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Food and Veterinary Office

OVERVIEW REPORT

Controls of plant protection products in Member States

FVO

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OVERVIEW REPORT
ON A SERIES OF AUDITS CARRIED OUT IN MEMBER STATES FROM 2012 TO 2014 IN ORDER TO EVALUATE CONTROLS OF PLANT PROTECTION PRODUCTS

Executive Summary

This report provides an overview of the outcome of a series of audits carried out by the Food and Veterinary Office (FVO) in 19 Member States (MSs) of the European Union (EU) between January 2012 and June 2014.This was the fourth series of FVO audits in this area.

The objective of the audits was to evaluate the control systems in place for pesticides, in particular, the implementation of requirements for the authorisation of plant protection products (PPPs) and official controls on the marketing and use of PPPs under Regulation (EC) No 1107/2009 and Directive 2009/128/EC, and the implementation of the requirements for official controls of PPPs at growers, as specified in Regulation (EC) No 882/2004.

While there were systems and procedures for the authorisation of PPPs in place in all Member States, related shortcomings were identified in two areas:

(a) Delays with re-authorisations of PPPs under Directive 91/414/EEC, and with mutual recognitions under Regulation (EC) No 1107/2009: Many authorised PPP had not been evaluated to EU standards, more than 15 years after the principles for evaluation had been established. Similarly, delays and problems with co-operation between Member States were identified for the zonal authorisation system under Regulation (EC) No 1107/2009. This highlights the difficulty of MSs to implement authorisation systems based on EU legislation;

(b) Emergency authorisations of PPPs under Regulation (EC) No 1107/2009: The report identifies problems with misuse of emergency authorisations for minor uses of PPPs, but also for other use extensions of approved PPPs. In addition, emergency authorisations for the same products have been granted for consecutive years, thus undermining the effectiveness of the strict criteria for regular authorisations established by EU legislation.

Systems were in place for official controls on the marketing and use of PPPs. One common weakness in controls at both market and user level, was the coverage of operators. With regard to official controls on the marketing of PPPs, there were further weaknesses related to unsatisfactory labelling checks and unsatisfactory quality controls of pesticides. As a consequence, there was insufficient assurance that counterfeit and illegal pesticides would be detected.

In general, official controls on the use of PPPs were more effective than controls on the marketing of PPPs. In most of the MSs visited, all relevant aspects were covered during inspections and comprehensive checks of records kept by professional users were taking place, which provided guarantees that PPPs are applied in accordance with the conditions specified on the labels.

Weaknesses were identified with regard to prioritisation of official controls. Co-ordination and co-operation between and, in some cases, within CAs was considered to be weak.

Initial measures were adequately put into place for the implementation of Directive 2009/128/EC, in particular, training and certification of professional users, safe handling and storage of PPPs, their containers and remnants, Integrated Pest Management (IPM) and application equipment. This is a step forward to ensure the sustainable use of pesticides.

Good practices were found with regard to systems for official controls as a whole, or certain aspects. These are described in the relevant chapters of the report.

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ABBREVIATIONS

CA(s)	Competent Authority(ies)
CIPAC	Collaborative International Pesticides Analytical Council
CPs	Country Profiles
DG (SANCO)	Health and Consumers Directorate-General of the European Commission
DG (SANTE)	Health and Food Safety Directorate-General of the European Commission
EU	European Union
Europol	European Police Office
FBO(s)	Food Business Operator(s)
FVO	Food and Veterinary Office
GAP(s)	Good Agricultural Practice(s)
IPM	Integrated Pest Management
MRLs	Maximum Residue Levels
MS(s)	Member State(s)
PPPs	Plant Protection Products
TC(s)	Third Country(ies)

1 INTRODUCTION

The series of audits on controls of plant protection products (PPPs) was undertaken from January 2012 to June 2014 by the Food and Veterinary Office (FVO) of the European Commission's Directorate-General for Health and Consumers (DG SANCO). The series consisted of 19 audits to European Union (EU) Member States (MSs). The programme involved meetings with central and regional/local Competent Authorities (CAs), visits to official laboratories for formulation analysis and, in the context of a follow-up of open recommendations from previous audits, visits to official laboratories for analysis of pesticide residues in and on food of plant origin. The audit itinerary also included on-the-spot visits at pesticide distributors and professional users to observe inspections for the purposes of official controls on the marketing and use of PPPs.

This series of audits was undertaken following the entry into force of the EU framework legislation in the area of pesticides and, in particular, Regulation (EC) No 1107/2009 and Directive 2009/128/EC. During these audits on controls of PPPs in MSs, the main focus was on the official controls of the marketing and use of PPPs. Authorisation of PPPs was also covered, including mutual recognition of authorization of authorisations and authorization of PPPs for emergency situations. In addition, some aspects were covered which were related to the sustainable use of pesticides, such as training and certification of pesticide distributors and professional users, handling and storage of PPPs, empty containers and leftovers, integrated pest management (IPM) and testing of application equipment.

Reports on individual audits are available on the website of Health and Food Safety Directorate-General (DG SANTE): http://ec.europa.eu/food/fvo/index_en.htm and can be consulted for further detail.

Details on specific reports (MSs, dates and audit references) are available in Annex I.

This report can only reflect the status observed at the time of the audits, although some systems may have improved in the meantime.

2 OBJECTIVES AND SCOPE

The objectives of the audits were to evaluate the control systems in place for pesticides, in particular:

- the implementation of requirements for the authorisation of PPPs and official controls on the marketing and use of PPPs under Regulation (EC) No 1107/2009 and Directive 2009/128/EC;
- the implementation of the requirements for official controls of PPPs at growers, as specified in Regulation (EC) No 882/2004; and
- the follow-up of recommendations made in previous audit reports on the evaluation of official controls within the context of the above objectives.

In terms of scope, the audits assessed the performance of CAs, as well as the organisation of the controls, including procedures for the authorisation of PPPs, controls of pesticide wholesalers, retailers and end-users of PPPs. In pursuit of these objectives, visits were arranged to the central, regional and/or local CAs, official laboratories for

formulation analysis, official laboratories for pesticide residues (only in the context of follow-up, when needed) and to the services in charge of inspections, including visits to wholesalers and retailers of PPPs, as well as end-users.

