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FINAL REPORT OF AN AUDIT  
CARRIED OUT IN  
THE UNITED KINGDOM  
FROM 14 TO 22 OCTOBER 2013  
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 the United Kingdom, carried out between 14 to 22 October 2013, under the provisions of Regulation (EC) No 882/2004 on official food and feed controls and Regulation (EC) No 1107/2009 on the placing of plant protection products on the market.*

*The objective of the audit was to evaluate the system of authorisation and the controls on the marketing and use of pesticides.*

*A comprehensive system is in place in the UK for the authorisation of pesticides. Authorisation procedures are fully in line with EU requirements. However, the deadlines prescribed in EU legislation for authorisation and re-registration of pesticides are not met in about ten percent of the cases.*

*There are no systematic, risk-based controls on the marketing of pesticides. Compliance of pesticides with requirements of the authorisation, including labels are not checked at distributors. Instead, investigations are initiated only in response to complaints or information on potential non-compliances obtained from external sources. There are certain initiatives for coordinated controls by the relevant authorities in order to combat illegal pesticides.*

*Although the formulation laboratory has the necessary capability for comprehensive controls, the number of pesticide samples analysed and the method of sampling does not provide adequate assurance for detection of non-compliances.*

*Although there are regular risk based controls on the use of pesticides at growers, in the framework of the cross compliance controls, the system does not cover about 10-15% of professional users in the UK, including numerous large and medium size fruit and vegetable farms.*

*Different central competent authorities (CAs) are responsible for official controls in the different countries of the UK. The central competent authorities have no information about the controls carried out by the local authorities. Therefore the UK does not provide an annual report to the Commission on the scope and results of official controls on the marketing and use of pesticides, as required by EU legislation.*

*There are detailed procedures in place for enforcement in the case of non-compliances, including prosecution and the application of penalties. However, the CAs do not always take appropriate actions to ensure that the operator remedies the situation. Sanctions are not always effective, proportionate and dissuasive.*

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

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**ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT**

<b>Abbreviation</b>	<b>Explanation</b>
CA(s)	Competent Authority(ies)
CC	Cross Compliance
CIPAC	Collaborative International Pesticide Analytical Council
CRD	Chemicals Regulation Directorate
DEFRA	Department for Environment, Food and Rural Affairs of the United Kingdom
DG (SANCO)	Health and Consumers Directorate-General
EU	European Union
FERA	Food and Environment Research Agency
FOD	Field Operation Division (regional) of the HSE
FTE(s)	Full Time Equivalent(s)
FVO	Food and Veterinary Office
FOD	Field Operation Directorate of the HSE
GAP	Good Agricultural Practice
HSE	Health and Safety Executive
IPM	Integrated Pest Management
ISO9	International Organisation for Standardisation
LA(s)	Local Authority(ies)
MRL	Maximum Residue Level
MS(s)	Member State(s)
NPET	National Pesticide Enforcement Team
PA	Paying Agency – there are four Paying Agencies in the UK
PHI	Pre-Harvest Interval
PPP(s)	Plant Protection Product(s)
RASFF	Rapid Alert System for Food and Feed

RPA	Rural Payments Agency
WIS	Wildlife Impact Investigation Scheme

## 1 INTRODUCTION

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

The audit took place from 14 to 22 October 2013. The team comprised three auditors from the FVO.

Representatives from the central competent authority accompanied the FVO team for the duration of the audit. An opening meeting was held on 14 October 2013 with the Competent Authorities (CAs). 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 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;
- the implementation of requirements for official controls on the use of PPPs under Regulation (EC) No 882/2004.

In terms of **scope**, the audit assessed the performance of CAs, 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
<b>Competent Authorities</b>		
Central	2	Chemical Regulations Directorate of the Health and Safety Executive of England and Wales (CRD); Rural Payments Agency of England (RPA)
Regional	1	Leicestershire County Council
<b>Laboratory</b>		
Public	1	Formulation analysis laboratory of the Food and Environment Research Agency (FERA)
<b>On-Site-Visits</b>		
Growers	2	Farms growing arable crops
Wholesalers and retailers	3	Two distributors of pesticides for professional use one retailer of pesticides for amateur use

### **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**

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

### **4 BACKGROUND**

#### **4.1 AUDIT SERIES**

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

[http://ec.europa.eu/food/fvo/specialreports/overview\\_search\\_en.cfm](http://ec.europa.eu/food/fvo/specialreports/overview_search_en.cfm)

During the previous audit series FVO teams identified that control systems vary considerably between MSs. 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 on the marketing and use of PPPs were frequently identified. The operation of formulation laboratories to test PPPs was generally considered to be satisfactory.

