European Commission

DG Health and Food Safety

Overview report

Pesticide Residue Control in Organic Production

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Luxembourg: Publications Office of the European Union, 2017

Electronic version
ISSN 2315-2168
ISBN 978-92-79-53001-2
doi:10.2875/35178
Catalogue number: EW-BC-15-051-EN-N

Paper version:
ISBN 978-92-79-53000-5
doi:10.2875/234104
Catalogue number: EW-BC-15-051-EN-C

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2016-8986 - MR

OVERVIEW REPORT

ON A SERIES OF AUDITS CARRIED OUT

IN EU MEMBER STATES

TO EVALUATE PESTICIDE RESIDUE CONTROL SYSTEMS IN ORGANIC PRODUCTION

2015-2016

Executive Summary

This overview report describes the results of a project of the European Commission's Directorate-General for Health and Food Safety to evaluate the official controls for pesticide residues in organic production. The project consisted of a questionnaire sent to all Member States, followed by a series of five audits carried out in 2015 and 2016.

The report concludes that there is comprehensive risk based sampling along the food chain, with numbers significantly exceeding the level of sampling required by EU legislation. This provides a sound basis to control pesticide residues in organic production and to identify and investigate any issues detected. Good communication between competent authorities within the Member States improves the understanding of pesticide related questions and contributes to the effectiveness of controls.

Nevertheless, the official instructions on the implementation of pesticide residue controls specific to organic production were often not sufficiently detailed and clear. The report highlights the lack of official sampling procedures in the production stages at Member State level, and the absence of defined criteria for the scope and sensitivity of laboratory analyses to be carried out. The absence of clear official criteria for the interpretation and follow-up of pesticide residue detections impedes consistent treatment regarding compliance with organic production rules. These shortcomings impact negatively on the effectiveness of controls. The inconsistency of compliance criteria impacts on enforcement, the EU single market and the import of organic products from non-EU Countries.

The evaluation of replies to the questionnaires received from EU competent authorities and laboratories is annexed to the report.

Table of Contents

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
EU	European Union
EURL	EU Reference Laboratory
GC	Gas Chromatography
ISO	International Organisation for Standardisation
LC	Liquid Chromatography
LOQ	Limit of Quantification: The lowest concentration or mass of the analyte that has been validated with acceptable accuracy by applying the complete analytical method. In Regulation 396/2005, MRLs that are set at the limit of quantification/determination are referred to as "LOD MRLs". For this report, the use of the term LOQ was used instead of LOD because it avoids possible confusion with "limit of detection".
MRL	Maximum Residue Level
NAB(s)	National Accreditation Body(ies)
NRL	National Reference Laboratory

1 INTRODUCTION

This overview report describes the results of a project of the European Commission's Directorate-General for Health and Food Safety aiming to help Member States to improve the effectiveness of pesticide residue controls specific to organic production.

Organic production is a system of farm management and food production that combines best environmental practices, a high level of biodiversity, the preservation of natural resources, the application of high animal welfare standards and a production method using natural substances and processes. The use of pesticides is significantly restricted, but certain plant protection products are allowed under well-defined conditions. Pesticide residue testing is one aspect of official controls on organic production. The control authorities or control bodies[1] must take and analyse samples for detecting products not authorised for organic production, for checking production techniques not allowed under organic production rules or for detecting possible contamination by products not authorised for organic production. Since January 2014, Article 65 of Regulation (EC) No 889/2008 requires that the number of samples to be taken and analysed by the control authority or designated control body every year shall correspond to at least 5% of the number of operators under its control. The selection of the operators where samples have to be taken shall be based on the risk of non-compliance with the organic production rules. No criteria are established at EU level for the sampling procedures of organic products, the pesticides to be included in these checks, or the sensitivity of methods.

The project of the European Commission's Directorate-General for Health and Food Safety consisted of a questionnaire sent to Member States, followed by a series of five audits. The questionnaire was sent to Member States in December 2014. It consisted of two parts: the first was addressed to the competent authorities for pesticide residues tests in organic production, while the second was addressed to laboratories analysing samples taken in these controls. A total of 25 Member States replied, and a total of 115 laboratories provided responses regarding the analyses undertaken. The analysis of responses to the questionnaire was summarised in a separate report, which was circulated to Member States in the Committee on Organic Production in December 2015, and which is attached as Annex 3.

The audits were undertaken from January 2015 to April 2016. Most audits were of one week duration and usually involved a team of two auditors and one national expert from a Member State. The programme involved meetings with central and/or regional authorities, visits to

[1] Under EU legislation on organic production, the competent authority, while retaining overall responsibility for organic controls, may delegate all or part of its control tasks to one or more private control bodies that it approves and supervises, or confer all or part of its control responsibility to one or more public control authorities. A mixed system (private control bodies and public control authorities) is also possible.

control bodies and control authorities, and laboratories undertaking analyses of pesticide residues in samples from organic production.

Details of the individual audit reports are provided in Annex 2 and are published on the Directorate-General for Health and Food Safety website: http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

This overview report describes the main findings and conclusions of the individual audit reports, together with examples of good practices and recommendations made to Member States, aimed at rectifying the shortcomings identified and enhancing implementation of the control measures in place and the effectiveness of the control system.

Obviously, this report can only reflect the status observed at the time of the audits, although some systems have improved in the meantime, based on recommendations made and on the general feedback given to Member States in the Committee on Organic Production.

The project was carried out with the assistance of the EU Reference Laboratory for pesticide residues in fruit and vegetables, located in Almeria, Spain.

