearly request that your response be treated as confidential**.

1.7 Any confidentiality disclaimer generated by your IT system in email responses will not be treated as such a request. Respondents should also be aware that there may be circumstances in which Defra will be required to communicate information to third parties on request, in order to comply with its obligations under the Freedom of Information Act 2000.

Key elements of the proposed guidance

Mutuality and equivalence between organic Control Bodies

1.8 Central to the EU organic regime is the principle that there is mutuality and equivalence of organic Control Bodies, EU standards and EU systems. The Regulations[4] require Control Bodies in one EU Member State to recognise the EU organic status of a product certified by a Control Body in another EU Member State. It follows that this applies equally between organic Control Bodies within an EU Member State. Therefore, the EU organic status of a product certified by one UK Control Body must be respected and recognised by another UK Control Body. The Regulations[5] also require that any operator who complies with the EU organic standards and pays a reasonable fee towards control

[4] Article 34(1) of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products

[5] Article 28(4) of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products

expenses should have access to EU certification. 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 the Regulations.

1.9 Defra's draft Guidance makes clear that a Control Body must not carry out testing on any product that has been previously certified as organic by another Control Body where its physical characteristics are unchanged, unless the Control Body has a suspicion that the product may contain a substance that is not permitted under the Regulations. However, a Control Body may test products that have not been previously certified as organic by another Control Body and previously certified products that have been physically changed since certification (e.g. oats that have since been rolled). Some bodies offer a scheme with private standards which are additional to those required by the EU organic regime. A Control Body may test products of its own operators for compliance against the Control Body's additional standards.

Contamination of organic products with prohibited substances

1.10 There is a restricted list of products which may be used in organic farming for certain defined purposes[6]. If a substance does not appear on the restricted list, it must not be used in organic production (a 'prohibited substance'). However, the Regulations do not rule out the presence of a prohibited substance where this may be explained in a way consistent with organic production methods. This may be the case for example, where they are not used in production but are present as a result of unavoidable contamination such as spray drift.

1.11 The Regulations do not specify what levels of prohibited substances might be acceptable in respect of contamination, nor is there any guidance from the Commission as to what levels of prohibited substances are, in this circumstance, consistent with the Regulations. The draft Guidance for UK organic Control Bodies and organic operators attempts to clarify the levels and circumstances under which the presence of a prohibited substance in respect of contamination might be acceptable under the Regulations.

Cost implications

1.12 An Impact Assessment has not been produced for the draft Guidance as it involves an approach under the existing EU organic regime which does not require any legislative changes. However, we recognise that there may be some costs associated with aspects of the procedure set out in the draft Guidance, particularly depending on whether one of the trigger threshold options (Section 4 refers) is adopted. We would welcome any views on costs and how these may be affected by the trigger threshold options.

[6] Article 16 of Council Regulation(EC) 834/2007 which is effected through Commission Regulation(EC) 889/2008 and its Annexes

Q1. Do you have any views on the costs associated with the draft Guidance? Do you have any views on how the trigger threshold options set out in Section 4 of this document might affect costs?

Section 2 – guidance for organic Control Bodies

Testing

2.1 The draft Guidance identifies the different types of testing that may take place and the specific reasons why samples might be taken (paragraphs 1 to 3 of the proposed Guidance Note for Organic Control Bodies refer). In accordance with the Regulations[7], testing must be undertaken where there is a suspicion that products not authorised for EU organic production have been used and the draft Guidance includes examples of how a Control Body may gain a suspicion (paragraph 2 of the proposed Guidance Note for Organic Control Bodies refers).

Q.2 Do you have any comments on the criteria for gaining a suspicion? Are they the right criteria for this purpose?

2.2 In accordance with the principles of mutuality and equivalence outlined in paragraphs 1.8 and 1.9 of this document, the draft Guidance makes clear that where a product has been previously certified as EU organic by another Control Body and its physical characteristics are unchanged, the product's current Control Body must not test it. However, the current Control Body may test the product where it has a suspicion that the product may contain a prohibited substance, where the product's physical characteristics have changed or where the Control Body is testing against its private standards.