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

The CAs of the MS 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 audits to the United Kingdom (UK) in 2005 and 2009. The reports of audits DG(SANCO)7562/2005 and DG(SANCO)/2009-8153 can be found at [http://ec.europa.eu/food/fvo/ir\\_search\\_en.cfm](http://ec.europa.eu/food/fvo/ir_search_en.cfm). The report of the 2005 audit concluded that there were a number of shortcomings in the implementation of controls on the marketing and use of PPPs, which reduced the overall effectiveness of controls. The lack of a coordinated and comprehensive control plan and lack of reporting of controls to the Commission were among others highlighted. The 2009 audit dealt with pesticide residues. All the recommendations of the reports were closed, some of them due to technical reasons.

## **4.2 COUNTRY PROFILE**

The FVO has published a country profile for the UK, which describes in summary the control systems for food and feed, animal health, animal welfare and plant health and gives an overview of 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](http://ec.europa.eu/food/fvo/country_profiles_en.cfm)

## **5 FINDINGS AND CONCLUSIONS**

### **5.1 RELEVANT NATIONAL LEGISLATION**

#### **Legal Basis**

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. The Plant Protection Product Regulations 2011, applicable in England, Scotland and Wales, the Plant Protection Product Regulations (Northern Ireland) 2011, applicable in Northern Ireland, the Plant Protection Product (Fees and Charges) Regulations 2011 and in the case of some commodity chemicals, which fall under the scope of Article 23 of Regulation 1107/2009, dealing with basic substances, the UK Control of Pesticides Regulations 1986 provide the necessary legal framework for the implementation of the provisions of the EU legislation concerning the authorisation of PPPs and official controls on the marketing and use of PPPs.

The Chemicals Regulation Directorate (CRD) of the Health and Safety Executive (HSE) stated that Directive 2009/128/EC has been fully implemented through national measures including transposition into national legislation. Legislation was used wherever this was legally necessary to meet the requirements of Directive 2009/128/EC. Regulations were supplemented by a range of other mechanisms and measures, which are identified in the National Action Plan for the Sustainable Use of Pesticides of the United Kingdom.

As required by Article 4 of Directive 128/2009/EC, the National Action Plan for the Sustainable Use of Pesticides of the United Kingdom was published in February 2013. It is intended to formally review the Plan every five years, but it will be kept under review and updated in the interim as necessary.

#### **Conclusions**

National legislation within the scope of the audit is in place. CRD stated that provisions of Directive 128/2009/EC have been fully transposed.

## 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.

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 (include where relevant).

#### Findings

The overall description of the CAs can be found in the UK country profile (DG SANCO 2012-6424) valid as of April 2013. CRD stated that there have been no changes in the meantime.

The Plant Protection Products Regulation 2011 designates the Secretary of State as the CA in relation to England and Wales and the Scottish Ministers in relation to Scotland. The Plant Protection Products Regulation (Northern Ireland) 2011 designates the Department of Agriculture and Rural Development for Northern Ireland as the CA.

Under an agency agreement with the Scottish ministers, the Secretary of State performs various competent authority functions in Scotland. The Secretary of State has entered into an agency agreement with the HSE under which HSE performs CA functions in relation to England, Wales and Scotland. The Department of Agriculture and Rural Development for Northern Ireland has entered into a separate agency agreement with HSE, under which the latter agrees to perform various competent authority functions on behalf of the former.

The effect of these arrangements is that HSE performs a range of CA functions, including the authorisation of plant protection products, in relation to the whole of the UK, whilst others, such as certain controls, including enforcement, are exercised by the Scottish Ministers and the Department of Agriculture and Rural Development in Northern Ireland.

Although enforcement in Scotland is exclusively the competency of the Scottish Ministers at present, there are ongoing discussions about whether this power should form part of an agency agreement with HSE.