3 LEGAL BASIS

The audits were carried out under the general provisions of EU legislation, in particular:

- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council;
- Article 68 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

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

4 BACKGROUND

4.1 AUDIT SERIES

Prior to this audit series, the FVO had carried out three series of audits to MSs covering controls on marketing and use of PPPs and pesticide residues. The general overview reports of these audit series can be found on the internet site of DG(SANTE): http://ec.europa.eu/food/fvo/specialreports/index_en.htm

The CAs of the MS subject to audit outlined in action plans how the recommendations made in these audit series would be addressed. These action plans are also published on the DG(SANCO) internet site together with the reports.

4.2 COUNTRY PROFILES

The FVO publishes country profiles (CPs) for the individual MSs, which describe in summary the control systems for food and feed, animal health, animal welfare and plant health and give an overview of the state of play of the implementation of recommendations of the previous FVO audit reports. These CPs can be found at: http://ec.europa.eu/food/fvo/country_profiles_en.cfm

All the FVO recommendations from the previous audit series have been closed due to actions taken by CAs of MSs.

5 FINDINGS AND CONCLUSIONS

5.1 RELEVANT NATIONAL LEGISLATION

Legal requirements

Article 291 of the Treaty on the Functioning of the EU establishes that MSs shall adopt all measures of national law necessary to implement legally binding Union acts.

Findings

Regulation (EC) No 1107/2009 is directly applicable in all MSs. In the majority of the MSs, additional national legislation was in place for the implementation of the

Regulation and, in particular, for enforcement measures and sanctions in the case of infringements, as well as for procedures and fees to be applied regarding the authorisation of PPPs.

Directive 2009/128/EC had to be transposed at MS level by 26 November 2011. In 2012, nine MSs were visited and, at the time of the audits, transposition had been finalised in five MSs. In one, the Directive had been partly transposed and in three, the transposition had been delayed, but procedures on the adoption of relevant national legislation were in the final stages of approval. Recommendations were made to the CAs of these three MSs in this regard and formal legal actions were taken by the Commission Services. In all ten MSs visited in 2013 and 2014, Directive 2009/128/EC had been transposed at the time of the audits.

In one MS, although national legislation was in place regarding training and certification of professional users and distributors of PPPs, the calibration and testing of application equipment, recovery and disposal of pesticide remnants and packaging, had not been enforced. In another MS, the Directive had been transposed at the time of the audit with the exception of Article 4 (1).

Conclusions

National legislation was in place for the implementation of Regulation (EC) No 1107/2009 and to transpose Directive 2009/128/EC. Recommendations were made to the CAs of MSs where the transposition of Directive 2009/128/EC was delayed or problems were identified with regard to enforcement.

5.2 ORGANISATION AND IMPLEMENTATION OF OFFICIAL CONTROLS

5.2.1 Designation of Competent Authorities

Legal requirements

Articles 75(1) and (2) of Regulation (EC) No 1107/2009 require MSs to designate a CA or CAs to carry out the obligations laid down in this Regulation, and to inform the European Commission of the details concerning its CAs.

Article 4(1) of Regulation (EC) No 882/2004 requires MSs to designate the CAs responsible for official controls.

Findings

In ten MSs, there were no changes in the structure and responsibilities of CAs as described in their CPs. In three MSs, there were slight changes with regard to allocation of responsibilities and, prior to the audits, re-structuring had taken place in six MSs.

Regarding PPP authorisation, although one single authority was responsible for the co-ordination and granting of authorisations in most of the MSs, there were different authorities involved in the expert evaluations for the purposes of authorisation. In five MSs, a single CA dealt with PPP authorisation and external experts from research institutes or private consultants were involved, where considered necessary.

Official controls on the marketing and use of PPPs were within the responsibility of one CA in most of the MSs. In three MSs, these tasks were allocated to more than one CA.

Conclusions

CAs were designated and their responsibilities were clearly defined.

5.2.2 Resources for Performance of Official Controls

Legal requirements

Article 75(3) of Regulation (EC) No 1107/2009 requires MSs to ensure that CAs have a sufficient number of suitably qualified and experienced staff to carry out their obligations efficiently and effectively.

Article 4 of Regulation (EC) No 882/2004 requires the CAs to ensure that they have access to a sufficient number of suitably qualified and experienced staff and that they have appropriate and properly maintained facilities and equipment. Article 6 requires CAs to ensure that staff receive appropriate training and are kept up-to-date in their competencies.

Findings

In all MSs visited, suitably qualified and experienced staff were available for the authorisation of PPPs and quality control of pesticides. With regard to marketing and use of PPPs, staff involved in the official controls had a relevant educational background and the necessary knowledge and experience to perform their tasks in 14 of the MSs visited and they received appropriate training to be kept up-to-date in their competencies and areas of activity. In the remaining five MSs, there were shortcomings identified with regard to either the professional background of staff, or the training provided, or both. In two MSs, staff members appointed at the central CAs had the relevant background and experience, but not those at regional and local level. In another MS, there were two different CAs dealing with official controls. Staff involved in official controls on the use of PPPs were experienced, competent and received regular training in their area of activity. However, staff members involved in official controls on the marketing of PPPs neither had a relevant background nor received a specialised training, which affected the effectiveness and efficiency of controls. In two further MSs, only limited PPP related training was provided to staff dealing with controls at pesticide distributors and professional users.

Practices seen in the Czech Republic and Slovakia could be identified as **good practices.** In both MSs, there were efficient systems in place for training of own staff, including induction training (at appointment), on-going training in accordance with annual training programmes, external training (mostly Better Training for Safer Food sessions) and ad-hoc training (in the case of new legislation entering into force or any specific problems indicated during routine inspections). The annual training programmes were developed based on the assessment of training needs, in close co-operation and consultation with staff from regional CAs. These training systems were further complemented by the requirements in place with regard to the educational background of staff, knowledge in their areas of responsibility and previous experience.

In most MSs, premises and equipment available allowed staff to adequately perform their tasks, the only exception being related to formulation analysis (see Chapter *5.2.4 Controls on the Marketing of Plant Protection Products*).

Conclusions

Suitably qualified and experienced staff were available to perform tasks related to PPP authorisation and official controls on their marketing and use. Appropriate training was

provided to keep CAs' staff up-to-date in their areas of responsibility, though some shortcomings were identified in individual MSs in this regard, which could affect the efficiency and effectiveness of official controls.