Taking samples of products for testing

2.3 The draft Guidance includes instructions for taking samples for testing. Regulation 882/2004 of the European Parliament and of the Council[8] ('Regulation 882/2004') requires that sufficient numbers of samples are taken for a supplementary expert opinion to be obtained should the results of the initial test be queried. The draft Guidance requires that at least three samples are taken in order to allow one sample to be sent for testing, a

[7] Article 65(2) of Commission Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation 834/2007

[8] Article 11(6) of 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. The conditions set out in this Regulation must be complied with when samples are taken and analysed. 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.

second sample to be kept by the operator and a third sample to be kept by the Control Body. Procedures must be in place to allow another sample to be sent for supplementary expert opinion should the results of the initial test be queried. This should be followed at all times, unless the product is highly perishable or there is a very low quantity of the product available. Paragraphs 11 to 13 of the proposed Guidance Note for Organic Control Bodies provide specific instructions on taking samples for different products. However, these instructions are based on the proposals of one of the organic Control Bodies.

Q.3 In order to produce an approach that is acceptable to the sector as a whole, do you have any views and proposals on alternative sampling methods?

Livestock testing

2.4 In accordance with the Regulations[9], the draft Guidance (paragraph 14 of the proposed Guidance Note for organic operators) requires Control Bodies to test livestock where there is a suspicion that they have been given feed containing prohibited substances or have been given more than three courses of treatments with chemically-synthesised allopathic veterinary medicinal products or antibiotics within 12 months, or more than one course of treatment if their productive lifecycle is less than one year[10]. We understand that there are currently no wholly reliable tests that can be undertaken on the animal itself although there are isotope tests that can be carried out on livestock products.

Q.4 Do you have any comments on the proposed procedure for testing livestock and the current limitations for testing the actual animal?

Laboratory testing

2.5 In accordance with Regulation 882/2004[11], the draft Guidance requires operators to use only those laboratories that are accredited in accordance with European Standards EN ISO/ IEC 17025 on "General requirements for the competence of testing and calibration laboratories" and EN ISO/ IEC 17011 on 'General requirements for accreditation bodies accrediting conformity assessment bodies" for the analysis of products for testing. Any laboratory used must be accredited by the relevant accreditation body in the Member State in which it is sited (in the UK this is the United Kingdom

[9] Article 65(2) of Commission Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation 834/2007

[10] Article 24(4) of Commission Regulation 889/2008 requires livestock and their products to lose their organic status where they receive more than three courses of treatments with chemically-synthesised allopathic veterinary medicinal products or antibiotics within 12 months, or more than one course of treatment if their productive lifecycle is less than one year.

[11] Article 12(2) of 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.

Accreditation Service (UKAS)). Accredited laboratories are accredited to undertake specific tests and Control Bodies must ensure that the laboratory chosen to undertake a particular test is accredited for that test. Control Bodies may also use laboratories in other Member States which have been accredited by the relevant accreditation body in that Member State for that particular test.

Q.5 We understand that there are some analytical differences between different laboratories. These differences are only slight but they could be significant where small quantities of residue are being analysed. Do you have any views on whether this is a significant issue and if so how it might be addressed?

Substantiated suspicion that a product contains a prohibited substance

2.6 The Regulations[12] set out the procedure that must be followed where the results of testing reveal that a product contains a level of a prohibited substance that is not consistent with organic production and there is a substantiated suspicion that it does not comply with the EU Organic Regulations.

2.7 In accordance with the Regulations, the draft Guidance requires the investigative process to determine as fully as possible the seriousness of the incident and whether the presence of the prohibited substance results from the unavoidable contamination of the organic product or its deliberate use. The draft Guidance sets out the investigative actions that might be undertaken (paragraph 24 of the proposed Guidance Note for Organic Control Bodies refers), which includes checking whether the level of prohibited substance is consistent with actual use of the product. The draft Guidance also lists possible causes of unavoidable contamination (paragraph 25 of the proposed Guidance Note for Organic Control Bodies refers) and causes of contamination that are inconsistent with organic production (paragraph 27 of the proposed Guidance Note for Organic Control Bodies refers).

Q.6 Do you have any views on the investigative actions that might be undertaken, in particular how the investigative process might assess whether the level of prohibited substance is consistent with actual use of the substance as opposed to unavoidable contamination?