HSE is a non-departmental public body of the Department of Work and Pensions, established by the Act on Health and Safety at Work of 1974. HSE has a wide range of activities and responsibilities related to safety at work. Besides the pesticides dossier, CRD is responsible for the implementation of the legislation on biocides and on chemicals in general, including implementation of EU rules on registration, evaluation, authorisation and restriction of chemicals (REACH).

CRD is the CA for the authorisation of pesticides for the entire territory of the UK and coordinates the control and enforcement activity of the HSE, related to marketing and use of pesticides, including enforcement in England and Wales.

There are four UK Paying Agencies (PAs). They are responsible for the implementation of cross compliance (CC) checks related to the EU Single Payment Scheme in England, Northern Ireland, Scotland and Wales. CC checks include controls on storage and use of PPPs at farm level.

Local Authorities (LAs) are the CAs in the case of implementation of the pesticides legislation related to controls of non-professional use and implementation of certain aspects of the safety rules on chemicals. Relevant departments of the LAs (Environment and Health, Trading Standards, Enforcement) are involved in this activity.

During the audit comprehensive information was provided about the authorisation of PPPs in the UK. The FVO team acquired information about the activity of the HSE/CRD in England and Wales. The team also learned about the activities of the RPA in England and the LAs in England and Wales. No information was received about official controls on the marketing and use of PPPs in Scotland and Northern Ireland and about the controls of growers in Wales.

## **Conclusions**

CAs within the scope of the audit have been designated and their responsibilities are defined. According to CRD, no official controls are delegated to control bodies. There is no Central Competent Authority for the controls on marketing and use of the PPPs in the UK. The findings and conclusions of the report relate to the authorisation process for the entire territory of the UK, to marketing in England and Wales and to use in England.

### *5.2.2 Resources for Performance 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**

CRD stated that in 2012/2013, the number of staff employed on PPP authorisations was 53.3 full time equivalents (FTEs). In order to deal with the volume of work regarding the authorisation of the PPPs, the number of relevant staff has been increased and it is planned that further staff will be recruited.

A degree in agriculture, chemistry or other relevant subject is required for staff responsible for the authorisation of pesticides. Newcomers receive initial training and work independently. However their work is subject to continuous peer review and he/she is mentored by a senior colleague until their first promotion.

CRD stated that at this directorate the number of staff involved in coordination of PPP control and enforcement related work, including participation of enforcement actions was five FTE.

The Field Operations Directorate (FOD) is the largest operational inspectorate in HSE and covers many employment sectors including construction, agriculture, general manufacturing, etc. FOD inspectors, amongst other things, are responsible for the PPP controls and enforcement in relation to storage and use in premises for which HSE is the enforcing authority. There are currently approx 30 FOD inspectors who are authorised to carry out PPP controls and enforcement. Authorised FOD Inspectors throughout England and Wales may be involved in PPP related controls as requested.

In addition, nine of the above 30 FOD inspectors are members of the National Pesticides

Enforcement Team (NPET), which is a “virtual” team to assist Natural England in the prosecution stages of investigations under the Wildlife Incident Investigation Scheme. NPET is governed by a Board which comprises representatives of CRD, HSE’s Agriculture Sector and FOD headquarters.

CRD stated that in broad terms, cases involving illegal supply of PPPs are handled by CRD, and cases relating to storage and use of PPPs fall to FOD. FOD’s work in relation to PPP is in response to complaints and incidents involving PPPs that are reported to HSE. Further details on FOD’s activity in this area is available at [www.hse.gov.uk/agriculture/resources/pesticides.htm](http://www.hse.gov.uk/agriculture/resources/pesticides.htm)

Inspectors of the 31 regional branches of the HSE may be involved in PPP related controls as requested. Inspectors of the Environment and Health, Trading Standards or Enforcement departments of the LAs also deal with certain inspections and enforcement measures, related to marketing and use of the PPPs. CRD stated that the number of staff engaged in PPP related controls by the LAs is not available.

The FVO team noted that HSE and LA inspectors involved in pesticide related controls have a wide range of tasks related to different controls on work and chemical safety. In general, pesticide controls comprise a very limited part of their portfolio. Therefore, FTE spent on pesticide controls cannot be calculated.

