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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
GERMANY
FROM 09 TO 16 MAY 2012
IN ORDER TO EVALUATE CONTROLS OF PESTICIDES

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Germany, carried out between 9 and 16 May 2012, under the provisions of Regulation (EC) No 882/2004 on official food and feed controls and Regulation (EC) No 1107/2009.

The objective of the audit was to evaluate the controls on Plant Protection Products (PPPs).

In Germany, overall there is a satisfactory system in place for control on the marketing and use of PPPs. The authorisation procedure for PPPs is well developed. Comprehensive controls on the marketing and use of PPPs are performed by highly qualified and experienced staff and control programmes are in place. Specific controls during the actual spraying of the PPPs and the combining of the results of cross compliance controls and controls on the use of PPPs result in efficient and effective controls. Shortcomings were found with regard to the number of samples for formulation analysis and the granting of emergency and minor uses of PPPs. No internal audits are performed on the controls of the marketing and use of PPPs.

The report makes a number of recommendations to the Competent Authorities, aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AG PMK	Federal Lander working group on PPP control <i>Arbeitsgemeinschaft Pflanzenschutzmittelkontrolle</i>
BMELV	Federal Ministry of Food, Agriculture and Consumer Protection <i>Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz</i>
BVL	Federal Office of Consumer Protection and Food Safety <i>Bundesamt für Verbraucherschutz und Lebensmittelsicherheit</i>
BY	Bavaria <i>Bayern</i>
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
DG (SANCO)	Health and Consumers Directorate-General
EU	European Union
FTE(s)	Full Time Equivalent(s)
FVO	Food and Veterinary Office
IPM	Integrated Pest Management
LLFG ST	State Agency for Agriculture, Forestry and Horticulture of Saxony-Anhalt <i>Landesanstalt für Landwirtschaft, Forsten und Gartenbau Sachsen-Anhalt</i>
LfL	Bavarian State Agency for Agriculture <i>Bayerische Landesanstalt für Landwirtschaft</i>
MLU ST	Ministry for Agriculture and Environment of Saxony-Anhalt

	<i>Ministerium für Landwirtschaft und Umwelt des Landes Sachsen-Anhalt</i>
MS(s)	Member State(s)
MS ST	Ministry of Social Affairs of Saxony-Anhalt <i>Ministerium für Soziales des Landes Sachsen-Anhalt</i>
PAPI	Official Register of Authorisations of PPPs <i>Pflanzenschutzmittel-Auswertung und Pflanzenschutzmittel-Information</i>
PPP(s)	Plant Protection Product(s)
RCA	Regional Competent Authority
ST	Saxony-Anhalt <i>Sachsen-Anhalt</i>
St MLF	Bavarian State Ministry for Agriculture and Forestry <i>Bayerisches Staatsministerium für Landwirtschaft und Forsten</i>
St MUG	Bavarian State Ministry for Environment and Health <i>Bayerisches Staatsministerium für Umwelt und Gesundheit</i>

1 INTRODUCTION

The audit formed part of the Food and Veterinary Office's (FVO) planned programme.

The audit took place from 09 May to 16 May 2012. The team comprised 2 auditors from the FVO and one expert from a European Union (EU) Member State (MS).

Representatives from the Central Competent Authority (CCA) accompanied the FVO team for the duration of the audit. An opening meeting was held on 09 May 2012 with the CCA, including the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV), the Federal Office of Consumer Protection and Food Safety (BVL), the Bavarian State Ministry for Agriculture and Forestry (St MLF), the Bavarian State Ministry for Environment and Health (St MUG), the Ministry for Agriculture and Environment of Saxony-Anhalt (MLU ST), the State Agency for Agriculture, Forestry and Horticulture of Saxony-Anhalt (LLFG ST) and the Ministry of Social Affairs of Saxony-Anhalt (MS ST). At this meeting, the objectives of, and itinerary for, the audit were confirmed by the FVO team and the control systems were described by the authorities.

