

SPECIAL ISSUE

EFSA's contribution to the implementation of the EU legislation on pesticide residues in food

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ABSTRACT

The active involvement of EFSA in the area of pesticide residues assessment started in 2006 following the adoption of new legislation on maximum residue levels (MRLs) of pesticides in food (Regulation (EC) No 396/2005). EFSA took on a new role as an independent risk assessment body in the process of MRL setting, providing important contributions in the EU-wide harmonisation of MRLs. With the development of a risk assessment model (EFSA PRIMo) the risk assessment process has become more transparent. EFSA is now involved in all routine MRL setting processes by giving advice to the risk managers and, so far, has given recommendations on ca. 1 200 MRLs. EFSA also provides other scientific assessments, in many cases where urgent advice is needed due to unexpected incidences which require immediate risk management action. Currently, high priority is given to the systematic MRL review, which involves making a comprehensive inventory of the scientific studies and performing risk assessments for the pesticides covered by this programme. Another major task for EFSA is the drafting of the Annual Report on Pesticide Residues, which gives an overview of the pesticide residues in food available to European consumers. EFSA has revised the data collection of monitoring results to allow more powerful data analysis to identify potential consumer risks and weak points in the food production system, and to develop strategies for improvements. EFSA places major emphasis on risk communication on topics related to pesticide residues, which is an integral part of EFSA's tasks as risk assessor. Building on the achievements of the last six years, future challenges for EFSA include the continued improvement of risk assessment methodologies (updating risk assessment models, developing new methodologies for cumulative risk assessment) and the timely provision of risk assessments for MRL applications and MRL reviews.

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KEY WORDS

Pesticides, residues, maximum residue levels (MRLs), consumer risk assessment, Regulation (EC) No 396/2005.

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INTRODUCTION

Risk analysis with its three components - risk assessment, risk management and risk communication - is the foundation on which the European food safety policy is based³. The involvement of the European Food Safety Authority (EFSA) in the risk assessment and risk communication process in the field of pesticide residues is a good example of how the risk analysis principles have been implemented in practice. In April 2005, with the entry into force of Regulation (EC) No 396/2005⁴, the regulation establishing the provisions for maximum residue levels (MRLs) of pesticides in food and feed, the role of EFSA as the independent body for performing scientific risk assessment in the framework of pesticide residues was clearly defined. As a result, EFSA was entrusted with a number of specific tasks for which a small team of EFSA scientists started to work on in 2006. The risk analysis principle also stresses the need to communicate the results of the risk assessment in an appropriate way to consumers, stakeholders and other bodies concerned. Thus, risk communication on issues related to pesticide residues is an integral part of EFSA's tasks as risk assessor.

The main activities of EFSA since 2006, with a particular focus on the added value of EFSA's involvement in pesticide residue risk assessment and risk communication, will be outlined in more detail in the following sections.

1. HARMONISATION OF MRLS FOR PESTICIDE RESIDUES AT EU LEVEL

European Union (EU) legislation on maximum residue levels has a long tradition: the first directive on legal limits on pesticide residues in food was adopted in 1976 (Directive 76/895/EEC⁵), followed by several legislative acts concerning MRLs for cereals, food of animal origin, fruits and vegetables (Directives 86/362/EEC⁶, 86/363/EEC⁷ and 90/642/EEC⁸). These basic directives were amended by ca. 70 directives covering in total approximately 250 different pesticides. Due to the frequent amendments and the need to implement the directives within national laws, the legislation was not very user friendly. The situation was further complicated by the fact that Member States had established national MRLs for active substances not covered by the EU legislation, often set at different levels. This could lead to a situation whereby a food product containing residues of a certain pesticide at a level that was acceptable in one Member State was found to infringe the MRL applicable in another Member State. Thus, this scattered system of national MRLs was unsatisfactory for the needs of the EU common market and had to be revised.