5.2.3 Authorisation of Plant Protection Products

Legal requirements

Article 29 of Regulation (EC) No 1107/2009 requires that a PPP shall only be authorised if it complies with specified requirements. The required contents of the authorisation are specified in Article 31. Article 57 requires that an updated electronic register must be publicly available.

Articles 40 - 42 of Regulation (EC) No 1107/2009 lay down the requirements and procedures for mutual recognition of authorisations between MSs. Article 53 of the Regulation provides for the authorisation of PPPs for limited and controlled use in emergency situations.

Findings

In all 19 MSs visited, procedures were in place for the authorisation of PPPs and EU requirements were generally followed with two exceptions, as follows: in one MS, there was a delay in the withdrawal of parallel trade permits due to national legal requirements and administrative procedures in place providing for such a withdrawal to be launched once the authorisation of the reference PPP(s) has been withdrawn; in another MS, approval of labels was not part of the authorisation procedure. Moreover, there was not a requirement for labels to be up-dated, even in cases where the Good Agricultural Practices (GAPs) have been significantly changed in the process of re-registration.

Regarding EU deadlines for authorization, re-authorisation of PPPs and/or withdrawal of the existing authorisations, there were delays for different reasons, including the limited capacity of the CAs involved in expert evaluations, organisational problems and the high number of applications. These delays varied from eight months up to five years.

Electronic registers were kept in all 19 MSs, were made publicly available and up-dated on a regular basis (frequency varying from daily up to once every three months), with one exception. With regard to providing information on revoked PPPs, good practices were seen in the United Kingdom and Sweden, where lists of PPPs revoked were publicly available and also contained information on the sell-out and use-by dates for each PPP, as well as information on their storage and disposal. In seven MSs (Germany, Greece, Hungary, Portugal, the Czech Republic, Finland and Denmark), the database available provided links to approved labels of PPPs, which could be also identified as good practice. However, this database was not used at all, or not sufficiently used by inspectors in two of these MSs.

<u>Mutual Recognition</u>

In all visited MSs, procedures were in place for mutual recognition of authorisations, which were in compliance with the requirements of Regulation (EC) No 1107/2009. Mutual recognition was the main tool for the authorisation of PPPs in one small MS, even before the entry into force of Regulation (EC) No 1107/2009. In seven MSs, applications had been rejected for the following reasons: the assessment for the PPPs concerned had not been performed in accordance with the uniform principles in the reference MSs, incomplete data package submitted, non-comparable climatic conditions

and assessment reports of the reference MSs not being available. In three of these MSs, one further reason for rejections was the failure to comply with specific national requirements in place. In fact, the system for mutual recognition in one of these MSs was practically not operational for the reason that assessments by other MSs were not accepted. Moreover, the European Commission had not been informed of these decisions, as required by Article 36(3) of Regulation (EC) No 1107/2009.

Representatives from MSs belonging to all three zones (A, B and C) highlighted that there was a very good co-operation between MSs within all the zones. The CA in charge of PPP authorisation in the United Kingdom uploads all authorisation reports to the Communication and Information Resource Center for Administrations, Businesses and Citizens of the European Commission (CircaBC), thus facilitating mutual recognition by other MSs, which is considered as **good practice**.

Emergency Uses

In all 19 MSs visited, there were procedures in place for placing on the market of PPPs for limited and controlled use in the case of emergency, which were in compliance with the requirements of Article 53 of Regulation (EC) No 1007/2009 and in particular, keeping the 120-day-period and informing the Commission and the other MSs.

The main weaknesses identified were related to the implementation of procedures, as follows: after entry into force of Regulation (EC) No 1107/2009, most of the emergency use authorisations granted in three MSs were, in fact, extension of authorisations for minor uses and/or minor crops. In three MSs, there were cases of emergency use authorisations for the same PPP, on the same crops, for a number of consecutive time periods. In two MSs, PPPs were authorised for emergency uses, for which authorisation had been refused following assessment. In one MS, the number of authorisations granted for emergency uses was very high and most of them were extension of authorisations for PPPs already placed on the market, which were considered not to be minor uses. There were a few cases in different MSs, where PPPs authorised for limited and controlled use contained active substances not approved in the EU.

In four of the MSs visited (Slovenia, Portugal, Poland and Slovakia), **good practices** were identified regarding emergency authorisations. In Slovenia, only a limited number of emergency use authorisations have been granted after entry into force of Regulation (EC) No 1107/2009. In all cases, the requirements for use were clearly defined, including risk mitigation measures and special requirements for recording of these uses. In Portugal, emergency use authorisations were granted on case-by-case basis taking account of all the information available on alternative methods for pest control, availability of PPPs already authorised for the same use, severity of infestation and the availability of Maximum Residue Levels (MRLs). In 2012, almost one third of the applications were rejected. In the case of rejection, an expert opinion was provided to the applicant. In Poland and Slovakia, a similar responsible approach was seen in granting emergency authorisations.

Conclusions

Legal requirements and procedures were in place for the authorisation of PPPs, mutual recognition of authorisations and authorisation of emergency uses, which follow the EU requirements. However, weaknesses were identified with regard to their implementation.

With regard to PPP authorisation, the significant delays of MSs in the evaluation or re-evaluation of PPPs highlight the difficulty to implement authorisation systems based on EU legislation.

Regarding mutual recognition of authorisations, shortcomings relate to delays in the evaluation, but also relate to the non-acceptance or lack of trust in the assessments of reference MSs. Similarly, EU requirements with regard to PPP authorisation for emergency uses were either misinterpreted or misused in one third of the MSs visited, thus undermining the effectiveness of the strict criteria for regular authorisations established by EU legislation.

5.2.4 Controls on the Marketing of Plant Protection Products

Legal requirements

Article 28 of Regulation (EC) No 1107/2009 lays down that a PPP shall not be placed on the market unless it has been authorised in the MS concerned.

Article 29 of Regulation (EC) No 1107/2009 sets out the requirements for the authorisation for placing PPPs on the market.

Article 5 of Directive 2009/128/EC requires MSs to ensure that all distributors of PPPs have access to appropriate training by bodies designated by the CAs. Certification systems have to be established by 26 November 2013.

Article 6 of Directive 2009/128/EC lays down that, by 26 November 2015, the sale of PPPs to professional users shall be restricted to persons holding a certificate.

Article 67(1) of Regulation (EC) No 1107/2009 requires that producers, suppliers, distributors, importers and exporters of PPPs shall keep records for at least 5 years.