2 OBJECTIVES AND SCOPE

The objectives of the audit were to evaluate the control systems in place for plant protection products (PPPs) , 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 requirements for official controls of the use of PPPs at growers under Regulation (EC) No 882/2004;

In terms of **scope**, the audit assessed the performance of the Competent Authorities (CA), as well as the organisation of the controls including the authorisation procedures, controls of the wholesalers and retailers of PPPs and controls of the growers.

In pursuit of these objectives, the following sites were visited:

Table 1: Mission visits and meetings

Visits/meetings		Comments
Competent Authorities		
Central	1	BMELV
Regional	2	Institute for Plant Protection (IPS) Bavaria St MLF Bavarian State Agency for Agriculture (LfL) MLU ST

On-Site-Visits		
Controls of growers	2	Bavaria and Saxony-Anhalt
Controls of wholesalers and retailers	2	Retailer in Bavaria and wholesaler in Saxony-Anhalt.

3 LEGAL BASIS AND STANDARDS

3.1 LEGAL BASIS

The audit was 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.

EU legal acts quoted in this report refer, where applicable, to the last amended version. Full references to the EU acts quoted in this report are given in Annex 1.

3.2 STANDARDS

The Guideline SANCO/12495/2011 on Method Validation and Quality Control Procedures for pesticide residues analysis in food and feed was relevant for this audit.

A list containing details of the applicable standard is provided in Annex 2. Reference to specific provisions of this text is provided at the beginning of each section.

4 BACKGROUND

4.1 MISSION SERIES

This audit is part of a series of FVO audits in MSs of the EU on controls of pesticides. Prior to the current audit series, the FVO carried out three series of missions to MSs which covered controls of the marketing and use of PPPs and pesticide residues. The general overview reports of the previous mission series can be found on the DG (SANCO) internet site:

http://ec.europa.eu/food/fvo/specialreports/index_en.htm

During the previous mission series the FVO teams identified that control systems vary considerably between Member States. The control system for pesticide residues was better developed than the control system for placing on the market and use of PPPs. However, deficiencies in the planning and conducting of inspections for control of the marketing and use of PPPs were frequently identified. The operation of formulation laboratories to test PPPs was considered to be satisfactory.

The planning and reporting of controls for pesticide residues in food of plant origin has improved significantly since the first mission series. Weaknesses were identified, in particular, regarding the assessment of self-control systems, the point of sampling, and enforcement measures taken in the case of non-compliance. The main deficiencies found in pesticide residue laboratories related to the

lack of adequate equipment and the implementation of quality control procedures.

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

In the framework of the last series, the FVO carried out a mission in Germany in 2008 (DG(SANCO)2008-7852) The report of this mission can be found at http://ec.europa.eu/food/fvo/ir_search_en.cfm. The overall conclusion of the mission report was that a multi-annual national control plan for pesticide residues should be established, information relating to serious risks to human health caused by pesticide residues should immediately be notified to the Commission under the Rapid Alert System for Food and Feed and methods for pesticide residue analysis should be validated.

4.2 COUNTRY PROFILE

The FVO has published a country profile for Germany, which describes in summary the control systems for food and feed, animal health, animal welfare and plant health and gives an overview on the state of play of the implementation of recommendations of the previous FVO mission reports. The country profile can be found at: http://ec.europa.eu/food/fvo/country_profiles_en.cfm

5 FINDINGS AND CONCLUSIONS

5.1 RELEVANT NATIONAL LEGISLATION

Legal Basis

Art. 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

The CA stated that the provisions of Regulation (EC) No 1107/2009 and Directive 2009/128/EC were implemented by the adoption of the amended Plant Protection Act of 6 February 2012 and of its various Federal ordinances. At Länder level the Regional Competent Authority (RCA) stated that full implementation is not complete yet but most provisions are already in place in the existing legislation. The requirements still to be implemented are expected to be completed by the deadlines set out in the EU legislation. The legislation is published on the BVL website: www.bvl.bund.de.

Conclusions

EU legislation is implemented or transposed as required at Federal level and available to the public. The implementation in the Länder is expected to be completed by the deadlines set out in the EU legislation.

5.2 ORGANISATION AND IMPLEMENTATION OF OFFICIAL CONTROLS

5.2.1 Designation of Competent Authorities

Legal Requirements

Article 75(1) and (2) of Regulation (EC) No 1107/2009 requires Member States 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.