With the introduction of Regulation (EC) No 396/2005, a fully harmonised MRL system could be established covering all pesticides that are expected to be found in or on food. Before this ambitious goal could be achieved, a risk assessment had to be performed to ensure that the proposed EU wide valid MRLs would not pose a consumer health risk for the European population. EFSA was therefore mandated by the European Commission to estimate the expected exposure of European consumers resulting from pesticide residues present in or on food at the level of the proposed temporary MRLs and assess possible short- and long-term risks, in particular for sensitive subgroups of the population such as children. The proposed temporary MRLs were derived from the national MRLs in place. The

³ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

⁴ 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. OJ L 70, 16.3.2005, p. 1–16.

⁵ Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables. OJ L 340, 9.12.1976, p. 26–31.

⁶ Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals. OJ L 221, 7.8.1986, p. 37–42.

⁷ Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin. OJ L 221, 7.8.1986, p. 43–47.

⁸ Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables. OJ L 350, 14.12.1990, p. 71–79.

request covered in total 281 pesticides with MRLs for all food commodities covered by the EU food classification for pesticide MRLs (ca. 260 different food commodities of plant and animal origin). The risk assessment had to be performed for realistic exposure scenarios relevant for the European population, considering in particular highly vulnerable population groups like children. Limiting factors for this exercise were the lack of information regarding the scientific basis for the national MRLs. Another difficulty of this exercise was the lack of a calculation tool for exposure assessment which would be sufficiently representative for the European population. Several national models existed but they were found to be not appropriate for the purpose because they were not sufficiently representative of all Member States. Taking into account the high number of pesticides that needed to be assessed, an efficient calculation tool was needed presenting the results in a format which allows risk managers to take appropriate risk management decisions. Thus, EFSA decided to develop a European model, implementing internationally agreed exposure assessment methodologies using food consumption data available at Member State level. The risk assessment performed with the EFSA Pesticide Residue Intake Model (PRIMo) ensured that MRLs were set at levels which are safe for the European population, including in particular vulnerable subgroups of the population.

The EFSA PRIMo comprises 27 diets⁹ (nine of which for children) for long-term exposure assessment representing 13 Member States plus 19 diets for short-term exposure assessment from 11 Member States. The short-term data include nine diets for children of different age groups.

In March 2007, EFSA presented the report on the potential chronic and acute risk to consumers' health arising from proposed temporary MRLs (EFSA, 2007), which was complemented by an addendum (EFSA, 2008) covering additional MRLs that were proposed as temporary MRLs. The report also highlighted the uncertainties and the constraints due to the limited information available. On the basis of these reports, the European Commission elaborated two comprehensive regulations (Regulation (EC) No 149/2008¹⁰ and Regulation (EC) No 839/2008¹¹), filling more than 500 pages in the Official Journal which entered into force on 1 September 2008. On this date, the ambitious goal to have uniformly applicable legal limits for the whole European Union was achieved.

The EFSA PRIMo was found to be a useful tool which improves the risk assessment practice for pesticide residues and allows calculations to be made in a systematic, structured way, improving the transparency of the risk assessment process. Taking into account the advantages of the model, the Standing Committee on the Food Chain and Animal Health (SCFCAH), the risk management committee responsible for the pesticide MRL legislation, approved the model to be used for deriving decisions on the MRL setting, not only in the framework of the temporary MRLs, but also for other MRL setting purposes. The calculation spreadsheet is available via the EFSA website for use by risk assessors or interested stakeholders¹².

⁹ The term "diet" refers to a set of consumption data for relevant food items consumed by a subgroup of the population (e.g. German children aged 2-5 years) derived from food surveys or other appropriate sources (e.g. food balance sheet). From food surveys, typically mean consumption figures, normalised by body weight, for each reported food item are derived for performing long-term exposure assessments; in addition, a high percentile consumption value (usually 97.5th percentile of the subgroup of consumers who have consumed a certain food item) is calculated to perform short-term exposure assessments.

¹⁰ Commission Regulation (EC) No 149/2008 of 29 January 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto. OJ L 58, 1.3.2008, p. 1–398.

¹¹ Commission Regulation (EC) No 839/2008 of 31 July 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Annexes II, III and IV on maximum residue levels of pesticides in or on certain products. OJ L 234, 30.8.2008, p. 1–216.