2.8 The draft Guidance clarifies the actions that a Control Body must take when it has a substantiated suspicion that a product does not comply with the requirements of the EU Regulations[13]. It may prevent the operator from marketing the product as EU organic for a defined period set by the Control Body but, before doing this, it must allow the operator to comment on the matter. If the Control Body is sure that the product does not fulfil the requirements of organic production, any reference to organic production must be withdrawn.

[12] Article 91(1) and (2) of Commission Regulation (EC) 889/2008 laying down detailed rules for the implementation of Council Regulation 834/2007

[13] Article 91(2) of Commission Regulation (EC) 889/2008 laying down detailed rules for the implementation of Council Regulation 834/2007.

2.9 The draft Guidance also clarifies the roles and responsibilities where an operator alerts the Control Body to a suspicion that the product is not in compliance with organic production[14]. In such cases, the operator will be expected to investigate the matter further and keep the Control Body informed of progress. The operator will only be able to sell the product as organic once it has submitted to the Control Body satisfactory evidence that the doubt has been eliminated. The operator must inform the Control Body if it is unable to provide satisfactory evidence that the doubt has been eliminated.

Investigation of products certified as organic by another Control Body

2.10 Where a product has already been certified by another Control Body but is found not to be in compliance with the organic production rules or there is a substantiated suspicion that this is the case, the second Control Body (that now holds the product and has undertaken the testing) must inform the first Control Body (that originally certified the product further up the supply chain) of the findings. This is required by the Regulations[15] but the draft Guidance clarifies the procedure that should be followed and the duties of the first and second Control Bodies (paragraphs 29 to 31 of the draft Guidance Note for Organic Control Bodies refers).

2.11 The draft Guidance includes timescales for different parties informing each other of the findings, undertaking investigations and providing results. This includes a requirement that the second Control Body informs the first Control Body of the findings within two working days of being notified of the substantiated suspicion and a requirement that the first Control Body reports the findings of its investigations to the second Control Body within 30 days of being informed of the matter.

Q.7 Do you have any comments on the timescales given for Control Bodies to inform each other of the findings and their investigations?

Actions to be taken where an irregularity or infringement is found

2.12 In accordance with the Regulations[16] the draft Guidance clarifies the procedure that a Control Body must follow where, following investigation, it concludes that the product has been produced in a way that is inconsistent with EU organic production methods (known as an irregularity or infringement). In such cases, the Control Body must remove the EU organic status of the entire lot or production run affected by the irregularity where this is proportionate to the nature and circumstances of the irregularity or infringement.

2.13 In cases where the infringement is more severe or the impact of the infringement will have a prolonged effect, the Control Body should prohibit the operator concerned from marketing organic products for a period to be agreed with Defra. This might involve an

[14] Article 91(1) of Commission Regulation (EC) 889/2008 laying down detailed rules for the implementation of Council Regulation 834/2007.

[15] Article 31 of Council Regulation (EC) 834/2007 on organic production and labelling of organic products

[16] Articles 30(1) and 30(2) of Council Regulation (EC) 834/2007 on organic production and labelling of organic products

operator further up the supply chain from where the original testing took place (e.g. the product was tested at the processing stage but the prohibited product was added during the production stage) and where this operator is certified by another Control Body, the relevant Control Bodies involved in the case should discuss the matter and consider a suitable period of prohibition which is to be agreed with Defra. Such periods of prohibition should be considered on a case-by-case basis.

2.14 The Regulations[17] require information on irregularities or infringements affecting the organic status of a product to be shared between Control Bodies and the Competent Authority. The draft Guidance provides further detail on what details should be shared, including details of the operator/ product concerned, details of the infringement or irregularity and the date on which the organic status of the product was withdrawn (paragraphs 36 and 37 of the draft Guidance Note for Organic Control Bodies refer). It also sets a deadline of two working days of the organic status of the product being withdrawn for the information to be shared.

Q.8 Do you have any comments on the details that should be shared and the proposed timeframe for doing so?

Section 3 – guidance for organic operators

Testing

3.1 The draft Guidance identifies the checks and self-risk assessments that organic operators might be required to undertake as part of their normal business pattern. This includes testing for quality, shelf life and pesticides. The draft Guidance also recognises other types of tests and audits that operators might need to undertake, including questionnaires and audits when supplying a product to major retailers or the identification of possible points within their system where contamination may occur or potential risks to organic management requirements. The checks, tests and audits identified are listed in paragraphs 1 to 4 of the draft Guidance Note for organic operators.