CRD and FOD staff involved in PPP related investigations have either a pesticide related background or have relevant experience in pesticide controls and enforcement issues. There is a continuous exchange of information between CRD staff and NPET members about specific cases and new developments.

CRD stated that there are robust formal training and development arrangements in place for HSE inspectors, which cover fully their investigatory and enforcement roles in relation to health and safety legislation, e.g. Health and Safety at Work etc Act 1974 and other relevant statutory provisions. This is supplemented by detailed sector/topic specific training, guidance and resources, including an introduction to pesticides. The internal training system of the HSE includes specific guidance for line managers and training logs and the whole system is subject to corporate learning and development oversight. All inspectors receive an introduction to the controls on chemicals, including pesticides supported by further detailed training as required.

The FVO team was informed about a training course organised in 2012 for HSE and LA inspectors. The scope included pesticide legislation, enforcement expectations and industry standards including labelling, use, storage and disposal, environmental impacts and record keeping.

Although there are certain training courses organised by HSE and the industry on PPP related issues, inspectors of the LAs acquire information related to PPP controls mainly in the form of self-education. There is detailed general information available on the websites of the HSE and of other governmental bodies on the legislation, on general inspection, official control and enforcement procedures. CRD publishes on its website and on the HSE intranet, information for guidance of the inspectors’ work. In addition, a wide range of information is available related to the use of pesticides on the websites of different non-governmental organisations. LA inspectors may contact CRD and NPET experts and require specific assistance.

The FVO met CRD staff, one the member of the NPET and LA inspectors. They all appeared to have sufficient knowledge and experience to perform their tasks.

Premises and equipment of the formulation laboratory of the Food and Environment Research Agency (FERA) allow for comprehensive analysis of active substance level, relevant impurities and co-formulants and the physical-chemical properties of pesticides. The laboratory has qualified and experienced staff.

## Conclusions

Suitably qualified and experienced staff are available for the authorisation of PPPs. The formulation laboratory has suitable equipment and experienced staff for the required analysis.

CRD staff and the authorised FOD inspectors, including members of the NPET have specific knowledge and sufficient work experience in PPP related issues. The general nature of training on PPPs provided to inspectors of the regional divisions of HSE does not equip them fully to carry out comprehensive controls on pesticides.

In general, LA inspectors have no specific knowledge or work experience, related to controls on the marketing of PPPs. There is no coordinated training system available for LA inspectors in these issues.

### *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

There were 279 active substances on the market in 2 657 authorised products and 803 parallel trade permits at the time of the audit. All active substances except asulam and chlorthalipicrin, for which emergency authorisations have been granted, are included in Regulation (EC) No 540/2011.

CRD received just over 1 500 applications in the period from 1 April 2012 to 30 March 2013. Of these applications, 50% required some evaluation of the data supplied by the applicant and the balance necessitated only administrative steps. Each week, all new applications requiring evaluation are examined to determine completeness before being accepted. Additional information is required at this stage in the majority of cases, and the applicant is given a defined period to provide this data. The clock starts when this data is provided.

UK has accepted 112 zonal applications since 14 June 2011. Two applications were withdrawn by the applicant. In four cases, the product was authorised, three of them within the maximum 18 month deadline. In the case of the other applications the deadline has not expired by the time of the audit.

The re-registration time-lines were examined for a range of products containing epoxiconazole, deltamethrin and mancozeb. Of the products examined, five were re-registered before the required deadline and one product containing deltamethrin was re-registered five years after the deadline. CRD stated that in all cases of delayed re-registration, the existing product registration is allowed to "run", provided Step 1 has been complied with and an application for re-registration has been received by CRD within the time-line prescribed in the relevant Commission approval directive. All registration reports are uploaded to the Communication and Information Resource Centre for Administrations, Businesses and Citizens of the European Commission (CircaBC) , to facilitate mutual recognition by other MS.

It is estimated that deadlines are adhered to in approximately 90% of cases where CRD is required to conduct an evaluation either as zonal rapporteur MS or for voluntary work-sharing re-

registration. It is difficult to determine this figure precisely due to limitations in CRD application tracking system. This is due to the huge volume of both active substance and product evaluation work in recent years, the UK policy of accepting all applications, staff resource issues and specific risk mitigation issues of UK relevance.

