

TECHNICAL REPORT

The activities of the Networks of the Pesticides Unit in 2011¹

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SUMMARY

EFSA has set up two Networks with Member State organisations in the area of pesticides:

- the Pesticide Steering Committee (PSC), which was established to manage and plan the overall pesticide risk assessment programme and consider ways to further streamline the process;
- the Networking Group on Pesticide Monitoring, which is intended to strengthen the collaboration between Member States, the countries of the European Free Trade Association (EFTA) which have an obligation to submit results of their national pesticide monitoring programmes, the European Commission and EFSA.

In 2011, the PSC has contributed to the planning of the peer review of the rapporteur Member States' assessments of active substances in the framework of Directive 91/414/EEC³. This planning, as well as the systematic monitoring of progress in the PSC, has permitted EFSA to prepare its part of the risk assessment process as adequately as possible to manage the high workload and yet meet the legal deadlines.

An important issue for the PSC in 2011 was the implementation of Regulation (EC) No 1107/2009⁴, which became fully applicable on 14 June 2011. Consideration was given *inter alia* to the MRL setting, the coordination with the European Chemicals Agency in the area of the classification of active substances and the procedure for the evaluation of claims for confidentiality with regard to documents EFSA has to make available to the public.

The PSC has also been the forum for the identification and the prioritisation of guidance documents to be developed or updated, in particular by the EFSA Panel on Plant Protection Products and their Residues.

The Networking Group on Pesticide Monitoring contributed to the development of the new reporting format to submit the results of the national pesticide monitoring activities (SSD-Standard Sample Description). The Networking group reviewed and adopted two guidance documents on the use of the Standard Sample Description. The work done with the Networking Group allowed to set up successfully the biggest data collection in EFSA to establish the largest database on pesticide residues in Europe (data and information about ca. 14 million analytical determinations for each of the reporting years 2009 and 2010). The implementation of the new format to report pesticide residues

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³ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market

⁴ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
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data (SSD) improved the quality of the data submitted and in consequence improved the accuracy of the actual exposure assessment of consumers via food containing pesticide residues.

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KEY WORDS

EFSA networks, Pesticide Steering Committee, Networking Group on Pesticide Monitoring

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BACKGROUND

In accordance with Article 22 (7) and 23 lit. g of the Regulation (EC) No 178/2002/EC⁵, the Authority shall promote the networking of scientific organisations of EU Member States operating in the fields within the Authority's mission.

The management Board of the Authority has adopted on 7 April 2010 a Decision concerning the establishment and operation of European networks of scientific organisations operating in the fields within the Authority's mission. Article 1 of that Decision lays down the role of networks: "the aim of the networks is to support the European Food Safety Authority (EFSA) and the Member States in carrying out its mission in accordance with the established standards of scientific excellence, transparency and responsiveness foreseen in Regulation No 178/2002/EC. These include *inter alia* facilitating the development of a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects and the exchange of expertise and best practices in the fields within the Authority's mission."

TERMS OF REFERENCE

Article 1(3) of the Decision of the Management Board requests EFSA to inform the Advisory Forum and the Scientific Committee of the activities of the networks through regular reports. For the purpose of implementation of this provision an annual report shall be drafted on the activities of the networks.

⁵ Regulation (EC) No 178/2002 of the European Parliament and the Council of 28 January 2002 laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in relation to food safety

ANALYSIS

1. Introduction

EFSA has set up two Networks with Member State organisations in the area of pesticides:

- the Pesticide Steering Committee (PSC), which was established to manage and plan the overall pesticide risk assessment programme and consider ways to further streamline the process. The main goals of the network are to:

- plan and monitor the risk assessment process;
- integrate the risk assessment and MRL setting processes;
- coordinate with the European Chemicals Agency (ECHA);
- give advice on prioritisation in the development and the updating of risk assessment guidance documents;

- the Networking Group on Pesticide Monitoring, which is intended to strengthen the collaboration between Member States, the countries of the European Free Trade Association (EFTA) which have an obligation to submit results of their national pesticide monitoring programmes, the European Commission and EFSA.

The Network functions as a consultation forum for all matters related to pesticide residues monitoring covered by Regulation (EC) No 396/2005⁶, including:

- the preparation of the Annual Reports on Pesticide Residues;
- the review of the EFSA standardised data model for reporting the monitoring results;
- the review of the methodology to risk assess the consumer dietary exposure to pesticide residues in food.

2. Pesticide Steering Committee

In 2011, the PSC met twice. The following items have been discussed:

2.1. Planning and monitoring of the risk assessment process

In 2011, the risk assessment process has been finalised for the so-called resubmitted active substances, i.e. those active substances not included in the Annex I to Directive 91/414/EEC⁷ during the review programme for all existing active substances (article 8(2) of the Directive), that were resubmitted for an Annex I inclusion under Regulation (EC) No 33/2008⁸. The progress at the level of the rapporteur Member States was closely monitored in the PSC meetings. This permitted EFSA to prepare its part of the risk assessment process as adequately as possible and to meet the legal deadlines for all of these substances.