2 OBJECTIVES AND SCOPE

The objectives of the project was to evaluate the official controls for pesticide residues in organic production, in particular the implementation of the requirements set out in Council Regulation (EC) No 834/2007 on organic production and Commission Regulation (EC) No 889/2008 which lays down implementing rules.

Particular attention was paid to the following areas:

- Competent authorities, control authorities and control bodies
- Sampling for detecting unauthorised products at organic operators
- Laboratory performance
- Measures in case of irregularities and infringements

3 LEGAL BASIS

Individual audits within this series were carried out based on Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council.

A full list of the legal instruments referred to in this report is provided in Annex I and refers, where applicable, to the last amended version.

4 BACKGROUND

4.1 PESTICIDE RESIDUE CONTROL IN ORGANIC PRODUCTION

In addition to this specific series of audits, DG Health and Food Safety also carried out a separate series of audits on organic production and labelling of organic products. This series covered a wider scope of EU legislation on organic production. The audits were carried out in Member States, as well as in non EU countries, and on control bodies operating in non EU countries which are recognised for the import of organic products into the European Union. Three overview reports of these audits are published, together with the reports of the individual audits, on the website of DG Health and Food Safety:

http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

4.2 PESTICIDE RESIDUE CONTROL IN CONVENTIONAL PRODUCTION

National and EU control programmes for pesticide residues in food are established under Chapter V of Regulation (EC) No 396/2005 of the European Parliament and of the Council. These programmes aim at assessing consumer exposure and ensuring compliance with maximum residue levels (MRLs) set for pesticide residues. The programmes focus on conventional production, but include a small number of samples from organic production.

A number of EU provisions were developed to ensure quality and effectiveness of these controls:

- Sampling procedures are specified in Commission Directive 2002/63/EC;
- The multi-annual EU pesticide residue control programmes specify which pesticides shall be included in the analyses. The control programme for 2016 was laid down in Commission Regulation (EU) 2015/595;
- The EU Reference Laboratories (EURLs) provide advice to National Reference Laboratories (NRLs) and official control laboratories. The EURLs also run proficiency tests for the laboratories, comprising multi-residue methods and single-residue methods. The pesticides included in the EU proficiency tests are aligned with the EU pesticide residue control programmes.
- The Guidance Document on Analytical Quality Control and Method Validation Procedures for Pesticide Residues Analysis in Food and Feed (SANTE/11945/2015)[2] is a collection of best practices, to be applied by pesticide residue laboratories analysing samples under Regulation (EC) No 396/2005. The Guidance document is revised every two years, taking into account technical and scientific development. The revisions of the document are co-ordinated by the EU Reference Laboratories (EURLs) for pesticide residues;

[2] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_wrkdoc_11945.pdf

Between 2007 and 2011, DG Health and Food Safety carried out a separate series of audits on pesticide residue controls under Regulation (EC) No 396/2005. The Overview Report is also available on the website of DG Health and Food Safety (see link above).

5 OVERVIEW OF MAIN FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES, CONTROL AUTHORITIES AND CONTROL BODIES

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 on designation of competent authorities and operational criteria;

Article 6 of Regulation (EC) No 882/2004 on staff performing official controls;

Article 27 of Regulation (EC) No 834/2007 on control system;

Article 92 of Commission Regulation (EC) No 889/2008 on exchange of information between control authorities, CBs and CAs.

Findings

1. The roles and responsibilities of competent authorities, control authorities, control bodies and the National Accreditation Bodies (NABs) were clearly described.
2. There was evidence of regular co-ordination and communication within and between authorities at all levels, through meetings, notes and guidance. Where relevant, co-ordination between regional authorities for organic production was established at national level through co-ordination groups.
3. Good communication was also seen between the competent authorities for organic production and the authorities responsible for implementation of the food safety control programmes for pesticide residues under Regulation (EC) No 396/2005. The latter authorities have provided analytical results of food safety samples to the authorities for organic production. The authorities for food safety controls have more experience with the interpretation of laboratory results on pesticide residues, and assist the authorities for organic production accordingly. For example, this was seen in relation to recurrent findings of the pesticides chlormequat in cereals, and pendimethalin and triallate in vegetables from areas surrounded by conventional cereal production. The co-operation helped the authorities for organic production to better understand the properties of these pesticides, and to decide whether sufficient precautionary measures were taken by the organic operators.
4. In Germany, the food safety control authority in one of the Länder operates a substantial monitoring programme on organic products, and regularly provides expertise in pesticide residue analysis and assessment of pesticide residue detections to the authority for organic production. This helps with decision making on possible unauthorised uses of pesticides, and the adequacy of precautionary measures, and is seen as a good practice.
5. There were also examples of communication on samples taken from organic production at import controls.

Conclusions on Competent Authorities, Control Authorities and Control Bodies

6. The good communication between the authorities improves the understanding of the pesticide residue related questions and contributes to the effectiveness of the controls.