¹² Available from <http://www.efsa.europa.eu/en/mrls/mrlteam.htm>

2. PROVISION OF SCIENTIFIC ADVICE FOR SETTING AND AMENDING MRLS FOR PESTICIDE RESIDUES BY EFSA

According to Article 10 of Regulation (EC) No 396/2005, EFSA is in charge of providing reasoned opinions on MRLs in case an applicant requests the setting or amending of MRLs. Typically, MRL applications refer to new uses of pesticides in an EU Member State or to requests concerning import tolerances for pesticides on crops which are not authorised in the EU. According to the procedures laid down in the MRL regulation, the Member State who receives the application from the applicant has to assess the studies underpinning the MRL request and draft an evaluation report; on the basis of this report, EFSA drafts the Reasoned Opinions with a view on the acceptability of the requested MRL from a consumer safety point of view. Thus, EFSA scientists perform an independent review of the evaluation done by the Member States. If the MRL requested is found to be sufficiently supported by data and no consumer risk is identified, then the European Commission prepares a Regulation setting or amending the MRL which is then presented to the SCFCAH.

Since 2008, a total of 335 MRL applications have been submitted to EFSA. Twenty-two of them have been withdrawn or rejected as not compliant with the legal provisions. By May 2012, EFSA had adopted 215 reasoned opinions on 239 MRL applications, covering in total ca. 1 200 individual MRLs requested. So far, 18 MRL Regulations have been published in the Official Journal, as a result of EFSA's scientific advice being turned into legislation.

3. SYSTEMATIC REVIEW PROGRAMME FOR MRLS OF PESTICIDE RESIDUES

Article 12 of Regulation (EC) No 396/2005 stipulates that EFSA shall provide reasoned opinions on the review of existing MRLs for certain active substances. For active substances included in Annex I to Directive 91/414/EEC¹³ before 2 September 2008, EFSA was expected to provide reasoned opinions by 2 September 2009; for active substances where a decision on inclusion or non-inclusion in Annex I to Directive 91/414/EEC had been or will be taken after 2 September 2008, EFSA has to provide a reasoned opinion within one year following the entry into force of the decision. The work program generated by this article has so far triggered the review of MRLs for a total of 411 pesticide active substances. Delays with regard to the legal deadlines are incurred for several reasons, including inconsistencies in the legal framework, i.e. between Regulation (EC) No 396/2005 and Directive 91/414/EEC. To remedy the situation, a work plan for the review of existing MRLs under Regulation (EC) No 396/2005 was elaborated by EFSA and agreed upon by the European Commission and the EU Member States. In particular, EFSA aims at giving priority to those active substances where the suspicion of a possible risk to consumers was notified to EFSA.

According to the legal provisions, EFSA shall base its reasoned opinions in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that in the framework of Directive 91/414/EEC only a few representative uses are evaluated, while MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the EU as well as uses authorised in Third Countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

In order to gain an overview on the pesticide residues data that had been considered for the setting of the existing MRLs, EFSA requested the rapporteur Member States, designated pursuant to Directive 91/414/EEC, to complete the Pesticide Residue Overview File (PROFile) for all active substances. The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes:

¹³ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

- an overview of all registered uses relevant to the setting of MRLs;
- data on the nature and magnitude of residues in primary crops;
- data on the nature and magnitude of residues in processed commodities;
- data on the nature and magnitude of residues in rotational crops;
- data on the nature and magnitude of residues in livestock commodities and;
- data on the analytical methods for enforcement of the proposed MRLs.

Not only does the PROFile assist EFSA in the validation and assessment of pesticide residues data previously evaluated by Member States, but it will also enable EFSA in the future to develop a database that will provide an overview of all MRLs recommended by EFSA as well as the scientific data supporting those recommendations.

Since 2008, EFSA has initiated the review of MRLs for a total of 411 active substances, out of which 56 were finalised by May 2012. This covers the review of ca. 1 800 individual MRLs so far.