⁶ 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

⁷ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market

⁸ Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I

The major peer review workflow in 2011 was however linked to the EFSA risk assessment of the substances of stage 4 of the review programme which were included in Annex I by the Directives 2008/127/EC⁹ and 2008/113/EC¹⁰. For these 59 substances, EFSA has to deliver a conclusion by 31 December 2012. Together with the members of the Pesticide Steering Committee, a work programme was established. By the end of 2011, conclusions have been adopted for 35 of these substances. For the remaining 24 substances, the peer review process is ongoing.

The third important peer review workflow concerned the new active substances. The implementation of Regulation (EU) No 188/2011¹¹ was discussed in the Pesticide Steering Committee. The status of all 71 substances covered by that programme was discussed and the appropriate next steps to be taken were agreed. By the end of 2011, 3 conclusions for new active substances have been adopted.

2.2. Preparation of the implementation of Regulation (EC) No 1107/2009¹²

Regulation (EC) No 1107/2009 became fully applicable on 14 July 2011. On that same date, Directive 91/414/EEC was repealed. The PSC discussed the following issues linked to the implementation of Regulation (EC) No 1107/2009:

- the submission of MRL applications as part of the active substance approval application under Regulation (EC) No 1107/2009; a recommendation for a streamlined procedure has been finalised; further consideration has been given to practical aspects such as the reporting of the MRL applications in the EFSA conclusions and how to address data gaps relevant for the MRL applications;

- considering the importance of the classification of the active substance under Regulation (EC) No 1272/2008¹³ in the decision making on the approval under Regulation (EC) No 1107/2009, and upon proposal of the Pesticide Steering Committee, the Bundesinstitut für Risikobewertung organised in April 2011 a Workshop on Harmonised Classification and Labelling of active substances in plant protection products; based upon the results of the Workshop a “Working document on processes for a harmonised classification of active substances in plant protection products” has been drafted and discussed in the PSC; the PSC agreed that a pilot project should be initiated;

- the Regulation requests EFSA to make a number of documents publicly available (summary dossiers, draft assessment reports, the EFSA conclusions, applications for renewal of approval), after removal of confidential data; a procedure for the evaluation of claims for confidential treatment has been discussed and agreed by the PSC.

2.3. Consultation on guidance documents

One of the tasks of EFSA’s PPR Panel is the development and updating of guidance documents in the area of pesticide risk assessment. The PSC is a forum for the identification and the prioritisation of guidance documents to be developed or updated. All information is summarised in an overview table, which is regularly updated and discussed at each meeting of the PSC.

⁹ Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances

¹⁰ Commission Directive 2008/113/EC of 8 December 2008 amending Council Directive 91/414/EEC to include several micro-organisms as active substances

¹¹ Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive

¹² Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

¹³ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

2.4. Other issues discussed by the PSC

Many other issues have been discussed during the 2011 meetings, such as:

- the preparation of OECD meetings in the area of pesticides;
- the format of the EFSA conclusions;
- the GLP requirements in the area of pesticides.

3. The Networking Group on Pesticide Monitoring

3.1. Establishment of the Networking Group on Pesticide Monitoring in 2009

Under Regulation (EC) No 396/2005, from the 1st of September 2008 the responsibility for the collation of pesticides monitoring data and the drawing up of the Annual Report on Pesticide Residues has been transferred from the Food and Veterinary Office of the European Commission to the European Food Safety Authority (EFSA).

In June 2009 EFSA published its first Annual Report on Pesticide Residues, which provided an overview on the pesticide residues in food observed throughout the European Union (EU) during 2007 and assessed the exposure of consumers through their diets. In addition, the report made a series of recommendations to further improve the data collection format. In order to strengthen the collaboration with the Member State authorities responsible for the implementation of pesticide monitoring at national level, EFSA established a network of experts.

The Networking Group met for the first time in November 2009. The following participants have been invited to collaborate via this network:

- Experts from EU Member States and EEA countries
- Representatives of the European Commission, DG SANCO, Unit E3
- Representatives of EUROSTAT
- Representatives of the EU/Community Reference Laboratories on pesticides

In 2011, the Networking Group on Pesticide Monitoring met 2 times. The discussions focussed on the following topics:

3.2. Implementation and review of the Standard Sample Description

In the past, the information and data required to prepare the Annual Report on Pesticide Residues were submitted using formatted Excel workbooks developed by the Commission. However, the format was no longer adequate to submit the huge amount of data. Member States were unsatisfied about the high workload to prepare the aggregated information which did not allow appropriate data validation. Since the reporting formats were not compatible with the national laboratory data management systems, the data reporting caused considerable costs at Member State level. In addition, important details of the findings could not be reported adequately and therefore the overall assessment of the data was impeded. Therefore EFSA initiated in 2009 a pilot project for the pesticide monitoring data collection: a new standardised data format to transmit the monitoring data ("Standard Sample Description" - SSD) was developed; this new model implemented also the use of standardised, controlled terminology. The objective of the project was the development of a general data model that can be used not only for the collection of pesticide data, but also for the reporting of a wide range of measurements taken for food and feed safety assessment in the remit of EFSA. The data submission

should be done via the EFSA web portal using the eXtensible Markup Language (XML) technology to facilitate data transfer and validation. The collection of the future pesticides monitoring data with the SSD provided an opportunity to improve the data collection process, making the process more efficient for the reporting organisations, improving the quality of the transmitted data and as a consequence allowing a more accurate risk assessment analysis for EFSA.