Emergency authorisations are only granted following an evaluation to demonstrate safety and when the CA are satisfied that an emergency authorisation is absolutely necessary. The UK granted 14 emergency authorisations in 2012 and six in 2013. Three applications were refused in this period and one was granted as an off label use instead. The 120 day use period was clearly stated on the approval certificate for the emergency authorisation examined by the FVO team. Emergency authorisations are not routinely published on the approved product register. CRD stated that it was not necessary, because all relevant stakeholders are informed.

Revocation and amendments to existing authorisations are completed as required. Procedures and deadlines applied in the case of flusilazole and clothianidin containing products were demonstrated to the FVO team.

In the official product register for each product, the date of first registration, registration type (authorisation or parallel import permit), user category, formulation type, level of each active ingredient, function, approved uses, Good Agricultural Practice (GAP) and risk mitigation measures are clearly stated. It is updated daily, as required. The register is available at:

<http://www.pesticides.gov.uk/guidance/industries/pesticides/topics/databases/databases-home>

The database is searchable under each of the criteria, both alone and in combination. A list of revoked products is published regularly showing both the last day of sale and the last day of use, storage and disposal as required.

As part of the product evaluation and authorisation process, the proposed product label is reviewed and the authorisation holder is informed of any required amendments. The range of approved pack sizes, rather than defined pack sizes is specified on the approval certificate. The final amended label in artwork format as used when marketing the product is not required by CRD.

The UK has received 44 applications for authorisation or modification of an existing authorisation by mutual recognition since 14 June 2011. Thirty five of these applications have been completed, all within the 120 days. Authorisation was refused in seven of the 35 cases – for failure to comply with national requirements in two cases and for failure to address the core birds and mammal risk assessment in the case of five products. Of the nine current applications, four will miss the 120 day target. In all cases, some evaluation work is undertaken in order to satisfy UK national requirements. The UK have recently started to provide comments to the zonal rapporteur MS within the six weeks commenting period for zonal authorisations.

## **Conclusions**

There is a comprehensive system in place for authorisation of the plant protection products. In terms of procedures the system is fully in line with EU requirements.

A regularly updated, comprehensive national register, containing all non-confidential information is available on the internet about the authorised PPPs as required by Article 57 of Regulation (EC) No 1107/2009. However, emergency authorisations are not routinely published.

The deadlines prescribed in EU legislation for authorisation and re-registration of pesticides are not met in about ten percent of cases.

#### 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 of Regulation 1107/2009 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

###### 5.2.4.1 National legal requirements

The UK has not put in place any legal requirement for pesticide distributors to be registered, which is in line with the EU legislation. Legal requirements are in place for pesticide distributors to keep records on sales for a period of five years, as required by EU legislation, including the client name and address, product trade name, quantity and delivery date.

Legal requirements are in place for PPPs authorised for professional use to be sold for use by certified professional users only, by 26 November 2015. Both pesticide distributors visited by the audit team confirmed that PPPs for professional use are only sold for use by trained and certified users. In practice, it is checked whether the buyer is certified or a declaration is required that the product is intended to be used by a certified person.

###### 5.2.4.2 Implementation of controls

There is no system in place of regular, planned, risk based official controls on the marketing of PPPs. There are no routine inspections at pesticide distributors. Official on-site visits may be carried out in response to complaints or based on information about suspected non-compliances, obtained from external sources. Official controls carried out by CRD experts, by the NPET or by inspectors of the HSE regional branches concentrate on investigations based on intelligence received by CRD. They do not have a standard, pre-defined scope, e.g. check of pesticides in stock, labelling and record keeping. In general, the goal of these inspections is to investigate the case and assess whether enforcement steps are necessary (*see section 5.2.9*).

Comprehensive information about controls carried out by LAs is not available. CRD is usually informed only about these cases when LA inspectors require assistance for their work.

Inspections are performed without prior warning, unless advance notice is necessary for operational reasons.

There is a rolling programme of label checks by CRD specialists. Labels of all authorised pesticides (including parallel trade permits) are checked every three to five years. Due to resource constraints, the program was suspended in 2013, but is intended to operate again in 2014. The labels to be checked are provided by the authorisation holder, rather than taken from the product available on the market. CRD does not operate a publicly available database of artwork labels of authorised products (*see section 5.2.3*).