Article 5 of Regulation (EC) No 882/2004 sets out the scope of possible delegation to control bodies, the criteria for delegation, and the minimum criteria which must be met by control bodies.

Findings

The designation of the CAs is described in the Country Profile. The FVO team was informed that no tasks are delegated to control bodies.

Conclusions

The CAs are designated. The CA stated that there is no delegation as described in Article 5 of Regulation (EC) No 882/2004.

5.2.2 Resources for Performance Controls

Legal Requirements

Article 75(3) of Regulation (EC) No 1107/2009 requires Member States 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; 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

At central level in the BMELV, 2.5 Full Time Equivalent (FTEs) are dealing with authorisations and controls on the marketing and use of PPPs; in the BVL, 97 persons are involved in authorisations, 40 have a university level education. In Bavaria (BY) the equivalent of around 7 FTEs perform the controls on marketing and use. In Saxony-Anhalt (ST), 1.39 FTEs perform controls on marketing, 2.29 FTEs perform controls on use. The inspectors often have a university degree in agronomy, sometimes with a specialisation in chemistry or PPPs.

Six inspectors from different states participated in the Better Training for Safer Food on marketing and use of PPPs. In BY inspectors take part in Spring service discussions (2 days), in a seminar entitled “Specialized Legal Monitoring Measures, Implementation of Plant Protection, and Processing” (2 days) and in Autumn service discussions (1 day).

In ST the inspectors attend an annual training course. There is no written procedure for the training of newcomers in either BY or ST. Newcomers perform inspections together with experienced colleagues.

Inspectors in ST also advise on the use of PPPs. The CA stated that in order to avoid a conflict of interest inspectors only advise in regions other than those wherein they do inspections.

All inspectors met by the FVO team were very well informed and were experienced in the control on marketing and use of PPPs. They were equipped with laptops containing the database on PPPs, a handbook with relevant control procedures and equipment for sampling.

Conclusions

Staff met were suitably qualified, trained and experienced. They were properly equipped.

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

An electronic register of PPPs is kept on the PAPI system. It is updated monthly. In addition, separate lists are maintained for authorised PPPs and parallel trade permits. These are available on the BVL website. The expiry date for the authorisation of all currently registered products is clearly shown on the BVL website.

In Germany there are 258 authorised active substances in 689 authorised products, which are marketed under 1287 different trade names. There are also 3112 products registered under parallel trade permits. This information is available on the BVL website.

Since 1st January 2010, Germany has authorised 20 PPPs by mutual recognition and refused one mutual recognition application. In this case, the data package supplied was considered to be incomplete. Registration by mutual recognition is used for a minority of PPPs.

Germany has granted 22 emergency authorisations in 2010, 21 in 2011 and 19 to date in 2012. Emergency uses are published on the BVL website and the Commission is informed. In some cases emergency uses were granted for the same product on the same crop for a number of consecutive periods. A herbicide containing the active substance linuron was authorised five times for emergency use between 25/03/2009 and 07/03/2012 for use on lamb's lettuce. A bactericide containing streptomycin was authorised five times between 01/04/2010 and 25/04/2012 for use on pome fruit. Several insecticides were authorised for emergency uses four or three times in the period 2009 – 2012.

Where particular problems with pests affect minor crops or cause significant damage only in certain areas, the CA may permit the use of an approved PPP in an area other than those specified in the authorisation. These permits are issued by the relevant Länder. BY issued 470 such permits in 2011, ST issued 84. ST issues permits in around 90% of cases where a request is made.

Conclusions

Procedures for authorisations comply with the legislation and the information is publicly available.

PPPs for emergency situations are sometimes authorised five times within a period of two years. This is not in line with the requirements of Article 53.1 of Regulation No (EC) 1107/2009 in which is stated that emergency authorisations should not exceed 120 days and these PPPs should only be placed on the market for limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means.

The practise of granting permits in specific Länder to individual growers to solve pest problems is not described in Article 51 of Regulation (EC) No 1107/2009 but follows national rules.