5.2 SAMPLING FOR DETECTING UNAUTHORISED PESTICIDES AT ORGANIC OPERATORS

Legal Requirements

Article 65(2) of Commission Regulation (EC) No 889/2008 on control visits;

Findings

7. The replies to the questionnaire sent to all Member States showed that over 22,000 samples were taken in official controls of organic production by competent authorities, control authorities and control bodies per year.
8. In all Member States audited, control bodies/authorities had started sampling programmes for pesticide residues in line with Regulation (EC) No 889/2008. In almost all cases they complied with the legal requirement that the number of samples to be taken and analysed every year shall correspond to at least 5% of the number of operators under their control.
9. Samples were generally taken across the production and processing chain, based on the identified risks. In addition to food and feed, a substantial number of samples were taken from leaves and soil. This sampling approach can achieve effective control, because it extends the scope of the checks to the production process.
10. In two of the Member States visited, the regional competent authorities operated additional official sampling programmes to verify the effectiveness of sampling programmes of control bodies/authorities.
11. In four of the Member States visited, agreed guidance documents were in place on procedures for taking pesticide residue samples in organic production. The guidance was included in the standard operating procedures of the control bodies/authorities.
12. In these four guidance documents, references were made to sampling procedures laid down in Directive 2002/63/EC on sampling procedures for food products on the market, with details on the numbers of primary samples, and the minimum weight and number of food units (for example one kilogram of apples, at least ten pieces) to obtain a representative laboratory sample. However, the audits found that frequently the samples did not contain the required minimum weight and unit numbers. This was due to the fact that staff in charge of sampling had not understood the minimum sampling requirements.
13. There were often no official procedures in place on how samples should be taken during the production in fields, orchards, vineyards or greenhouses, such as samples of leaves, soil and water. However, the precise conditions of sampling (location, weight, number of units) influence the likelihood that pesticide residues are found. For example, there were often no instructions on how many leaves have to be collected for a sample, and in which part of the plant (inner/outer leaves), and field, the sample should be taken. Similarly, the sampling procedures were not suitable to identify spray drift of pesticides from neighbouring plots with conventional production, or consider that residues from spray drift are generally restricted to the edges of the fields. Notably, Member States reported that one third of all samples containing pesticide residues relate to spray-drift from

neighbouring plots, but the sampling procedures in place were often not suitable to support this assumption.

14. Good practices observed at control bodies were:
    a. Control staff noted pesticides of particular concern in the request for analysis, which is helpful for the laboratory;
    b. The potential for spray drift from neighbouring fields was noted in the sampling form, with a simple map showing neighbouring crops and wind direction. This can help with interpretation and follow up of the laboratory report.

Conclusions on sampling for detecting unauthorised pesticides at Organic Operators

15. The number of samples taken for pesticide residue analysis in official controls of organic production complied with EU legislation and demonstrates a high level of control.
16. A lack of official procedures for sampling during the production process, and weaknesses with implementation of sampling procedures by control staff, pose a risk that the interpretation of laboratory results is affected by a sampling procedure which is not fit for its purpose.

5.3 LABORATORY PERFORMANCE

Legal Requirements

Article 5 of Regulation (EC) No 882/2004 on delegation of specific tasks related to official controls;

Article 12 of Regulation (EC) No 882/2004 on official laboratories;

Article 33 of Regulation (EC) No 882/2004 on national reference laboratories.

Guidelines

Guidance Document (SANTE/11945/2015).

Findings

17. The replies to the questionnaires showed that only 40 % of authorities designate laboratories for the analyses of organic samples. Consequently, the competent authority oversight of the laboratories used for analyses of pesticide residues in organic production varied: Two of the Member States had officially designated the laboratories used for pesticide residue analysis in organic production. In two other Member States, the laboratories were not officially designated, but control bodies notified their use to the competent authorities. In the fifth Member State, the competent authority was not aware of which laboratories were being used by the control bodies.
18. The replies to the questionnaires also showed that a large proportion of the laboratories analysing samples from organic production (66 %) were not part of the network of National Reference Laboratories (NRLs) for pesticide residues. This meant that they would not take part in the laboratory network co-ordinated by the NRLs and the EU Reference Laboratories (EURLs), including the possibility to participate in the relevant

proficiency tests organised by the EURLs. The audits conformed that many of the laboratories had not been notified to the respective NRLs.

19. Only some of the laboratories participate in the proficiency tests organised by the EURLs. These proficiency tests include single residue methods and multi-residue methods with a very broad scope. Their results allow for a comprehensive conclusion about the competence of the participating laboratories.

20. All laboratories were accredited and regularly assessed by the NABs. In two of the five Member States visited, the NABs considered the Guidance Document on Analytical Quality Control and Method Validation Procedures for Pesticide Residues Analysis in Food and Feed (SANTE/11945/2015) as technical requirements in the accreditation process of laboratories to ISO/IEC 17025:2005. This was seen as a good practice as it helped to achieve a consistent level of quality control procedures for pesticide residue analysis.

21. The laboratories had state-of-the-art equipment in place, which allows for a broad range of pesticides to be analysed. Nevertheless, the competent authorities had often not specified their requirements as to which pesticides the laboratories should include in their analysis. Single residue techniques were often requested by the control bodies in cases of suspicion, but not in routine control. Multi-residue analyses combining both liquid chromatography (LC) and gas chromatography (GC) techniques were often not requested from the laboratory, except in particular cases of higher risk. In consequence, GC was used as the only laboratory detection technique in many cases.

22. In this context it should be noted that analysis by GC techniques is not suitable to detect modern polar (water-soluble) pesticides, which are widely used by conventional farmers. Neither is an LC technique suitable to detect many of the relevant pesticides used in conventional production. Finally, some relevant pesticides cannot be detected by a multi-residue method, and a single-residue method is required for their analysis.

23. The equipment in the laboratories technically allows for high sensitivity of analytical methods. Nevertheless, the audits identified laboratories where the sensitivity of methods applied referred to the EU maximum residue level (MRL) for conventional food, rather than to lower values which can result from unauthorised use of pesticides in organic production. In these laboratories, many limits of quantification (LOQs) were chosen at the MRL for conventional food, although the laboratory had the technical qualification for lower LOQs.