A voluntary certification system for pesticide distributors has been operated by a private commercial organisation for many years. Participating stakeholders are visited annually by inspectors of the organisation, who complete an inspection according to a check-list. General store safety, general rules on storage of hazardous chemicals and work safety conditions for store operators are checked. However, specific identity or label checks on the PPPs in store are not covered. If no problems are found, a certificate is issued and the store is entered into the certification register. The register is not publicly available, however upon request, the organisation will provide information. If problems are found, rectification is required. However, the implementation of the corrective measures is not verified until the next annual inspection. Non-compliances identified during the inspections are not routinely reported to the relevant CA.

Holding a certificate is recognised by the private quality assurance schemes and enhances the perception of the operator but it is not a pre-condition for marketing pesticides. The considerable certification fee may deter smaller operators from participation. In England and Wales about 600 premises dealing with distribution of pesticides are certified in this system.

#### *5.2.4.3 Illegal Pesticides*

CAs do not apply any systematic approach to identify illegal pesticides. CRD maintains regular contact with CAs of other MS, responsible for the authorisation of PPPs. CRD also participates in the activities of the relevant OECD working group in order to exchange information on illegal pesticides. The FVO team was informed about certain regional and local initiatives, which aim for more harmonised and reinforced border control practices, including checks on imported pesticides. An enhanced level of cooperation of the authorities is part of the planned developments. In the region visited, the FVO team received information about an initiative of cooperation by the local authorities for increasing efficiency of the border controls.

#### *5.2.4.4 Training and Certification of Pesticide Distributors*

Sellers are required to employ staff suitably qualified to provide advice and information as appropriate. For distributors of professional products this means a person with the advisor certificate. The UK has not put in place any legal requirement for advisers to be trained on PPP issues as Directive 2009/128/EC does not impose a requirement on advisers to have a certificate.

At the time of the audit, there was one private commercial organisation designated for providing training and certification for distributors and advisers. Currently, the recognised training certificate for those who store, sell, supply, or otherwise market a pesticide is the Certificate for Sale and Supply issued by that organisation.

CRD approves the content of the initial training course provided by organisations seeking a designation. There is a close working relationship between CRD and the designated organisation, ensuring that all changes in the scope and content of the training programme are communicated to

CRD for their approval. CRD may initiate changes in the programme if necessary.

A certificate is issued to candidates, who pass an exam after having completed initial training. Certified persons are listed in the appropriate register of the organisation. This register is not publicly accessible, however, on request the organisation provides information.

Ongoing training is carried out under supervision of the designated organisation. The certificates are revised annually. The certificate is not renewed unless the person acquires a sufficient number of points during the course of a year. Points are earned by attendance at or participation in recognised training or other events such as conferences, workshops, demonstration of trial results open days etc.

CRD or HSE does not assess the content of the recognised events directly. CRD is represented on the board of the designated organisation and therefore has input into event recognition and points determination criteria.

#### *5.2.4.5 Handling, storage and safe disposal of packaging and remnants of plant protection products*

National legal requirements make the the professional user and the distributor of the PPP responsible for appropriate handling, storage and safe disposal of packaging and remnants. In general, distributors do not collect empty containers or remnants from the end users. They may take back pesticides in unopened packaging.

There are no official controls on these aspects at distributors.

#### *5.2.4.6 Formulation analysis*

Official samples of pesticides are analysed for survey and enforcement related purposes.

Annual formulation analysis survey programmes are undertaken by CRD to determine if PPPs marketed in the UK comply with the conditions of authorisation. Depending on the available budget, three to four active substances are targeted and a number of products containing these active substances authorised in the UK are selected for the survey. The programme identifies the active substances to be surveyed and the scope of the analysis. The range of PPPs sampled is determined by CRD, taking into consideration pragmatic aspects.

Survey samples for formulation analysis are not taken by inspectors of the CAs at the premises of the distributors, but they are purchased by CRD in the form of commercial orders. Therefore individual samples are selected by the distributor and not by CRD. In 2011/2012, 70 samples were taken. Non-compliances are detected in about 1% of cases.