Article 68 requires MSs to carry out official controls in order to enforce compliance with this Regulation.

Article 13 of Directive 2009/128/EC requires MSs to adopt the necessary measures to ensure that handling and storage of pesticides and handling, recovery or disposal of their packaging and remnants do not endanger human health or the environment.

Findings

In most MSs, systems were in place for official control on the marketing of PPPs with the exception of two MSs, where there was no systematic approach.

<u>Planning and Implementation of Official Controls</u>

There was a requirement in place for pesticide distributors to be registered with the CAs in eleven of the MSs visited. In two of the MSs, only operators dealing with certain hazardous chemicals, including pesticides classified as toxic, very toxic or corrosive, were required to hold a permit. Official controls were carried out exclusively at permit holders, thus covering only a limited number of pesticide distributors. In one MS, there was a voluntary system for certification of pesticide distributors, which was operated by a private commercial organisation. However, there was no exchange of information between the private organisation and the relevant CAs. The list of certified distributors was not publicly available. In the remaining five MSs, although routine inspections were performed at pesticide wholesalers and retailers, due to the lack of a register there were no sufficient guarantees that all operators were covered by official controls.

In eleven of the MSs visited, inspections at pesticide distributors were performed in accordance with national control programmes. However, in two of these MSs the programmes only indicated the number of inspections per inspector per year. There was no indication of risk criteria to be taken into account and/or frequency of controls. A risk

based approach was seen to be applied in five MSs, taking account of previous history, the size of establishment and statistics on sales. In these MSs, frequency of controls varied from once a year up to once every three to five years (depending on the type of establishments, sometimes varying from one region to another in the same MS).

Regarding the scope of inspections, in 18 of the MSs visited the following main aspects were covered: documentary checks (licenses of premises and / or operators; records on sales; documentary evidence of training and / or educational background of staff members); checks of storage facilities, including storage conditions and checks of the PPPs in stock (authorisation status, labeling and expiry dates). In the remaining MS, official controls were only performed in the case of complaint and/or suspicion and the investigation was focused solely on the problematic issue.

With regard to labelling checks, these were considered not to be sufficiently effective in eight of the MSs visited for different reasons, *inter alia,* the lack of information on the approved labels at the time of the inspection, lack of adequate equipment and / or national database of approved labels, lack of guidelines and / or written instructions on the performance of official controls, lack of or insufficient training for inspectors. In these MSs, labels were checked for completeness, but their content was not verified. In one MS, an off-line version of the national database using outdated information to verify the authorisation status of the PPPs in stock and the conditions of use.

The practices introduced in the remaining eleven MSs could be considered as **good practices** where the labels of randomly chosen PPPs were compared with the approved ones contained in the national database.

The system for official controls on the marketing of PPPs seen in Romania, could be identified as **good practice,** including a system for certification of PPP distributors, a risk-based, three-year rolling national control programme, monthly inspection programmes at regional level, comprehensive on-the-spot checks, sampling for formulation analysis under an annual sampling programme, safety of operators and environmental aspects being subject to official controls by different CAs. Further detail could be found in the audit report DG(SANCO)/2014-7179.

Training and Certification of Pesticide Distributors

In the MSs visited, a system for training and certification of pesticide distributors had already been introduced at the time of the audits, with the exception of five MSs. In three of these MSs, a system was imminent and it was expected to become operational before 26 November 2013. In the fourth MS, no measures had been foreseen regarding additional training of distributors to update their knowledge. In the last of the five MSs in question, there was a delay in establishing a system due to a delay in the designation of training providers.

In two MSs, certificates issued were not subject to renewal, which is not in line with the requirements of Article 5 of Directive 2009/128/EC.

In the Czech Republic, Slovakia and Portugal, the systems in place for training and certification were considered to be comprehensive and these could be recognised as **good practices**. There were different types of certification and different training modules depending on the category of operators. Both training providers and the content of training courses had to be approved by the relevant CAs. Training providers were subject to supervision. A similar approach was seen in one more MS. However, neither initial nor additional training was required for the purposes of certification, contrary to the requirements of Article 5 of Directive 2009/128/EC.

Handling, storage and safe disposal of packages and remnants of PPPs

In 15 MSs, measures had been adopted regarding handling and storage of pesticides, including handling, recovery and disposal of their packaging and remnants. These were obligations of pesticide distributors, under national legislation. Collection, transport and safe disposal of both packaging and remnants was carried out by approved companies. The situation found in Romania, could be considered as **good practice,** whereby a system was in place for collection of empty packages, pesticide remnants, expired and withdrawn pesticides at national level, which was organised by the relevant central CA, in co-operation with representatives from the pesticide industry. This was operated at county level. Collection of such materials was based on contracts between waste management companies and operators. With regard to contracting of collections, a similar situation was seen in Slovakia. In four further MSs, the pesticide industry was also actively involved.

In the majority of MSs visited, empty packages, pesticide remnants, expired and/or withdrawn PPPs were stored separately and this was checked during inspections.

The following weaknesses were identified regarding handling of empty packages and pesticide remnants, *inter alia,* high costs of disposal (two MSs), no national legal requirements in place (one MS) and legal requirements not being enforced, with limited exceptions, in cases of toxic and very toxic pesticides (one MS).

Formulation analysis

Formulation laboratories for quality controls of pesticides were designated in 18 MSs. In one of these MSs, the formulation laboratory designated had not been operational since 2005.

In seven of the MSs visited, laboratories for formulation analysis were accredited to ISO 17025 and in two further MSs, laboratories were certified for compliance with the Good Laboratory Practice. Most of the accredited formulation laboratories participated in Proficiency Tests and international collaborative tests organised by the Collaborative International Pesticides Analytical Council (CIPAC). All laboratories visited used CIPAC methods and/or methods provided by the PPP manufacturers. In two MSs, the formulation laboratories were able to analyse almost all of the pesticides authorised for placing on the market.

With regard to laboratory resources, there was no LC-MS/MS equipment in the formulation laboratories of eight MSs and, in one MS, such equipment was available, but not used for quality controls of pesticides. In most MSs, no screening methods were used for formulation analyses and/or laboratory staff were lacking the experience and the knowledge to use these methods. For these reasons, formulation analysis only covered the identity and content of active substance(s) and some physical-chemical properties, but not co-formulants and relevant impurities. As a consequence, this was a constraint for the identification of illegal and/or counterfeit pesticides.