Conclusions on laboratory performance

24. The laboratories used for the analysis of samples from organic production have equipment which allows for methods with a broad range of pesticides and high sensitivity. Nevertheless, the full capability of the laboratories is often not satisfactorily used for samples from organic production. This can be attributed to the lack of clear official specifications on the analyses to be performed.

25. The lack of official specifications for the scope of analyses to be carried out impacts negatively on the control system: as gas chromatography is used as the only laboratory detection technique in many cases, the analyses do not include many of the relevant pesticides.

26. The lack of notification of laboratories to the NRLs obstructs the important exchange of relevant information and knowledge provided by the network of NRLs and EURLs, and

the participation in official proficiency tests.

27. The consideration of the Guidance Document on Analytical Quality Control and Method Validation Procedures for Pesticide Residues Analysis in Food and Feed (SANTE/11945/2015) helps to achieve a consistent level of quality control procedures for pesticide residue analysis.

5.4 MEASURES IN CASES OF PESTICIDE RESIDUE DETECTIONS

Legal Requirements

Article 54 of Regulation (EC) No 882/2004 on action in case of non-compliance;

Article 55(1) of Regulation (EC) No 882/2004 on sanctions;

Article 30 of Regulation (EC) No 834/2007 on measures in case of infringements and irregularities;

Article 91 of Commission Regulation (EC) No 889/2008 on measures in case of suspicion of infringements and irregularities;

Article 92 of Commission Regulation (EC) No 889/2008 on exchange of information between control authorities, control bodies and competent authorities;

Article 92(d) of Regulation (EC) No 889/2008 on catalogue of measures in case of irregularities and infringements.

Findings

28. The replies to the questionnaires indicated that 8.48 % of the samples taken contained pesticide residues. Regulation (EC) No 889/2008 allows the use of a small number of pesticides in organic production, and some of the pesticide detections relate to such authorised use. In total, 5.8% of the operators sampled were found to be non-compliant.

29. In their replies to the questionnaires, Member States reported that 2.86 % of samples contained pesticide residues which were related to non-authorised use of pesticides. In another 2.93 % of samples, the pesticide residues identified were reported to relate to spray drift from neighbouring plots. For another 2.69 % of samples, the pesticide findings were stated to relate to other reasons. The reasons reported were cross-contamination through containers or storage boxes, contamination through imported organic ingredients, contamination through soil or ground water or inadequate sampling procedure (see paragraphs 11 and 12). In cases of low residue levels, some control bodies did not investigate the reasons (see paragraphs 34 and 35). In many cases, the reasons were stated to be unknown (see paragraph 41).

30. The competent authorities of the Member States audited have adopted and communicated to control bodies catalogues of measures in case of irregularities and infringements, in line with Article 92d of Regulation (EC) No 889/2008. The audits confirmed that competent authorities, control authorities and control bodies take action against non-compliant operators in line with the national catalogues.

31. The measures established by the competent authorities and applied by the control authorities/bodies differ considerably, as described in the following paragraphs:

Investigation threshold or action levels

32. Only in some Member States and control authorities/bodies, all results above the Limits

of Quantification (LOQ) lead to investigations to establish whether there was an unauthorised use of a pesticide and whether sufficient precautionary measures are in place against accidental contamination, such as spray drift of pesticides from neighbouring fields.

33. The LOQs applied on organic produce varied between laboratories (see paragraph 23), and this variation means that the threshold to trigger investigation varies in practice. Nevertheless, the LOQ in place in the majority of laboratories was 0.01 mg/kg.

34. Some control bodies initiate investigations only for results above 0.02 mg/kg, arguing that when they account for measurement uncertainty of 50 %, results between 0.01 and 0.02 mg/kg would not be quantifiable with an LOQ of 0.01 mg/kg. This is technically incorrect, as any result above the LOQ can be quantified. The lack of investigations for results above the LOQ is contrary to Article 30 of Regulation (EC) No 834/2007 and Article 91 of Commission Regulation (EC) No 889/2008.

35. Similarly, some control bodies apply processing factors to the analytical results for processed products. For such products, e.g. dried spices, the residue level is calculated back to the original material. This way, a factor of up to 10 was applied to dried products, and no investigation was started if the analytical result, after application of the processing factor, is at or below 0.02 mg/kg. The use of generic processing factors is technically incorrect: depending on the properties of the pesticides and the process, the pesticide level can become higher or lower during the processing stages.

Investigation

36. In most of the Member States audited, official guidelines with instructions were in place regarding the investigations to be conducted in case of pesticide residue detections. These guidelines provided general principles for control authorities/bodies on how to proceed in these cases, and sometimes substantial information to help with interpretation of residue detections.

37. During the investigations, the organic produce is blocked and not certified, in line with Article 91 of Regulation (EC) No 889/2008. At one control body, any level of pesticide residues above the LOQ is investigated, but only results above 0.02 mg/kg lead to blocking of the consignment.

38. The level and nature of investigations varies between control bodies and Member States. In some control bodies, low levels of residues (e.g. 0.01 - 0.02 mg/kg), lead to a letter being sent to the organic operator, informing them of the result, and asking for an explanation. No on-the-spot investigations at the operator are carried out for such low residue levels.

39. Pesticide residues were often detected on leaves. Some control bodies applied mathematical models to pesticide residue concentrations detected on leaves, to determine whether the concentration is likely to result from unauthorised pesticide use, and taking into account data from field trials. Where the pesticide residue concentration is below a calculated level, the detection is considered to result from spray drift from neighbouring fields.