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 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 sales 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 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.

Findings

Samples taken for formulation analysis are analysed for identity and content of the active substance, relevant impurities, solvents, physical-chemical and technical properties. Planned samples are taken, targeted on two or three active substances every year. The CA stated that the choice of the active substances is risk-based. Specific samples are taken, in suspicious cases such as damage and illegal imports. In 2011 109 planned samples were taken. The targeted active substances were tebuconazol and metamidon. The non-compliance rate was 3%. The number of specific samples in 2011 was 88. The non-compliance rate was 25%.

According to the federal Plant Protection Monitoring Measures Programme the wholesalers should be monitored at least annually and retailers at least every three to five years. In 2010, 2,558 enterprises were controlled in Germany and in 2011, 2,545 enterprises were controlled.

In BY, 490 inspections were performed in 2010, with 61 non-compliances and 461 in 2011 with 81 non-compliances. In total BY has 3,226 enterprises registered for the marketing of PPPs, 3,212 retailers and 14 wholesalers. With these numbers it is impossible to meet the required frequency.

The CA stated that the actual number of enterprises is lower, by about 10% because some companies have ceased operating without giving notice to the CA.

The non-compliances found in BY include expired authorizations, non-compliant labels, and a parallel import number not yet issued. There were no illegal PPPs found.

In ST, 120 controls on marketing are performed every year. The number of companies marketing PPPs is 397. In ST no non-compliances were found in 2010 or 2011, in contrast with approximately 20% of non-compliances in BY.

Controls are unannounced, except for wholesalers in ST, which are announced within 24 hours because the responsible person has to be present.

The audit team attended two inspections on the marketing of PPPs, one in BY and one in ST. Both inspections were systematic inspections, covering all aspects and, in the case of a retailer, all PPPs were checked for authorisations. The CA stated that in BY at wholesalers all PPPs are also checked. In ST at wholesalers between 30 and 50 PPPs are randomly checked.

The other type of inspections are triggered inspections. This takes place to check if a specific PPP is still for sale, shortly after the end of the authorisation period as well as the grace period.

The inspection observed in BY was at a retailer of PPPs and was performed by one inspector. Inspections in BY are performed by two persons only in special circumstances. The inspector checked the certificates of two of the staff for the required education or training. These certificates had no expiry date, the validity is unlimited. The inspector checked the PPPs in store with the PAPI database downloaded on his laptop. This database is updated every month. Normally he would list any expired PPPs the company had in store in order to check at the next inspection if these PPPs were still present or disposed of in the appropriate manner. The inspector took a PPP sample for formulation analyses because this PPP contained one of the active substances targeted for inspection this year. No non-compliances were found during the inspection. The inspector completed his report on a standard checklist, providing one copy for the company, one for the local Agency for Food, Agriculture and Forestry and one for the LfL.

The inspection observed in ST was at a wholesaler of PPPs and was performed by two inspectors. In ST inspections are normally performed by two inspectors. The inspectors checked the certificates of two of the staff for the required education and training. They checked at random a number of the PPPs in store with the PAPI database downloaded on the laptop. They checked the labels of three PPPs. No non-compliances were found. They completed a report on a standard check list, and the company could make a copy of this report.

Both companies inspected had stocks of combination packs made up of two different PPPs in separate containers to be sold as a unit.

The CAs informed the FVO team that no routine inspections are performed at producers and re-packaging companies.

The audit team was informed that empty containers and remnants are collected by approved companies.

Conclusions

Controls on the marketing of PPPs take place as laid down in Article 68 of Regulation 1107/2009.

The unlimited validity of certificates of PPP distributors is not in line with Article 5.2 of Directive 2009/128/EC. However the CA stated that the certification system will be updated and comply before the deadline stated in the legislation.

Considering the number of 689 authorised products, and 3,112 products registered under parallel trade, the number of samples for formulation analysis is too low and the targeting on two or three active substances every year out of 258 authorised active substances is not sufficient to allow effective controls of authorised PPPs.

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, requires that food business operators (FBOs) producing or harvesting plant products are, in particular, 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 integrated pest management, 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 integrated pest management on a voluntary basis.