In the majority of MSs visited, formulation analyses were considered to be unsatisfactory due to the lack of risk based sampling, the low number of samples taken and the limited scope of analysis or a combination of all three. In one MS, samples were not taken in all regions. In two MSs, samples had not been taken since 2005 and 2006 respectively. Another weak point to highlight is that deficiencies regarding quality controls were identified in MSs with an extensive use of PPPs and, respectively, high volumes of agricultural production. Effectiveness of quality controls of pesticides was compromised due to the long turnaround time, which varied from a few weeks (for

priority samples) up to six months (for routine samples). Moreover, in one of these MSs, samples were not taken during inspections at pesticide distributors, but purchased directly from the authorisation holders.

In five of the 19 MSs visited, in addition to the identity and content of active substance(s) and, in some cases, physical-chemical properties, the scope of analysis also covered co-formulants and relevant impurities. In all these MSs, PPP quality controls were risk based. This could be identified as **good practice,** which provides better guarantees that PPPs placed on the market meet the EU requirement and allows for counterfeit and illegal pesticides to be detected.

Counterfeit and illegal pesticides

In most of the MSs visited, there was no systematic approach or strategy regarding counterfeit and illegal pesticides. The limited analytical scope of PPP quality controls and the weaknesses identified in labelling checks were further constraints on effective detection. As more than one CA was involved in these activities in most of the MSs, insufficient co-operation and co-ordination was another limitation.

The worst situation was found in three MSs, where, in addition to the lack of targeted controls for illegal and counterfeit pesticides, the systems in place for official controls on the marketing of PPPs as a whole were considered to be weak. In addition, controls on PPPs imported from Third Countries (TCs) were either weak or did not exist and formulation analysis was either absent or not effective.

The procedures in place and actions undertaken in France and Germany could be identified and recommended as **good practices** to follow. In both MSs, the CAs in charge performed targeted controls for illegal and counterfeit pesticides, in addition to routine official controls on the marketing and use of PPPs. These activities were carried out in close co-operation with Customs Services and financial police within the country, as well as with CAs of other MSs and the European law enforcement agency, Europol. The situation in Poland could also be identified as **good practice,** where, in addition to targeted controls and co-operation with other authorities and MSs, additional inspections at manufacturers and packing facilities in the case of suspected fraud, and the substantial sampling programme for formulation analysis, have further contributed to the effectiveness of controls on illegal and counterfeit pesticides.

Conclusions

Systems were in place for official controls on the marketing of PPPs in the MSs visited with two exceptions. The main weaknesses identified regarding marketing controls include the following: no system in place for official controls at pesticide distributors, no full coverage of pesticide distributors by the control systems, unsatisfactory labelling checks and the limited scope covered by formulation laboratories, which only analyse the identity and content of active substance(s). These weaknesses limit the effectiveness of official controls on the marketing of PPPs and, consequently, provide insufficient guarantees that PPPs placed on the market meet the requirements of Regulation (EC) No 1107/2009.

The lack of adequate equipment, the insufficient experience of staff or both did not allow for screening methods to be introduced and the scope of formulation analysis to be extended to cover co-formulants and relevant impurities. The limited analytical scope, in particular, is considered to be a constraint for the detection of counterfeit and illegal pesticides.

Systems were in place for training and certification of pesticide distributors, with a few exceptions, which provides sufficient assurance that PPPs are sold by staff who were properly trained and have the knowledge to advise professional users on the safe use of PPPs. Legal provisions were in place and measures were undertaken for the handling, storage, transport and safe disposal of empty containers, expired PPPs and remnants in the majority of MSs visited, which provides guarantees for a better protection of human health and the environment.

5.2.5 Controls on the Use of Plant Protection Products

Legal requirements

Article 4(1) of Regulation (EC) No 852/2004, and Annex I, Part A.III of the same Regulation, require that food business operators (FBOs) producing or harvesting plant products are to keep records on any use of PPPs.

Article 55 of Regulation (EC) No 1107/2009 requires that the use of PPPs shall comply with the general principles of IPM, as referred to in Article 14 of Annex III to Directive 2009/128/EC, which shall apply at the latest by 1 January 2014. Article 14(5) of the Directive specifies that MSs shall establish appropriate incentives to encourage professional users to implement crop or sector-specific guidelines for IPM on a voluntary basis.

Article 67(1) of Regulation (EC) No 1107/2009 requires that professional users keep, for at least 3 years, records of the PPPs they use. Article 55 specifies that PPPs shall be used, *inter alia*, in compliance with the authorised conditions specified on the labels.

Article 68 of Regulation (EC) No 1107/2009 requires MSs to carry out official controls in order to enforce compliance with this Regulation.

Article 5 of Directive 2009/128/EC requires MSs to ensure that all professional users have access to appropriate training by bodies designated by the CAs. It was directed that certification systems be established by 26 November 2013.

Article 8 of Directive 2009/128/EC requires MSs to ensure that pesticide application equipment in professional use is subject to inspections at regular intervals. By 26 November 2016, all equipment shall have been inspected at least once.

Article 13 of Directive 2009/128/EC requires MSs to adopt the necessary measure to ensure that handling and storage of pesticides and handling, recovery or disposal of their packaging and remnants do not endanger human health or the environment.

Article 8(5) of Directive 2009/128/EC requires professional users to conduct regular calibrations and technical checks of the pesticide application equipment.

Findings

<u>Planning and Implementation of Official Controls</u>

In all 19 MSs, systems were in place for official control on the use of PPPs. In four of the MSs visited, official controls on the use of PPPs were only performed under the cross-compliance checks at growers receiving direct payments under the single payment scheme as provided for in Council Regulation (EC) No 1782/2003. In the remaining MSs, with one exception, cross-compliance checks were performed by CAs different than those who were in charge of routine inspections on the use of PPPs. In most cases there was a lack of, or insufficient, co-ordination and co-operation between CAs involved in both types of controls. In other cases, there was an exchange of information

on the results of inspections and/or irregularities identified, but this was not used sufficiently for the purposes of risk assessment in the planning stage.

In the majority of MSs visited, inspections at professional users were performed in accordance with annual or multi-annual national controls programmes or guidelines provided by the central CAs. None of the MSs visited had a register of professional users. In one MS, such a register was in the process of development. In some MSs, the main source of information on growers was the database of the Paying Agencies. As a result, official controls on the use of PPPs were mainly performed at growers receiving direct payments or subsidies under Agri-Environmental measures. In most MSs, this meant that an undefined number of professional users were not covered by official controls.