In enforcement cases, official samples are taken by the inspectors of the CRD, HSE or of the local authorities at distributors or growers. In every case, the relevant CA purchases the sample. 37 enforcement samples were taken in 2011/2012.

The formulation laboratory of FERA is the only laboratory, which analyses official samples of PPPs in the UK for the purpose of quality control in the framework of annual contracts with CRD. The current budget enables the laboratory to analyse about 30-60 samples annually. CRD may request urgent analysis, which can be completed in weeks. The analysis may take several months if samples are not prioritised.

The laboratory is not accredited to ISO 17025, however, it complies with the requirements of good laboratory practice. A service of the Department of Health controls and approves the laboratory's

good laboratory practice compliance biannually.

The laboratory regularly participates in Proficiency Testing Schemes for active substances and relevant impurities, organised by the Association of American Pesticide Control Officials and by the Federal Agency for the Safety of the Food Chain in Belgium. In addition, they participate in ring tests organised by the Collaborative International Pesticides Analytical Council (CIPAC) and maintain close working relations with the English Speaking Pesticide Advisory Council.

The laboratory is equipped with a broad range of analytical equipment, including gas chromatograph coupled to mass spectrometer, high performance liquid chromatograph coupled to mass spectrometer or to tandem mass spectrometer, high resolution liquid chromatograph with time-of-flight, quadrupole-time-of-flight or nuclear magnetic resonance detector. The active ingredients are usually identified and their quantity is measured using either high performance liquid chromatography with ultra violet detector or gas chromatography with flame ionisation detector.

It was stated that the laboratory is able to analyse almost the entire range of active substances to be found in PPPs authorised in the UK. They are also able to analyse a range of co-formulants and physical-chemical properties.

The laboratory uses validated methods, according to FAO Specifications and as described in the CIPAC Handbooks. If FAO or CIPAC methods are not available for a particular active substance or co-formulant, the laboratory uses methods provided by the PPP manufacturers or by other scientific sources or they attempt to develop an appropriate method. An in-house validation takes place in every case before a new method is used for official analysis.

## **Conclusions**

Pesticide distributors are required to keep records on sales for a period of five years, as laid down in Article 67 of Regulation (EC) No 1107/2009. Distributors visited by the audit team complied with this requirement.

There is no system of regular official controls in the UK on the marketing of PPPs which is not in line with Article 68 of Regulation (EC) No 1107/2009.

The current system of official controls does not include checks to verify the compliance of the artwork labels with the authorisation requirements. Therefore it is not ensured that product labels contain all the requirements of the authorisation certificate as required by Regulation (EU) No 547/2011. Furthermore the lack of a publicly available database of artwork labels does not facilitate the identification of counterfeit products.

The current system of controls, in particular due to the lack of regular, risk based controls, does not ensure that official controls on the marketing of PPPs are effective and efficient and is not able to sufficiently identify non-compliances, unless external information (complaint, MRL exceedance etc.) is available. Moreover, sufficient guarantees could not be provided that PPPs placed on the market in the UK fully comply with the requirements of Article 28 of Regulation (EC) No 1107/2009.

The formulation laboratory has adequate equipment and experienced staff for comprehensive analysis of pesticide samples. However, the number of samples analysed, and the method of sampling do not provide adequate assurance for detection of non-compliant, including counterfeit pesticides. It has also to be noted that the level of non-compliances detected by the UK are far below the average of that of the other MS.

### 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 Integrated Pest Management (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. 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

##### 5.2.5.1 Record keeping

Legal requirements are in place for professional users to keep records on the application of PPPs for a period of three years in line with provisions of the EU legislation. Minimum requirements for record keeping are laid down in the Code of Practice for Using PPPs, published by CRD. The spraying records at the grower visited by the FVO team included the trade name and national authorisation number of the product, application rate, name and size of the plot, date of application dose, volume, total amount of PPP used, start and finish time of the application and additional relevant comment concerning the application.

##### 5.2.5.2 Implementation of Controls

Systematic, programmed official controls on the use of PPPs are performed exclusively by the RPAs in the framework of CC controls. As the relevant EU legislation requires controls on 1% of the direct payment claimants, RPA carried out over 1 300 CC checks in 2012. About 800 of the growers controlled used PPP, therefore CC controls included elements on the storage and use of pesticides on these holdings.