During the 2010 meetings of the Networking Group the final revision of the SSD to be used by all reporting countries for the submission of the pesticide monitoring data of 2008¹⁴ was developed, taking into account also the experiences gained during the pilot project. A specific training was provided for the experts involved in the data compilation at Member State level. Finally, during the meetings, guidance and on-line training were provided on the pesticide monitoring data transmission via the EFSA Data Collection Framework application. By September 2010, all Member States had successfully implemented the SSD at national level and reported to EFSA data and results concerning the 2009 pesticide monitoring (ca. 14 millions analytical determinations) in line with the new data model. On the basis of these data EFSA has created the largest database in Europe on pesticide residues. For the reporting year 2010 approximately the same amount of results/analytical determinations were submitted to EFSA).

In 2011, on the basis of the experience gained with the first year of full implementation of the SSD at national level, the Networking Group reviewed the SSD data model and the standardised catalogues to improve the quality of data to be reported. Overall, with the full implementation of the SSD the data submission-validation-acceptance cycle has greatly improved, the level of detailed information has increased; the latter allowed EFSA to perform a more accurate exposure assessment and more powerful data analysis to be presented in the 2010 EFSA Annual Report on Pesticide Residues.

3.3. Guidance documents on the use of the Standard Sample Description

Two guidance documents on the use of the Standard Sample Description have been prepared by EFSA: one general document for all the EFSA data collection (including pesticide monitoring) and one specific for the pesticide monitoring. In 2011, the latter has been reviewed and adopted by the Networking Group.

3.4. Adoption and taking note of the Standard Sample Description

In the SCoFCAH meeting held in December 2010 all delegations expressed a favourable opinion on the use of the SSD and the EFSA Guidance Documents on its use. The Committee took note of this agreement in line with the procedure laid down in Art 31(2) of Regulation (EC) No 396/2005.

Furthermore, in the SCoFCAH meeting held in December 2011 a favourable opinion was expressed by the national delegations on the 2012 Control Regulation. In this legal act, for the first time it is clearly indicated that the future pesticide monitoring results shall be reported according to the SSD, making the use of the SSD legally binding at European level. Thus, the Standard Sample Description is officially approved to be used for the future data collection of pesticide monitoring data.

3.5. Additional activities

Beside physical meetings in Parma, EFSA and national experts of the Networking Group continued their collaboration via exchange of information through a dedicated workspace and discussion forum on the EFSA Extranet, through an helpdesk functional inbox for e-mail exchange and support requests, via tele- and web-conferences and by organising bilateral visits and meetings at national competent authorities in the Member States.

¹⁴ According to Regulation (EC) No 396/2005 Member States have to submit the results of the 2009 monitoring by end of August 2010.

CONCLUSIONS

The Pesticide Unit Networks play an important role in EFSA's co-operation with the Member States.

The PSC has proved to be helpful in planning and monitoring the pesticide risk assessment process, and is thus contributing to the compliance with the legal deadlines by all participants. The discussions in the PSC have been helpful to raise awareness about numerous issues and to enhance the understanding of the positions of all participants in the process.

The Networking Group on Pesticide Monitoring has been considered as extremely helpful by the networking partners: the positive perception of the Networking Group and the relevance of the discussions is demonstrated by the high number of participants (on average 40 participants per meeting) and the active participation of the participants during the meetings. The work done in the Networking Group allowed setting up successfully the biggest data collection in EFSA and the largest database on pesticide residues in Europe (data and information about ca. 14 million analytical determinations for each of the reporting years 2009 and 2010). The implementation of the new format to report pesticide residues data (SSD) improved the quality of the data submitted and in consequence improved the accuracy of the actual exposure assessment of consumers via food containing pesticide residues. The positive feedback received from the European Commission, Member States and other stakeholders confirms that the progress that has been achieved in the field of pesticide monitoring is very much appreciated.

Technical support provided by EFSA to experts of the Networking Group on Pesticide Monitoring has been appreciated by the Member States and the European Commission. The discussion with the Networking Group members has also proved to be fruitful to strengthen the collaboration with the Member States and the European Commission services on issues concerning the pesticide monitoring activities.

GLOSSARY

ECHA European Chemicals Agency

EEA European Economic Area

EFSA European Food Safety Authority

EFTA European Free Trade Association

EU European Union

GLP Good Laboratory Practice

MRL Maximum Residue Level

OECD Organisation for Economic Co-operation and Development

PPR Panel Panel for the Plant Protection products and their Residues

PSC Pesticide Steering Committee

SCoFCAH Standing Committee on the Food Chain and Animal Health

SSD Standard Sample Description