Article 67(1) of Regulation (EC) No 1107/2009 requires that professional users, for at least 3 years, keep 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. Certification systems have to 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

In BY, 984 controls of users were performed in 2010. For 2012, 1,025 inspections are planned. In ST, 369 controls of users were performed in 2011.

For PPP users different types of inspections are in place. The two inspections attended by the audit team were company (farm) inspections. During these inspections the training certificate of the user was assessed, the equipment was checked for the technical data and the plate confirming that it was checked and calibrated by a technical company, approved by the CA to carry out checks on PPP equipment. PPP spraying equipment has to be checked once every two years. The storage of the PPPs and the documentation on the use of PPPs was checked. By means of the PAPI database downloaded to the laptop, a check was carried out to confirm if the PPPs in store were authorised and the documented use was correct.

Inspections also take place during use of PPPs. The competence of the user is assessed and the spraying equipment and data of the PPPs are checked during the spraying of the PPPs. In case of doubt the inspector can take a sample of the treatment solution in the equipment. Two other types of inspections include inspections on keeping the required distance from surface waters and use in areas in which this is banned. Soil, leaf, or blossom samples can also be taken.

During the two inspections of users no non-compliances were detected by the inspectors. The user in BY had a PPP in store with an authorisation that had expired in 2007. According to the information from the PAPI database this PPP did not have to be disposed although its use was prohibited.

The CA stated that every year 1 % of the farms receiving direct payments under the single payment scheme as provided for in Council Regulation (EC) No 1782/2003 are controlled, the cross compliance checks. These checks are performed by the same CA in the Länder that performs the controls on the use of PPPs, though in BY they are carried out by other units within the Food, Agriculture and Forestry Agencies. Part of these cross compliance checks are controls on the use of PPPs. Non-compliances detected regarding the use of PPPs either during cross compliance checks or during controls on the use of PPPs result in a reduction of the direct payments.

The CA has developed guidelines for the use of Integrated Pest Management (IPM).

Packages and remnants of PPPs are collected by approved companies.

Conclusions

Records are kept by professional users of PPPs as required by Article 67(1) of Regulation (EC) No 1107/2009, Article 4(1) of Regulation (EC) No 852/2004, and Annex I, Part A.III of the same Regulation.

Controls on the use of PPPs take place as laid down in Article 68 of Regulation (EC) No 1107/2009.

Measures have been taken to address the requirements regarding IPM Guidelines, training and certification of PPP professional users, inspections on the application equipment, handling and storage of PPPs and treatment of packages and remnants of PPPs as laid down in Directive 2009/128/EC.

The storage of a PPP with an authorisation expired in 2007 is not in compliance with Article 46 of Regulation (EC) No 1107/2009 which gives a grace period of maximum 18 months for the disposal, storage and use.

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 food business operators' 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

Controls are planned at central level and priorities are established based on the result of the previous year. In the context of formulation analyses, sampling is targeted on up to three active substances

each year. Specific planning is organised in every state.

In the case of a non-compliance there are follow-up inspections. Targeted inspections are based on calculated risks and other information that might indicate non-compliance. Inspections during the spraying of the PPPs increase the possibility of detecting non-compliances.

Conclusions

Controls are carried out, based on risk and with the appropriate frequency.

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 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

Procedures for control activities are laid down in the handbook on the plant protection control programme. The last version is from February 2011, however, it is under revision at the moment.

Reports are drawn up from all inspections and the company receives a copy of the report. The audit team received copies of the reports sent to the European Commission in 2009 and 2010.

Conclusions

Official controls are carried out in accordance with documented procedures. Reports are sent to the Commission as required by EU legislation.

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

Co-ordination between the CAs of the federal states and central level takes place via regular

meetings of the Federal Länder Working Group on PPP control (AG PMK). The FVO team saw evidence that there is good co-operation within the authorities of the two federal states visited regarding cross compliance controls and controls on the use of PPPs.

Conclusions

There is efficient and effective co-ordination and co-operation within the CAs and between the CAs of the federal states and the CCA.