Q.9 Do the checks, tests and audits reflect those that, in your experience, are undertaken by operators as a normal part of their business?

3.2 In accordance with the principles of mutuality and equivalence outlined in paragraphs 1.8 and 1.9 of this document, the draft Guidance makes it clear that where a product has been previously certified as EU organic by a Control Body, an operator must not test the product to assess its organic integrity. However, an operator may test the product where they have a suspicion that it may contain a prohibited substance or where the product's physical characteristics have changed since it was certified.

[17] Article 30(2) of Council Regulation (EC) 834/2007 on organic production and labelling of organic products

Taking samples of products for testing

3.3 The draft Guidance clarifies that the organic Control Body is responsible for taking samples of products for testing but there are actions that the operator is expected to undertake as part of the procedure. These are set out in the draft Guidance Note for organic operators (paragraphs 5 to 8 refer) and include the need to make traceability information for the products to be sampled readily available (such as the batch number of the product, details of the supplier and delivery documents). The operator should also be present when the samples are taken, bagged and sealed in order to answer any questions, provide any additional information requested and as a witness.

Q.10 Do you have any comments on the proposed actions that operators should take when samples are taken?

Querying the results of sampling and analysis

3.4 Regulation 882/2004[18] permits operators to query the results of any testing that is carried out on their products and to ask for a supplementary expert opinion. Where the operator requests a supplementary expert opinion, the draft Guidance requires the Control Body to undertake further analysis of the product, including the analysis of another available sample. Alternatively, the operator may arrange for further analysis itself, but any analysis undertaken would need to comply with the requirements of the Regulations.

3.5 The draft Guidance clarifies the procedure and timescales that should be followed in the UK when operators query the results of testing. This includes the requirement for the operator to inform its Control Body of a wish to query the result no later than 48 hours after being notified of the outcome; the requirement for the Control Body to set out to the operator how it intends to take the query forward and the need for the Control Body to inform the operator of the results of further analysis within 24 hours of receiving the results. The cost of this further analysis may be recovered from the operator where the same or similar results are obtained.

Q.11 Do you have any comments on the proposed procedure and the timescales involved for when an operator queries the results of a test?

Substantiated suspicion that a product contains a prohibited substance

3.6 In accordance with the Regulations[19], the draft Guidance sets out the procedure that an operator must follow when it suspects that a product it has produced, prepared, imported or received from another operator is not in compliance with organic production rules. Such a suspicion might arise from the testing referred to in paragraph 3.1 above, a

[18] Article 11(5) and (6) of Regulation 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

[19] Article 91(1) of Commission Regulation (EC) 889/2008 laying down detailed rules for the implementation of Council Regulation 834/2007.

visual inspection of the product (which indicates that contamination might have occurred) or reliable information received from another source e.g. a member of the public. In such cases, the operator must inform its organic Control Body immediately and will normally be expected to investigate the matter further, keeping the Control Body informed of progress. The operator will only be able to sell the product as organic once it has submitted to the Control Body satisfactory evidence that the doubt has been eliminated. The operator must inform the Control Body if it is unable to provide satisfactory evidence that the doubt has been eliminated.

3.7 Where a Control Body receives the results of permissible testing, the Control Body must follow the procedures referred to in paragraph 2.8 of this document. The operator is expected to assist in the investigation of such results[20]. Operators will be informed of the test results and will have a chance to comment on the findings. If the operator is unable to provide a satisfactory explanation of the findings, it may be forbidden from marketing the product as EU organic for a defined period while investigations continue. The operator must co-operate fully with any investigation undertaken by the Control Body including the provision of information and documents. The draft Guidance for organic operators sets out the procedures that operators should follow in paragraphs 16 and 17.

Q.12 Do you have any comments on the proposed procedures that operators should follow when there is a substantiated suspicion?

Actions to be taken where an irregularity or infringement is found

3.8 The draft Guidance sets out the action that should be taken by the Control Body where an irregularity or infringement is found, including action that should be taken where a severe or prolonged infringement has been found (paragraphs 2.12 to 2.14 of this document refer). The operator must comply with the actions taken by the Control Body.

Section 4 – adoption of “trigger levels” for the investigation of prohibited substances on organic products

4.1 We wish to consult on the option of adopting “trigger levels” for the investigation of prohibited substances on organic products. This is currently not included in the draft Guidance but we would welcome your views on whether you think such an approach should be adopted and, if so, how it should work.