4. THE ANNUAL REPORT ON PESTICIDE RESIDUES

In the general risk management framework, the setting of legal limits is only one of the tools used to ensure consumer health protection. Another important risk management tool is the monitoring of food placed on the market to verify compliance with legal standards. Therefore Regulation (EC) No 396/2005 imposes Member States to control food placed on the market, to take appropriate measures in case infringements are identified and to report the results of the control activities to the European Commission. In this context, EFSA is mandated by the MRL legislation with the drafting of an Annual Report on Pesticide Residues on the basis of the information provided by Member States¹⁴. According to the MRL Regulation, EFSA should in particular give an overview of the official control activities performed, summarise the results, provide information on possible reasons for MRL exceedances, assess consumer exposure to pesticide residues and perform an analysis of the chronic and acute risks for European consumers.

So far, EFSA has published three Annual Reports on Pesticide Residues found in food on the market in 2007, 2008 and 2009, respectively (EFSA 2009, 2010, 2011). In each report, the results concerning ca. 800 different pesticides in about 70 000 samples of nearly 200 different types of unprocessed food are presented. The data generated by Member States and compiled by EFSA is one of the most comprehensive data collections in the area of pesticide residues and is a valuable source of information for identifying weak points in the food safety systems and for developing strategies to improve the MRL compliance. The reports also comprise the outcome of the consumer risk assessment of pesticide residues.

In 2009, during the drafting of its first Annual Report on Pesticide Residues, EFSA identified limitations and deficiencies in the format of reporting the monitoring results. The format was found to no longer be adequate for submitting the large and increasing volume of data. Since the information submitted to EFSA was reported in aggregated form, it was not possible to perform all the evaluations as requested by European legislation, in particular regarding realistic, quantitative estimation of the actual consumer exposure. Therefore, EFSA took the initiative to develop a new data collection format (SSD - Standard Sample Description) which would overcome these deficiencies. In a pilot project launched in 2009 with six Member States the suitability of the SSD was tested and, following some modifications found to be necessary during the pilot phase, the SSD was used by all Member States for reporting the monitoring results in 2010 (reporting the results of the previous year). The SSD was developed with a view of satisfying not only the needs of reporting pesticide monitoring data, but also

¹⁴ Before Regulation (EC) No 396/2005 became applicable, reports summarising the results of control activities throughout Europe were prepared by the European Food and Veterinary Office (FVO). Available at: http://ec.europa.eu/food/fvo/specialreports/pesticides_index_en.htm. The task was handed over to EFSA in September 2008.

for other food-related data collections, e.g. for reporting contaminants in food. Close collaboration with the national competent authorities ensured that the SSD format was compatible with the national data management systems in place and, where necessary, EFSA provided support to overcome problems in the implementation. Although the introduction of the new reporting format required major changes in data management systems at Member State level, the transition was smooth due to the good collaboration between the competent national authorities and EFSA.

In 2010, EFSA started collecting the annual results of pesticide monitoring at the most detailed level (ca. 14 million analytical determinations) using the SSD to establish the largest database on pesticide residues in food in Europe. This is the biggest data collection in EFSA and it will open the door for more detailed data analysis (e.g. trend analysis regarding the presence of residues in food, findings of multiple residues on individual samples), for *ad-hoc* reports in support of specific requests of the European Commission (e.g. advice on the preparation of the annual EU legislation on the control activities, the preparation and prioritisation of the FVO inspections, to check compliances with the requirements of EU food safety and quality legislation within the European Union and on compliance with EU import requirements in Third Countries exporting to the EU) and will allow cumulative risk assessments to be carried out as soon as the methodology is available.

In the monitoring report referring to the results of the 2009 data (EFSA, 2011), the first year where all Member States reported their findings in line with the SSD, EFSA could derive a number of specific recommendations for future monitoring plans and activities related to the enforcement of pesticide legislation and identify critical areas of concern regarding compliance with MRLs. Some of the follow-up activities that take these recommendations into account have already been initiated.