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 they 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 case of non-compliance, Articles 68 and 69 of the Plant Protection Act and the Administrative Offences Act give the possibility to punish with a fine up to € 50 000. The average level of fines in ST was between €50 and €250. In BY the fines were between € 35 and € 5 000. In case of serious infringements it may be deemed a criminal offence and may be prosecuted by the public prosecutor. Two cases of non-compliances were presented to the audit team in BY and two in ST. Because non-compliances are also communicated to the cross compliance authority, the reduction of subsidies is often much higher than the fines.

Conclusions

In case of non-compliance appropriate action is taken. Sanctions are imposed, and are effective and proportionate, in line with EU legislation.

5.2.10 Verification Procedures and Audit

Legal Requirements

Under Article 4 of Regulation (EC) No 882/2004 Competent Authorities are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner. Article 8 states that they must have procedures in place to verify the effectiveness of official controls, to ensure effectiveness of corrective action and to

update documentation where needed.

Findings

Verification of the effectiveness of controls and audits in the context of the marketing and use of PPPs are not carried out, but are required under Regulation (EC) No 882/2004 for controls on the use of PPPs in food production. The CA stated that Article 68 of Regulation (EC) 1107/2009 sets rules on how to carry out controls to enforce compliance with this Regulation. Special legislation supersedes general legislation.

Conclusions

Verification and audits are not carried out. For controls on the use of PPPs in food production, verification and audits are required under Regulation (EC) 882/2004.

6 OVERALL CONCLUSION

In Germany, overall there is a satisfactory system in place for control on the marketing and use of Plant Protection Products (PPPs). The authorisation procedure for PPPs is well developed. Comprehensive controls on the marketing and use of PPPs are performed by highly qualified and experienced staff and control programmes are in place. Specific controls during the actual spraying of the PPPs and the combining of the results of cross compliance controls and controls on the use of PPPs result in efficient and effective controls. Shortcomings were found with regard to the number of samples for formulation analysis and the granting of emergency and minor uses of PPPs. No internal audits are performed on the controls of the marketing and use of PPPs.

7 CLOSING MEETING

A closing meeting was held on 16 May 2012 with representatives of the CCA and with representatives of the two Länder in question. At this meeting, the FVO team presented the main findings and preliminary conclusions of the audit. The representatives of the CAs offered some clarifications on the findings.

8 RECOMMENDATIONS

The Competent Authorities are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below, within twenty five working days of receipt of this audit report. The CA should:

Nº.	Recommendation
1.	Ensure that authorisations for emergency situations do not exceed 120 days and are granted only where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means as required by Article 53.1 of Regulation (EC) No 1107/2009.

N°.	Recommendation
2.	Ensure that the number of samples for formulation analysis is sufficient to enforce compliance with Regulation (EC) No 1107/2009, as required by Article 68 of the same Regulation, taking into account the number of authorised active substances, authorised PPPs and registered parallel trade PPPs.
3.	Ensure that PPPs with an expired authorisation are disposed of in compliance with Article 46 of Regulation (EC) No 1107/2009.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6282

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
<i>Horizontal Legislation</i>		
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. 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. 16/2011	OJ L 6, 11.1.2011, p. 7-10	Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed
<i>Legislation on Plant Protection Products</i>		
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

Legal Reference	Official Journal	Title
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
<i>Legislation on Pesticide Residues</i>		
Reg. 396/2005	OJ L 70, 16.3.2005, p. 1-16	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Dir. 2002/63/EC	OJ L 187, 16.7.2002, p. 30-43	Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC
Reg. 1274/2011	OJ L 325, 08/12/2011, p.0024-0043	Commission Implementing Regulation (EU) No 1274/2011 of 7 December 2011 concerning a coordinated multiannual control programme of the Union for 2012, 2013 and 2014 to ensure compliance with maximum residue levels of pesticide residues and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin

ANNEX 2 – STANDARDS QUOTED IN THE REPORT

Reference number	Full title	Publication details
SANCO/12495/2011	Method Validation and Quality Control Procedures for pesticide residues analysis in food and feed, Document SANCO/10684/2009.	http://ec.europa.eu/food/plant/protection/resources/qualcontrol_en.pdf