In all MSs visited, legal requirements were in place for growers to keep records on the application of PPPs. The records required varied between MSs. In four MSs, the records kept were insufficient to provide all information needed to verify that the conditions of use specified on the label were complied with.

Regarding the scope of inspections, in the majority of the MSs visited, the main aspects checked at growers included the following: documentary checks (licenses; records on the use of PPPs; training certificates; certificates for technical checks of application equipment; contract or other documentary evidence showing safe disposal of empty packages, expired PPPs or remnants, invoices for PPP purchases etc. and checks of storage facilities (storage conditions, separate storage of remnants and empty containers and checks of the PPPs in stock).

In five MSs, a physical check of application equipment was also part of the inspection. In five further MSs, a labelling check of PPPs in storage was included. In addition, in two MSs, safety issues were also checked during inspections.

In 13 MSs, comprehensive checks were performed on records kept by growers to verify the authorisation status of PPPs and conditions of use. In the remaining six MSs, records and, if applicable, labelling checks were considered **not to be sufficiently effective** for the same or similar reasons to those listed under Chapter *5.2.4 Controls on the Marketing of Plant Protection Products.*

In Denmark, the system in place for official controls on the use of PPPs, including both cross-compliance checks and routine controls at professional users, could be identified as **good practice**. It included risk based planning, preparatory work before inspections, comprehensive checks during inspections, exchange of inspectors between regions to avoid conflict of interests. Since 2009, official controls on the use of PPPs also covered non-farm users, such as golf courses, and spraying contractors. More details could be found in audit report DG(SANCO)/2014-7181.

Other **good practices** in individual MSs include field inspections at the time of application, targeted inspections on the application of PPPs in water protection zones, sampling and analysis of spray tank mixtures and plant tissues to verify, if GAPs were followed and to identify any possible illegal (non-authorised) uses.

Training and Certification of End Users

With regard to training and certification of end users, the situation found was similar to that for pesticide distributors. In 16 of the MSs visited, systems were in place for training and certification of professional users and advisors. In three of these MSs,

systems had been introduced many years before the entry into force of Directive 2009/128/EC.

In some MSs, weaknesses were identified, including no requirements for operators applying pesticides to be trained and licensed (one MS), certificates issued were not subject to renewal (two MSs) and validity of certificates varied from one region to another (one MS).

Similar to the case of training and certification of pesticide distributors, the situation found in the Czech Republic and Slovakia could be identified as **good practice**. Similar practices were also applied in Sweden and Denmark. Another **good practice** was seen in Sweden, where specialised permits were required to use PPPs for seed treatment. These were obtained by professional users after having attended a specialised training provided by the central CA and these were subject to renewal, following additional training.

Handling, storage and safe disposal of packages and remnants of PPPs

The situation found is identical to that at pesticide distributors.

Regarding treatment of empty packages, the worst situation was seen in one MS, where the user visited had burned them directly on the field. In response, the CA explained they advise growers to apply a triple rinsing of empty containers and to send them for household waste recycling. A similar rinsing practice was seen in two further MS, for containers with a capacity below 50 litres (in the first MS) and for all types of empty containers from formulations which were not classified as toxic or very toxic (in the second MS). Containers with a capacity above 50 litres and empty packages of toxic or very toxic PPPs respectively were treated as hazardous waste and these were collected by approved service providers.

Application Equipment

At the time of the audits, legal requirements were in place and measures had been put into place for checks of application equipment in eleven of the MSs visited. Calibration certificates and plates/labels of calibration on the machinery were checked during routine inspections at professional users. In four of these MSs, systems had been in place for checking application equipment for many years before the entry into force of Directive 2009/128/EC.

In five MSs, legal requirements were in place, but checks of application equipment had not yet been introduced. In the remaining three MSs, national legislation was still awaited. However, evidence was provided by the CAs of all the eight MSs concerned indicating time frames, which were in compliance with the deadlines set out in Directive 2009/128/EC. In addition, voluntary schemes were operated for annual checks of application equipment in two of these MSs. There was only one exception, where, although legal requirements were in place, no deadlines were fixed for implementing measures to be undertaken. Moreover, neither the inspectors nor the grower met were aware of any facilities for calibration of the equipment in the region visited.

Integrated Pest Management (IPM)

At the time of the audits, national legal requirements were in place and measures had already been put into place to promote IPM in all 19 MSs. Additionally, in nine of the MSs, either guidelines or manuals on IPM for individual crops or groups of crops had been developed. In two MSs similar guidelines were under development and in another two MSs, this was planned for the near future. IPM was covered as a topic in the specialised training for the purposes of professional users' certification in five MSs.

In two MSs, some IPM aspects were introduced as legal obligations for growers. These IPM-related issues were checked during the routine inspections at growers. In one of these MSs, specific IPM-focused inspections were taking place at registered IPM growers and these were performed by the CA in charge of official controls on the use of PPPs. In four further MSs, there were a high number of growers who either participated in Integrated Production Schemes or were certified under private schemes.

Measures undertaken in Portugal regarding IPM could be identified as **good practice**. The first crop-specific manuals on IPM were drafted by the CA in 2004 and up-dated in 2009. At the time of the audit, 71 crop-specific manuals were available and the second up-date was under preparation. Although previously, manuals were distributed to stakeholders upon paying a fee, the new up-dates were to be made publicly available on the web-site of the CA. Further details could be found in audit report DG(SANCO)/2012-6298.

Conclusions

Official controls on the use of PPPs were of better quality and more effective than controls on the marketing of PPPs. Systems were in place in all 19 MSs and all relevant aspects were covered during inspections in the majority of the MSs visited. The comprehensive checks of records kept by professional users, which were taking place in most of the MSs, provided further assurances that PPPs are applied in accordance with the authorised conditions specified on the labels. One of the weaknesses identified at user level was the lack of, or insufficient, co-ordination and co-operation between CAs in charge of cross-compliance checks and those dealing with routine controls at professional users, which is a constraint for the better targeting of controls and selection of operators. Another weak point was the lack of reliable sources of information on operational professional users. For this reason, controls were mainly focused on growers receiving direct payments or subsidies under Agri-Environmental measures and thus an undefined number of professional users were excluded from the control system.