40. Spray drift from neighbouring fields, and other reasons for contamination with pesticide residues, are considered acceptable in some Member States, if sufficient precautionary measures are taken to prevent such contamination. However, no official criteria existed to decide on the adequacy of precautionary measures, and the decision commonly depends on a case-by-case judgment by experts in the control authorities/bodies. While a case-by-

case approach allows for flexibility, it also means that no consistent rules apply.

41. Some of the control authorities/bodies stated that systematic on-the-spot investigations take place, to follow up case-by-case all detections of pesticide residues. Such investigations included visits to neighbouring conventional farms, the taking of additional samples, and inspections of pesticide records of these neighbouring farms. However, control body staff stated that such on-the-spot investigations can be very labour intensive and are not always conclusive.

Enforcement

42. In two Member States visited all detections of pesticide residues above the LOQ lead to enforcement action and sanctions. This approach ensures that irregularities/infringements of the same nature and seriousness are treated uniformly.

43. Measures were always taken when irregularities and infringements were identified. None of the five Member States visited had fixed residue limits in place above which enforcement action was to be taken.

Reporting to competent authority

44. Procedures were in place for control authorities/bodies to regularly inform the competent authorities of pesticide residue results. Detections of unauthorised pesticides have to be notified immediately to the competent authority, and in one Member State an IT application was established for better communication.

Conclusions on measures in cases of pesticide residue detections

45. The sampling programmes for pesticide residues in organic production are a suitable tool to identify issues related to pesticide residues.

46. The fact that measures applied in case of pesticide residue detections differ considerably across the EU leads to inconsistent enforcement action. This was particularly evident for low levels of pesticide residues: These are investigated by control authorities/bodies in some Member States and enforcement action is taken systematically, while control authorities/bodies in other Member States neither investigate nor apply sanctions for low residue levels.

47. Guidelines introduced by the competent authorities provide instructions and extensive technical information to control authorities/bodies which help them investigating pesticide residue detections individually. Due to the lack of clear compliance criteria a consistent treatment of pesticide detections regarding compliance with organic production rules is not ensured.

6 MATTERS FOR CONSIDERATION BY MEMBER STATES

Recommendations addressed to individual Member States were presented in reports specific to those Member States and follow-up is only done in that context. However, in this Overview Report it is appropriate to highlight matters for consideration by all Member States, in light of issues identified during the project and lessons learned:

- Implement clear instructions regarding the sampling procedures for pesticide residue analysis during the production process. Where appropriate, sampling procedures should be suitable to identify spray drift of pesticides from neighbouring plots.

- Specify the requirements for the methodology and scope of laboratory analysis, to facilitate the reliable detection and quantification of the presence of substances not authorised for organic production.

- Ensure that laboratories for pesticides residues in organic production are designated, and their designation is communicated to the National Reference Laboratory (NRL) to facilitate the activities specified in Article 33 of Regulation (EC) No 882/2004.

- Consider the Guidance Document on Analytical Quality Control and Method Validation Procedures for Pesticide Residues Analysis in Food and Feed (SANTE/11945/2015) to achieve a consistent level of quality control procedures for pesticide residue analysis.

- Implement clear instructions on the follow-up of pesticide residue detections.

7 ACTION TAKEN OR ENVISAGED BY THE COMMISSION SERVICES

For each audit a copy of the final report was sent to the competent authorities in the Member State concerned with a request for an action plan indicating the steps envisaged to address the recommendations made in the audit report.

A deadline was set for the receipt of these plans and the response of the competent authority is analysed. Where it is considered that a response did not address the issues raised, the Commission services actively pursued the matter with the authorities.

The Commission regularly monitors the progress on the actions undertaken by the competent authorities to address the recommendations. The outcome of this monitoring activity is described in the Country Profiles which can be found at its website (link provided in section 1). In addition to the follow-up of the audits, the Commission services took, and are regularly taking action, with a view to enforcing the EU legal provisions on organic production and labelling of organic products.

On 24 March 2014, the Commission adopted a legislative proposal for a new Regulation of the European Parliament and of the Council on organic production and labelling of organic products[3].

The proposal aims at improving the existing legislation with the objectives of 1) removing obstacles to the sustainable development of organic production in the Union, 2) guaranteeing

[3] COM(2014)180 final.

fair competition for farmers and operators and allowing the internal market to function more efficiently, and 3) maintaining or improving consumer confidence in organic products. It includes a harmonised approach to tackle the presence of pesticide residues and other non-authorised products and substances in organic production.

The proposal is currently under Inter-institutional discussions.

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 396/2005	OJ L 70, 16.3.2005, p. 1-16	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Reg. 834/2007	OJ L 189, 20.7.2007, p. 1-23	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
Reg. 889/2008	OJ L 250, 18.9.2008, p. 1-84	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
Dir. 2002/63/EC	OJ L 187, 16.7.2002, p. 30-43	Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC
Reg. 2015/595	OJ L 99, 16.4.2015, p. 7–20	Commission Implementing Regulation (EU) 2015/595 of 15 April 2015 concerning a coordinated multiannual control programme of the Union for 2016, 2017 and 2018 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin

ANNEX 2 - DETAILS OF INDIVIDUAL AUDITS

Member State	Dates of Audits	SANTE ref. no.
United Kingdom	26/01 to 30/01 2015	2015-7490
Poland	22/06 to 26/06 2015	2015-7488
Germany	07/09 to 11/09 2015	2015-7491
Spain	08/03 to 15/03 2016	2016-8751
Finland	18/04 to 22/04 2016	2016-8750

The reports on individual audits are published on the Website of DG Health and Food Safety: http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

ANNEX 3

ANALYSIS OF THE REPLIES TO A QUESTIONNAIRE

RECEIVED FROM MEMBER STATES AND LABORATORIES IN 2015

Contents

1 INTRODUCTION

This annex to the overview report provides an analysis of responses to a questionnaire regarding pesticide residue controls in organic production in the EU. The questionnaire was sent to EU Member States in December 2014. The questionnaire consisted of two parts: the first was addressed to the Competent Authorities (CAs) for pesticide residues tests in organic production, while the second was addressed to laboratories analysing samples taken in these controls.