4.2 A trigger level is a mg/kg level of a prohibited substance at which an investigation into the presence of that substance should be undertaken. If Defra established trigger

[20] Article 4 of Regulation (EC) No 882/2004 requires such assistance.

levels for the investigation of prohibited substances, the presence of a prohibited substance above the trigger level would require further investigation while any level below that trigger level would not require further investigation even where it is above the Limit of Detection[21].

4.3 The introduction of trigger levels for different products and substances would enable organic Control Bodies to focus resources on investigating residues of prohibited substances that are more likely to result from practices that are inconsistent with organic production methods. It would also ensure consistency across the UK, better understanding of the framework by operators and eliminate the scope for disagreements over what are the appropriate thresholds.

4.4 We would also welcome your views on including a requirement that no more than two prohibited substances should be present in a product and if this number is exceeded, regardless of the level, further investigation would also be necessary.

Q.13 Do you have any views on the adoption of trigger levels for the further investigation of products?

Q.14 Do you have any views on including a requirement that no more than two prohibited substances should be present in a product and if this number is exceeded regardless of the level, further investigation would also be necessary?

4.5. We have identified four options for investigation of prohibited substances, which are set out in more detail below.

Option 1 – specific trigger levels for different organic products and prohibited substances

4.6 Under this proposal, Defra, in conjunction with technical experts would set specific trigger levels for particular prohibited substances on particular organic products. This would involve Defra working with technical experts to determine which prohibited substances might be present in which organic products and coming up with a suitable trigger level for the further investigation of the residue. This would be based on the levels at which prohibited substances in particular organic products are deemed to be accidental and present no risk to the integrity of the organic Regulations.

4.7 If the trigger level was not exceeded, no investigation would be necessary even where it is above the Limit of Detection. However, if the trigger level was exceeded, the Control Body would have a “substantiated suspicion” that the product had not been

[21] The Limit of Detection is the smallest concentration or amount of a substance or product that, under analysis, can be reliably shown to be present in a product.

produced in compliance with the EU organic standards and further investigation would be required.

4.8 The advantage of this option is that it would be specifically tailored to prohibited substances on particular organic products. However, having so many trigger levels for different substances on different products is not a straightforward system and there is a risk of confusion to organic Control Bodies and operators.

Q.15 Do you have any comments on the setting of trigger levels for different organic products and prohibited substances?

Option 2 – trigger levels based on BNN values

4.9 BNN values were developed in Germany for the investigation of residues of prohibited substances in organic products by the organic processors' and traders' association, Bundesverband Naturkost Naturwaren Herstellung und Handele.V ('BNN').

4.10 BNN values are as follows:

The trigger level is 0.010 mg/kg for all residues of prohibited substances in organic products with an adjustment made for dehydrated products. The trigger level of 0.010 mg/kg would be adjusted in proportion to the dehydration factor of a product with a further adjustment factor of 25% to account for any testing inaccuracies. Therefore, if a product is dehydrated by a factor of 4, the trigger level for that product would be 0.050mg/kg (i.e. 0.010 multiplied by 4 with a +25% adjustment).

4.11 If the trigger level was not exceeded and no more than two prohibited substances were detected in the product, investigation would not be necessary. However, if the trigger level was exceeded in one or more prohibited products, the Control Body would have a "substantiated suspicion" that the product has not been produced in compliance with the EU organic standards and further investigation would be necessary. Further investigation would also be necessary if three or more prohibited substances were detected below the trigger level in the product.

4.12 The advantage of adopting BNN values as the trigger level is that they are used by a number of organisations in several EU Member States, including Germany, the Netherlands, France, Luxembourg, Austria and Spain and it would bring the UK in line with the current practice in those Member States. BNN values are also relatively simple to apply as they are the same for all prohibited substances (with an allowance for dehydrated products). However, the trigger value of 0.010mg/kg does not distinguish between different products and substances and it might be that this level results in unnecessary investigations of some products while other products containing low levels of residues are not investigated.

Q.16 Do you have any comments on setting trigger levels based on BNN values?