Measures were put into place in the majority of MSs for the implementation of Directive 2009/128/EC, in particular, training and certification of professional users, safe handling and storage of PPPs, their containers and remnants, IPM and application equipment. This is a step forward to ensure that PPPs are applied in accordance with the authorisation conditions, actions are undertaken to make use of alternative methods for pest control in order to avoid the unnecessary use of PPPs and to protect human health and the environment.

5.2.6 Prioritisation of official controls

Legal requirements

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency, taking account of (a) identified risks; (b) the FBOs past record as regards compliance; (c) the reliability of any own checks that have already been carried out; and (d) any information that might indicate non-compliance.

Findings

In nine of the MSs visited, official controls on the marketing and use of PPPs were performed regularly on a risk basis and risk criteria for planning of controls were clearly defined. In five further MSs, a risk-based approach was in place for official controls at

user level, but not for inspections at distributors of PPPs. There were some further weaknesses identified. At PPP distributors, there was no fixed frequency of controls and the high non-compliance rate from previous years was not taken into account (one MS), no fixed frequency for inspections at PPP distributors, but only the number of inspections per inspector per year (two MSs). At professional users, the frequency of controls was considered to be inadequate taking into account the high number of growers, the high volumes of fresh fruit and vegetable production and the high non-compliance rate from previous years (one MS); the low number of inspections compared to the total number of professional users in the country (one MS); results from own controls, cross-compliance checks and/or controls under private schemes available, but not checked, or checked, but not taken into account when planning official controls (four MSs).

In three MSs, there was no risk based approach for official controls on either marketing or use of PPPs.

Conclusions

The weaknesses identified with regard to prioritisation of official controls could be a constraint on the effectiveness and efficiency of the control systems operated.

5.2.7 Procedures for Performance and Reporting of Control Activities

Legal requirements

Article 8 of Regulation (EC) No 882/2004 requires that CAs carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Article 9 of the above Regulation requires CAs to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

Article 68 of Regulation (EC) No 1107/2009 requires MSs to transmit to the Commission a report on the scope and the results of controls to enforce compliance with this Regulation within six months of the end of the year.

Findings

Documented procedures were in place for official controls within the scope of the audit and standard check-lists were followed by the inspectors in 17 of the MSs visited. In the remaining two MSs, there were neither documented procedures nor written instructions for staff dealing with official controls on the marketing and use of PPPs. In addition, some weaknesses were identified in four MSs, as follows: documented procedures in place were very general, covering all areas of activity, but not specifically PPP related controls (one MS), documented procedures were related to performance of official controls, but did not cover planning of controls, risk categorisation of operators and sampling (one MS), written procedures were developed at local level, but there was no harmonised approach at national level (one MS), documented procedures and written instructions for inspectors were only available for official controls on the use of PPPs, but not for the marketing of PPPs (one MS).

In all 19 MSs, inspection reports were drafted during inspections. In one MS, there were no standard templates for inspection reports harmonised at national level. In another MS, there were standard templates, but these were used for all types of controls and not

PPP specific. In two MSs, inspection reports contained neither corrective measures nor deadlines for operators in the case of non-compliances found.

Three MSs did not report results from official controls to the Commission. In addition, one MS submitted annual reports to the Commission, which did not include results from all local CAs, but only covering 75 % of municipalities.

Conclusions

Official controls were performed in accordance with documented procedures and reporting on controls was in line with the requirements of Regulation (EC) No 882/2004. However, weaknesses found in this regard in a few MSs could compromise effectiveness of official controls.

5.2.8 Co-ordination and Co-operation between and within Competent Authorities

Legal requirements

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination between CAs.

Article 4(5) of Regulation (EC) No 882/2004 requires that, when, within a CA, more than one unit is competent to carry out official controls, efficient and effective co-ordination and co-operation shall be ensured between the different units.

Findings

Effective co-ordination and co-operation within and between CAs was in place in seven MSs. In two MSs, there was no systematic co-operation between the CAs involved in official controls on the marketing of PPPs and those dealing with controls on the use of PPPs. In three MSs, there was no communication and co-operation between CAs in charge of cross-compliance checks and CAs responsible for official controls on the use of PPPs. In two further MSs, there was a similar situation with regard to controls of illegal and counterfeit pesticides. Some further weaknesses were found in individual MSs, among which were the following: no systematic communication between regional CAs, poor co-operation between central and regional CAs, insufficient communication and co-operation between CAs and IPM certification bodies and between multiple CAs involved in similar controls.

Conclusions

Co-ordination and co-operation between and, in some cases, within CAs was considered to be weak. For this reason, there are no guarantees that there is no duplication of work and available resources are efficiently used, which could affect effectiveness of official controls.

5.2.9 Enforcement Measures

Legal requirements

Article 72 of Regulation (EC) No 1107/2009 states that MSs shall lay down the rules on penalties applicable to infringements and ensure that these are implemented. The penalties shall be effective, proportionate and dissuasive.

Article 54 of Regulation (EC) No 882/2004 requires a CA which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation.

Article 55 of Regulation (EC) No 882/2004 states that MSs shall lay down the rules on sanctions applicable to infringements of feed and food law and other EU provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

Findings

In all MSs visited, national legal requirements were in place for measures to be taken in the case of non-compliances or irregularities identified, including administrative sanctions and fines to be imposed. In 14 MSs, adequate measures were taken to ensure that non-compliant operators would remedy the situation and follow-up inspections were taking place. In two MSs, insufficient follow-up was taking place to ensure that corrective actions are undertaken by operators found to be non-compliant. In four MSs, sanctions and fines imposed were considered not to be effective, proportionate and dissuasive.

Conclusions

Enforcement measures were in compliance with the EU requirements. In a few MSs, there are no guarantees that non-compliant operators would be incentivised to achieve compliance due to the inadequate follow-up measures by CAs, inadequate sanctions or a combination of both.

6 GOOD PRACTICES

During the audits, good practices were identified in either individual MSs or groups of MSs and these were described in the relevant chapter of this report. Good practices were found with regard to systems for official controls as a whole for both marketing and use of PPPs. In addition, good practices were identified with regard to specific aspects as follows:

- Training of staff from CAs;
- Authorisation of PPPs, including mutual recognition and emergency authorisations;
- Labelling checks of PPPs;
- Training and certification of pesticide distributors and professional users;
- Handling and storage of PPPs, their containers and remnants at both distributor and user level;
- Formulation analysis;
- Controls for illegal/counterfeit pesticides;
- IPM.