This analysis was circulated to Member States in the Regulatory Committee on Organic Production in December 2015.

2 REPLIES FROM COMPETENT AUTHORITIES

A total of 25 Member States replied to the questionnaires. No replies were received from Bulgaria, Hungary and Slovenia. Due to the regional responsibilities for control in Germany and Spain, these Member States submitted separate regional replies. For this reason, a total of 42 replies were received from Competent Authorities. The authorities were offered to select a period of one year between 2012 and 2014. The periods reported by the authorities differed.

2.1 SAMPLING

2.1.1 Documented procedures

Documented procedures for controls are required under Article 8(1) of Regulation (EC) No 882/2004. The majority of CAs (71 %) have documented procedures in place for sampling organic produce for pesticides residue analysis. For 9.5% of CAs, most procedures were documented while 2.4% declare that only some procedures were documented. Two CAs claimed that they have specific procedures for sampling in accordance with Directive 2002/63/EC, while three others have specific legislation, at national and regional level, in place for the purpose.

The documented procedures adopted by CAs will help with establishing effective pesticide residues controls.

2.1.2 Transport of samples

A total of 64 % of the respondents avoid spoilage of samples by relying on short transport time (less than 24 hours), combined with cooled transport (50% of the cases). No specific requirements are set by almost 20% of CAs. In two cases, laboratories have the responsibility to collect samples. Six respondents (14 %) indicated a transport time between 24 and 48 hours or more. The Guidance SANCO/11945/2015 specifies that samples should preferably be transported to the laboratory within one day, in order to avoid spoilage of samples during transport.

2.1.3 Type of samples

Most CAs reported the sampling of food and feed both in their regular controls and in case of suspicion as showed in table 1. Analysis of plant tissue (leaves) during regular controls was reported by 74 %, while analysis of soil and water is reported to occur more frequently in case of suspicion, rather than on regular basis. CAs also reported occasional analyses of bee wax, bark, animal hair, essential oil, wines and contact materials.

Tab. 1. Percentage of analysis for main items.

Item	Control	Percentage
Food	Regular control	83 %
	In case of suspicion	76 %
	Not carried out	7 %
Feed	Regular control	81 %
	In case of suspicion	74 %
	Not carried out	12 %
Leaves	Regular control	74 %
	In case of suspicion	76 %
	Not carried out	12 %
Soil/water	Regular control	45 %
	In case of suspicion	71 %
	Not carried out	24 %
Other	Regular control	21 %
	In case of suspicion	17 %

2.1.4 Place of sampling

The CAs reported regular sampling at the production and at the processing stage (table 2). Samples at retail stage were reported by 62 % of the authorities, while the figure for reported samples at import is 69 %.

Tab. 2. Percentage of analysis in stages of food chain.

Stage	Control	Percentage
Production	Regular control	86 %
	In case of suspicion	79 %
	Not carried out	5 %
Processing	Regular control	86 %
	In case of suspicion	74 %
	Not carried out	7 %
Retail	Regular control	62 %
	In case of suspicion	55 %
	Not carried out	24 %
Import	Regular control	69 %
	In case of suspicion	62 %
	Not carried out	24 %

2.1.5 Number of samples taken

The figures reported for number of samples per year do not relate to the same year, and the sums are only indicative.

Competent authorities may take directly samples, even if they have conferred controls to Control Authorities or delegated to Control Bodies. A total of 39 % of CAs reported different numbers of samples, while the remainder did not report sampling. In total, over 2,000 samples taken by CAs per year were reported.

A total of 17 % of CAs reported that no samples were taken by Control Bodies or Control Authorities, while 38 % reported between 1 and 100 samples taken per year, 12 % between 100 and 300, and 33 % more than 300 samples. Some of the replies relate to the period before 2014, when there was no minimum number of samples required by EU legislation. In total, over 20,000 samples were taken by Control Bodies and Control Authorities per year, although there was a huge difference in sampling activity between MSs.

The sum of over 22,000 samples taken in official controls of organic production demonstrates a high level of sampling activity.

2.1.6 Reasons reported for positive samples

In total, 658 samples with pesticide residues (2.86 % of the over 22,000 samples taken) were reported to relate to non-authorised use of pesticides.

In another 670 cases (2.93 %), samples with pesticide residues were reported to relate to spray drift from neighbouring plots. For another 617 samples (2.69 %), the pesticide findings were stated to relate to other reasons. The reasons reported were cross-contamination through containers or storage boxes, contamination through imported organic ingredients, contamination through soil or ground water or inadequate sampling procedure. In cases of low residue levels, some Control Bodies did not investigate the reasons. In many cases, the reasons were stated to be unknown.

The total number of operators sampled per year was over 16,000. In total, over 900 of the operators were found to be non-compliant (5.8% of the operators sampled). EU legislation requires that samples are taken based on a risk-analysis, and some of the samples were taken based on concrete suspicion of non-compliance. Therefore, the share of 5.8 % non-compliant operators is not representative.