Option 3 – setting trigger levels that are a proportion of the MRL

4.13 Under this proposal, the trigger level for the investigation of residues of prohibited products or substances in organic products would be a proportion (15%) of the MRL. The MRL for food that is dehydrated is based on the MRL for the fresh food and then adjusted by a processing factor. The trigger level for dehydrated foods would therefore be 15% of the adjusted MRL.

4.14 If the trigger level was not exceeded and no more than two prohibited substances were detected in the product, investigation would not be necessary even where it was above the Limit of Detection. However, if the trigger level was exceeded in one or more prohibited products, the Control Body would have a "substantiated suspicion" that the product has not been produced in compliance with the EU organic standards and further investigation would be necessary. Further investigation would be necessary if three or more prohibited substances were detected at levels below the trigger level in the product.

4.15 The advantage of this option is that it would enable the trigger level to adjust to different types of product and substance according to the MRL. Having a trigger level of 15% of the MRL means that low levels of residues resulting from deliberate use would be picked up but there may be cases where the MRL is only slightly higher than the Limit of Detection, meaning that 15% of the MRL falls below the Limit of Detection. However, it is acknowledged that this "differential" approach might be more complex to administer.

Q.17 Do you have any comments on setting trigger levels that are a proportion of the MRL? Do you have any views on setting the trigger level at 15% of the MRL?

Option 4 – investigation of all positive test results (no trigger levels)

4.16 Under this option, any positive test result would lead to a "substantiated suspicion" that the product had not been produced in compliance with the EU organic standards and further investigation would be necessary.

4.17 The advantage of this option is that a suitable procedure for setting trigger levels would not be required and Control Bodies would not need to take trigger levels into consideration when analysing test results. This option would also capture all contamination of organic products and reduce the risk of unscrupulous operators diluting their products so they show levels of contamination below the trigger level. However, adopting this approach would lead to an increased number of investigations, some of which may be unnecessary and the associated costs of this. It would also ignore the fact that the EU Regulations include a degree of tolerance for unavoidable contamination caused by prohibited substances.

Q.18 Do you have any comments on investigating all positive test results (i.e. setting no trigger levels)?

Q.19 Do you have any other suggested approaches to adopting "trigger levels"?

Annex A – List of Questions

Q1, Do you have any views on the costs associated with the draft Guidance? Do you have any views on how the trigger threshold options set out in Section 4 of this document might affect costs?

Q.2 Do you have any comments on the criteria for gaining a suspicion? Are they the right criteria for this purpose?

Q.3 In order to produce an approach that is acceptable to the sector as a whole, do you have any views and proposals on alternative sampling methods?

Q.4 Do you have any comments on the proposed procedure for testing livestock and the current limitations for testing the actual animal?

Q.5 We understand that there are some analytical differences between different laboratories. These differences are only slight but they could be significant where small quantities of residue are being analysed. Do you have any views on whether this is a significant issue and if so how it might be addressed?

Q.6 Do you have any views on the investigative actions that might be undertaken, in particular how the investigative process might assess whether the level of prohibited substance is consistent with actual use of the substance as opposed to unavoidable contamination?

Q.7 Do you have any comments on the timescales given for Control Bodies to inform each other of the findings and their investigations?

Q.8 Do you have any comments on the details that should be shared and the proposed timeframe for doing so?

Q.9 Do the checks, tests and audits reflect those, that in your experience, are undertaken by operators as a normal part of their business?

Q.10 Do you have any comments on the proposed actions that operators should take when samples are taken?

Q.11 Do you have any comments on the proposed procedure and the timescales involved for when an operator queries the results of a test?

Q.12 Do you have any comments on the proposed procedures that operators should follow when there is a substantiated suspicion?

Q.13 Do you have any views on the adoption of trigger levels for the further investigation of products?

Q.14 Do you have any views on including a requirement that no more than two prohibited substances should be present in a product and if this number is exceeded regardless of the level, further investigation would also be necessary?

Q.15 Do you have any comments on the setting of trigger levels for different organic products and prohibited substances?

Q.16 Do you have any comments on setting trigger levels based on BNN values?

Q.17 Do you have any comments on setting trigger levels that are a proportion of the MRL? Do you have any views on setting the trigger level at 15% of the MRL?

Q.18 Do you have any comments on investigating all positive test results (i.e. setting no trigger levels)?

Q.19 Do you have any other suggested approaches to adopting “trigger levels”?