5. URGENT ADVICE REQUESTED BY THE EUROPEAN COMMISSION OR MEMBER STATES ON SPECIFIC QUESTIONS

In accordance with Article 43 of Regulation (EC) No 396/2005, the European Commission or Member States may request from EFSA on any measure related to pesticide residues in food. Since 2008 EFSA has received 39 of this type of requests which typically refer to specific alerts or unexpected incidences which require immediate risk management action. Due to the urgency of the matter, very short deadlines are usually given to EFSA (between one day and three months). The nature of the requests requires a close collaboration between risk managers and risk assessors to ensure that the assessments provided by EFSA fully address the needs of the risk managers.

6. RISK COMMUNICATION

EFSA's role is not only to assess potential risks associated with the food chain but also to communicate the findings to interested parties and the general public in a transparent and comprehensive way. Through its risk communication activities, EFSA seeks to raise awareness and to explain the results and implications of its scientific work.

Considering that pesticides were perceived by European citizens as one of the major food-related risks¹⁵, the communication of the results of its scientific assessments in the field of pesticide residues is taken as an important task that is crucial to foster public understanding of pesticide-related risks and the related risk management measures taken.

The risk communication is done by the following means:

- Publication of its scientific assessments in the framework of the pesticide MRL setting activities on the EFSA website¹⁶. When drafting the assessments, EFSA puts specific emphasis on a clear presentation of the relevant data and facts, explaining the underlying

¹⁵ « Special Eurobarometer 354 – Food-related risks ». Document available online:

<http://www.efsa.europa.eu/en/riskcommunication/riskperception.htm>

¹⁶ All reasoned opinions, statements and scientific reports on pesticide residue evaluation are available at

<http://www.efsa.europa.eu/en/publications.htm>

assumptions and uncertainties and, if relevant, constraints, including an explanation of their impact on the conclusions derived. The conclusions and recommendations derived by EFSA are clearly highlighted.

- Publication of the Annual Reports on Pesticide Residues on the EFSA website as well as any comments by the European Commission or Member States. A dedicated press release is issued when the Annual Reports are published. The results are mainly presented as graphical data in order to communicate the information in a clear and comprehensive way. For interested readers additional background information is provided on the legal framework, in a specific glossary and in detailed appendices. The publication of EFSA's Annual Reports on Pesticide Residues usually triggers an important media response, in both general and specialised media, including environmental and consumer publications. Therefore, upon the publication of the report, EFSA also provides interviews and addresses specific media and stakeholder requests on the data presented in the Annual Reports and contributes to the drawing up of articles.
- Disseminating the information about EFSA's activities and outputs at scientific conferences and events organised for the general public.
- Replying to enquiries and providing general advice to the interested public on the pesticide residue legislation, MRLs and on the findings of residues of pesticides in food.

CONCLUSIONS

Taking stock after six years of active contribution in the area of risk assessment and risk communication concerning pesticide residues in food, it becomes evident that many of EFSA's objectives, as defined in the food law and in specific legislation on pesticide MRLs, have been achieved. The most important achievements are the following:

- contribution to the full harmonisation of MRLs;
- development of a suitable risk assessment model used for pesticide residue exposure (EFSA PRIMo);
- setting up a workable procedure for assessing routine MRLs in collaboration with Member States;
- establishment of a comprehensive MRL review programme, aiming to make a complete inventory of the scientific and technical data supporting the MRLs;
- provision of timely advice to the European Commission on urgent requests;
- development of a new reporting format for submission of analytical results on pesticide control activities which allows more powerful analysis of the results, including improved consumer exposure assessments;
- publication of Annual Reports on Pesticide Residues.

EFSA's work in this area has contributed to the recognition of EFSA as the reference body for European food safety. However, it should be mentioned that important work still needs to be done. In particular, the following issues still need to be tackled in the future work programmes of EFSA:

- further progress on the MRL review programme;
- increasing the capacity for routine MRL applications to avoid delays in the MRL setting;
- update of the EFSA PRIMo, taking into account new consumption data generated in national food surveys;
- establishment of a methodology for performing cumulative risk assessment.

EFSA will continue to ensure that European consumers can be confident that the advice being produced is of the highest standard of independence, excellence and transparency.

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