In summary, broadly two thirds of the pesticide detections could not be related to a non-compliant use of unauthorised pesticides. Article 63(1)(c) of Regulation (EC) No 889/2008 requires that operators draw up and maintain precautionary measures in order to reduce the risk of contamination by unauthorised products or substances. Such measures are to be verified by the Control Authorities or Control Bodies which identify deficiencies and require corrective measures.

This report cannot provide an analysis of the criteria or procedures in place on how to evaluate the pesticide detections for possible non-compliances. No such criteria are

established at EU level. Nevertheless, according to Article 4 of Regulation (EC) No 834/2007, organic production methods are based on risk assessment and the use of precautionary and preventive measures. Regulation (EC) No 834/2007 does not specify residue levels below which no action is required from Control Bodies or Control Authorities. Spray drift from neighbouring plots was attributed to broadly one third of pesticide detections. No EU criteria or guidance are established on how to identify spray drift, and it is assumed that procedures will differ between MSs. Furthermore, the related sampling procedures are not harmonised. Residues from spray drift are generally restricted to the edges of the fields, and to a limited time after the use of pesticides. It is not known whether these samples were taken at the edges of fields, in order to investigate possible spray drift from neighbouring fields.

Considering the high percentage of pesticide detections due to spray drift or other reasons, the operators should strengthen their preventive measures. The consistency of pesticide residue testing could be improved by clarifying the related procedures and criteria at EU level.

2.2 DESIGNATION OF LABORATORIES

2.2.1 Designation of laboratories

Only 40 % of CAs designate laboratories for the analyses of organic samples. The lack of designation, and implied lack of accurate description of the tasks that the laboratories may carry out, are not in line with Articles 5 and 12 of Regulation (EC) No 882/2004. A consequence of the lack of designation is that the laboratories testing samples from organic production are not known to the NRLs (see section 5.6).

Where CAs designate laboratories for pesticide residue analysis in organic production, they apply different criteria for the designation. The majority of CAs (13 out of 17) require accreditation of methods and a defined analytical scope of the methods. Other criteria for designation of laboratories were defined as turn-around time for analytical results and geographical proximity to the place were samples were taken.

Summing up the CAs replies, a total 192 laboratories were designated for analysis of pesticide residues in organic produce. Several laboratories were designated by more than one region or MS. Furthermore, a large number of CAs do not designate laboratories and did not reply to this question. Therefore, the exact number of laboratories used for pesticide residue testing is unknown. It is highlighted, nevertheless, that 40 of the designations relate to laboratories in Italy and 62 to laboratories in Spain.

2.2.2 Definition of analytical scope

In just 12 % of responses, the scope of analytical methods is determined only by the CAs. The majority of CAs does not require a minimum scope of the analytical methods, and the scope is determined by the Control Bodies/Authorities (52 %) or the laboratory (2.4 %). In the remaining cases, the scope is determined by different combinations of CAs, Control

Bodies/Authorities and laboratories.

The scope of analysis is a key factor for the consistency and effectiveness of controls. The lack of clear criteria for the analyses does not ensure that the laboratories effectively use the available methods for organic samples.

2.3 ENFORCEMENT

There are no threshold levels to decide on non-compliance established by Regulation (EC) No 834/2007, and a large number of the CAs (60%) have not defined such levels. When thresholds have been established by the CAs, any lack of investigation below a threshold would not be in compliance with Regulation (EC) No 834/2007.

Thresholds are used in 13 of the responding MSs (Austria, Belgium, Croatia, Czech Republic, Estonia, Italy, Latvia, Malta, the Netherlands, Romania, Portugal, and some regions of Germany and Spain). Threshold levels were established at 0.01 mg/kg (ppm) in the majority of the authorities who responded (64 %). One CA reported a threshold of 0.02 ppm, another CA 0.05 ppm, a further 0.1 ppm, one 1 ppm, and finally two CAs reported 10 ppm. The higher threshold values reported are possibly based on a misunderstanding of the unit specified in the questionnaire (ppm). Nevertheless, the difference between answers highlights the very different approaches taken by MSs to decide on non-compliances. As a consequence, the same sample could be considered compliant in one MS, and non-compliant in a different MS, which can affect the EU single market.

The vast majority of the authorities (95 %) responded that a further investigation is the immediate consequence of the threshold exceeded. For 64 % of the authorities, a further investigation is combined with a declassification of the product, a declassification of the field (36 % of the cases), a declassification of the operator (29 % of the cases) or a warning of the operator (48 % of the cases).

One third of CAs did not report the use of specific expertise in investigations to assess compliance. Six CAs (14 %) reported the use of expert advice while 31 % of the CAs reported a combination of degradation curves, spray drift curves and processing factors. The rest of the CAs reported one or two of the tools mentioned above (24 %).

3 REPLIES FROM LABORATORIES

A total of 115 laboratories responded to the on-line survey.

3.1 PESTICIDES IN MULTI-RESIDE METHODS FOR ORGANIC SAMPLES

According to the responses received from the laboratories, the available methods of analysis can test for an average of 376 pesticides. For 54 % of the laboratories, the scope was between 200 and 500 pesticides, and 22 % of the laboratories reported a scope exceeding 500 pesticides. This demonstrates that the laboratories have adequate methods in place to analyse

for a very large number of pesticides. This does not imply, however, that the full range of methods is used routinely for organic samples.