7 RECOMMENDATIONS

The reports of the individual audits contained recommendations made to the CAs of the MSs visited. In their action plans the CAs provided commitments to address these recommendations.

The main deficiencies giving rise to recommendations were the following:

- Requirements of Directive 2009/128/EC not, or not fully, transposed – four MSs;
- Insufficient training to keep CAs' staff up-to-date in their areas of responsibility as required by Article 6 of Regulation (EC) No 882/2004 – five MSs;
- EU deadlines for the authorisation and re-registration of PPPs not complied with – ten MSs;
- Authorisations for use of PPPs in emergency situations granted not in compliance with the requirements of Article 53 of Regulation (EC) No 1107/2009 – four MSs;
- No guarantees that all pesticide distributors are covered by controls under Article 68 of Regulation (EC) No 1107/2009 – five MSs;
- Insufficient verification that PPPs placed on the market are labelled in accordance with the requirements laid down in Article 65 of Regulation (EC) No 1107/2009 and Regulation (EU) No 547/2011– six MSs;
- Quality controls of pesticides not part of official controls on the marketing of PPPs or not effective (due to the limited scope of analysis or the low number samples taken or both) in order to ensure that PPPs placed on the market meet the requirements of Article 29 of Regulation (EC) No 1107/2009 – nine MSs;
- Insufficient guarantees that PPPs or their remnants and empty packages are appropriately stored and safely disposed of as required by Article 13 of Directive 2009/128/EC – five MSs;
- No guarantees that all professional users are covered by official controls under Article 68 of Regulation (EC) No 1107/2009 – eight MSs;
- Inspections at professional users performed with prior warning contrary to Article 3(2) of Regulation (EC) No 882/2004 – six MSs;
- Official controls within the scope of the audit not performed regularly, on a risk basis and with appropriate frequency as laid down in Article 3 (1) of Regulation (EC) No 882/2004 – eleven MSs;
- Lack of, or insufficient, co-operation and co-ordination between CAs involved in controls within the scope of the audit which is not in line with Article 4 (5) of Regulation (EC) No 882/2004 – ten MSs;
- Inappropriate enforcement measures due to the lack of or insufficient follow-up at non-compliance operators and/or sanctions imposed not effective, proportionate and dissuasive contrary to Articles 54 and 55 of Regulation (EC) No 882/2004 – six MSs. both.

8 ACTION TAKEN BY COMMISSION SERVICES

8.1 FOLLOW-UP OF AUDIT RECOMMENDATIONS

For each audit a copy of the draft audit report was sent to the national CAs with a request for an action plan to be provided where actions to be undertaken to address individual recommendations and deadlines for their implementation had to be indicated.

A deadline was set for the receipt of these plans and responses of the CAs were analysed. In cases, where responses to individual or all recommendations were considered to be either unsatisfactory or incomplete, the Commission's services actively pursued the matter with the authorities concerned.

Progress on the actions undertaken by MSs to address recommendations is described in the Country Profiles, which can be found at the following website: http://ec.europa.eu/food/fvo/country_profiles_en.cfm.

As of May 2015, most of the MSs visited have addressed all recommendations made during the latest audit series.

8.2 ADDITIONAL ACTIONS BY COMMISSION SERVICES

Before the audit series started, a presentation was given by the FVO at a meeting of the Standing Committee on the Food Chain and Animal Health (SCFCAH) – Pesticides legislation, where representatives from all MSs were present. In this presentation, an overview of the findings of the previous mission series was presented, an update on the relevant legislation was given and further details with regard to the objectives and audit scope of the current audit series.

In 2012, nine MSs were visited. Then, in the beginning of 2013, an Interim report containing the main findings, good practices and common weaknesses was presented to MSs' representatives at the SCFCAH in May 2013. On completion of the audit series, the FVO presented a preliminary overview at the Standing Committee for Plants, Animals, Food and Feed in December 2014.

Several training sessions were organised by the Commission under the Better Training for Safer Food (BTSF) programme, which were focused on official controls on the marketing and use of PPPs in 2013 and 2014, where experts from MSs directly involved in inspections at regional/local level or who dealt with planning, co-ordination of and reporting on control activities at central level were present. Based on availability, representatives from the FVO attended these sessions and gave presentations.

In the light of the outcome of the latest audit series and taking account of the main weaknesses found in MSs, another BTSF session was planned to be held on 23 – 25 September 2015 on laboratory analysis of PPPs for the detection of illegal and counterfeit pesticides, which aims at exchange of good practices. This training will be organised by the Commission and will take place in FVO, Grange. It is expected, that key experts from MSs will attend to discuss issues related to formulation analysis and illegal/counterfeit PPPs, and ultimately to improve MSs' performance in this area.

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. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	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
Reg. 1107/2009	OJ L 309, 24.11.2009, p. 1-50	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
Dir. 2009/128/EC	OJ L 309, 24.11.2009, p. 71-86	Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides
Reg. 540/2011	OJ L 153, 11/06/2011, p.0001-0186	Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances
Reg. 547/2011	OJ L 155, 11/06/2011, p.0176-0205	Commission Regulation (EU) No 547/2011 of 08 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products

ANNEX II DETAILS OF AUDITS UNDERTAKEN

Member State	Dates of audit	SANCO reference number
Italy	31/01-08/02/2012	2012-6277
Bulgaria	13-20/03/2012	2012-6279
France	13-20/03/2012	2012-6281
Greece	02-09/05/2012	2012-6285
Germany	09-16/05/2012	2012-6282
Hungary	04-08/06/2012	2012-6287
Latvia	10-14/09/2012	2012-6294
Slovenia	08-12/10/2012	2012-6295
Portugal	20-27/11/2012	2012-6298
Cyprus	05-12/03/2013	2013-6635
Spain	06-13/03/2013	2013-6637
Poland	28/05-05/06/2013	2013-6640
The Czech Republic	10-17/09/2013	2013-6647
The United Kingdom	14-22/10/2013	2013-6643
Romania	18-26/03/2014	2014-7179
Finland	05-09/05/2014	2014-7181
Sweden	13-20/05/2014	2014-7182
Slovakia	16-20/06/2014	2014-7183
Denmark	17-24/06/2014	2014-7184

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