On average, 291 of the 376 pesticides (77 %) are covered by the scope of accreditation to ISO 17025. This means that the national accreditation bodies have checked the validity of the analytical results for the majority, but not all, of the pesticides analysed for.

3.2 SINGLE RESIDUE METHODS

The majority of laboratories (60%) reported to have single residue methods available for the analysis of organic samples. The most common single residue methods are for detecting dithiocarbamates (36 %), chlormequat/mepiquat (35 %), glyphosate (30 %) and quaternary ammonium pesticides (quats) (10 %). Laboratories also implemented the Quick Polar Pesticides Method (QuPPe method) of the EU Reference Laboratory (EURL) for single residue methods. Further single residue methods are available for perchlorate/chlorate, ethephone, fosethyl aluminium, fenbutatin oxide, MCPA, 2,4-D, and daminozide.

In conclusion, a very large number of single residue methods is available in laboratories used for organic samples.

3.3 ANALYSIS OF ORGANIC SAMPLES

The large majority of the laboratories (86%) use the same analytical methodology, scope, procedures, quality controls and instruments as for conventional samples. For the few laboratories which are using a different approach, two claim to use separate machines, one a different extraction method and two completely different methodology, scope, procedures, controls and instrument. The rest of the laboratories use an additional clean-up when dealing with organic samples.

A total of 24 laboratories (21 %) offer a lower reporting limit for organic samples, with six offering a reporting limit of 0.01 ppm and eleven reporting to 0.003 ppm. Two laboratories offer a lower limit of 0.001 ppm where baby food is involved.

In conclusion, the methods and sensitivity of methods applied is mostly the same for organic and conventional samples. It is noted that for conventional samples the required sensitivity is linked to the Maximum Residue Level (MRL), which is higher than 0.01 mg/kg in most cases. For organic samples, residues below the MRL can result from the use of unauthorised pesticides. In this regard, the fact that methods of analysis for organic products are not specified by CAs appears to be a weakness in the control systems.

3.4 SANTE QUALITY CONTROL GUIDELINES FOR PESTICIDE RESIDUE ANALYSIS

Almost all laboratories reported the implementation of the SANTE Method Validation and Quality Control Procedures for Pesticide Residues, document SANTE/11945/2015. While 79 % of laboratories reported to follow it, 17 % reported to follow it mostly, and 4 % reported to follow it partly.

The high percentage of laboratories which stated to follow the quality control procedures established by DG Health and Food Safety is reassuring. However, as a large percentage of the laboratories are not co-ordinated the national reference laboratories, this statement is not checked. As shown in section 5.1, a large number of pesticides are covered by the accreditation of laboratories, offering some assurance on the quality of analysis. Nevertheless, the sector specific requirements for pesticide residue analysis specified by the SANTE Method Validation and Quality Control Procedures for Pesticide Residues are not normally considered in the accreditation process.

3.5 PARTICIPATION IN PROFICIENCY TESTS

The EURLs for pesticide residues organise annual proficiency tests. The target list of these proficiency tests is linked with the multi-annual EU pesticide control programme under Regulation (EC) No 396/2005, and covers over 150 pesticides. The EURLs also offer proficiency tests for single residue methods and for low concentrations of pesticides. The tests organised by the EURLs are the most comprehensive proficiency tests available in the EU. Participation in these tests is obligatory for official control laboratories for pesticide residues under Regulation (EC) No 396/2005. Satisfactory participation in these tests can confirm the quality of analysis for the pesticides covered in the test.

According to the responses received, 43 % of laboratories for organic samples never participated in these tests. Some 54 % of laboratories replied that they participated during the last two years 2013 and 2014 (see table 3).

Tab. 3: Percentage of laboratories participating in the proficiency tests organised by the EURLs for pesticide residues

Year	Number of laboratories	Percentage
Never	49	42.6%
2014	52	45.2%
2013	10	8.7%
2012	1	0.4%
2009	1	0.4%
2007	2	1.7%

Some 89 % of laboratories responded that they participated in proficiency tests organised by other providers in the last two years. The most common proficiency tests followed by the

laboratories are FAPAS (54 %) in the United Kingdom and BIPEA (28%) in France.

Notably, 11 laboratories (9.6 %) responded that they have never participated in proficiency tests for pesticide residues, raising doubts as to the quality of results reported.

3.6 NETWORK OF THE NATIONAL REFERENCE LABORATORY FOR PESTICIDE RESIDUES

The network of EURLs and NRLs was established by Regulation (EC) No 882/2004, which also applies to controls in organic production. The tasks of the reference laboratories are to co-ordinate the activities of official control laboratories, to organise proficiency tests, and to provide them with technical and scientific advice.

A large part of the laboratories (66 %) analysing samples from organic production responded that they are not part of the NRL network for pesticide residues. Only a minority of laboratories is included in the services provided by the NRLs. The activities offered to them are specified in table 4:

Tab. 4: Activities of the laboratories involved in the NRL system.

Training, meetings, circulation of information, proficiency tests.	23.2%
Meetings, circulation of information	13%
Proficiency tests	13%
Meetings, circulation of information, proficiency tests	11.6%
Circulation of information	10.1%
Meetings	7.2%
Training	5.8%
Different combinations	16.1%

The fact that the majority of laboratories analysing samples from organic production are not included in the EURL/NRL network is a significant constraint for the quality of analytical work carried out by these laboratories. It is a consequence of the lack of designation of these laboratories by the CAs (see section 4.2.1).

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EW-BC-15-051-EN-N

ISBN 978-92-79-53001-2
doi:10.2875/35178