As not all users of professional use PPPs receive EU subsidies in the framework of the Single Payment Scheme, CC controls do not cover the entire scope of professional users. There is no national register of growers other than those who receive direct payments. CRD informed the FVO team about the total number of farmers, based on the statistical data available and RPA provided information about the total number of farms, which receive payments in the framework of the Single Payment Scheme. (In England the total number of farmer is about 128,000; 111,798 farms are claimants of EU direct payments) These data show that about 10-15% of the growers using PPPs authorised for professional purposes are not covered by the CC scheme. Numerous large and medium size fruit and vegetable growers with significant pesticide use are not controlled, because they do not claim EU direct payments.

Farmers do not receive advance notification of cross compliance inspections.

The audit team observed one CC check at a 250ha grower of arable crops (winter wheat, barley, oilseed rape, sugar beet). The grower purchases and applies pesticides according to the guidance of an adviser. The personnel responsible for pesticide application possessed a certificate for this activity.

The CC check was performed by an inspector of the territorial office of the RPA, according to a detailed standard procedure and using a pre-defined check-list and questionnaire. The inspector checked the PPPs stored in the farm and identified the products by the national authorisation number (MAPP number), as indicated on the label. These were cross-checked with the national registration database to determine whether the authorisation of the products in question was still valid.

Inspectors are required to check a minimum of 10% of the parcels. In the case of this farm, detailed analysis of records representing about 30% of the parcels was done. Records of professional advice received and spraying records were checked in detail, including the products rate of use, number of applications and pre-harvest interval. All parcels were inspected to verify that buffer zones were adhered to. A report was prepared about the controls with the help of a specific IT application.

The RPA inspector informed the FVO team that CC checks are labour intensive, and the PPP related part often requires a full day, excluding cross check with the register of authorised pesticides and reporting.

### *5.2.5.3 Integrated Pest Management*

Measures related to the Integrated Pest Management (IPM) are set out in the UK National Action Plan for the Sustainable Use of Pesticides as required by Directive 2009/128/EC. Currently almost all training courses on use of pesticides include IPM elements. IPM will be a mandatory element of training for all certificated users of pesticides.

There are about 50 crop specific IPM protocols in the UK, developed by industry. Growers in Crop Quality Assurance Schemes are encouraged to follow these protocols. CRD is usually involved in the development of these crop specific protocols.

The FVO team was informed that in line with the sustainable farming policy of the Government, a broad IPM approach will be applied including measures beyond those listed in Annex III of Directive 2009/128/EC. This will include specific measures to encourage amenity pesticide users (e.g. golf courses) to adopt IPM.

Both growers visited, and their advisers, were aware of IPM in general and implemented appropriate measures. Evidence was provided during the visits on crop rotation, cultural control techniques, reduced rates of pesticide use, resistance management and pest monitoring.

Although it was not required by the relevant EU legislation, application of IPM was controlled in the framework of CC checks at the time of the audit. RPA noted that the planned EU Common Agricultural Policy 2015 Horizontal Regulation limits the scope of CC to the provisions of the first and second sentence of Article 55 of Regulation (EC) No 1107/2009, thus compliance with provisions of Directive 2009/128/EC, including IPM will not be covered from 2014.

#### *5.2.5.4 Training and Certification of Professional Users*

There are legal obligations in force for training and certification of professional users of pesticides. Growers may only purchase and apply PPPs for professional use if they are trained and certified users, or if they use the services of trained and certified users to apply the product. Until November 2015, a derogation applies for those growers who were born before 31 December 1964.

Currently, there are two organisations designated for organising approved training events and issuing Certificates of Compliance for professional users (sprayers) of pesticides. Training schemes include initial training and issuance of a certificate for candidates, who provide evidence of sufficient knowledge related to use of pesticides. The legislation distinguishes 13 training/competence modules. Candidates must successfully complete a foundation module (assessed by computer based multiple choice questions before they are assessed on specific issues (e.g. boom sprayer, seed treatment). Certified persons are listed in the appropriate registers, which are not publicly available. Each scheme operates a points system serving as a basis for the annual renewal of the certificates. CRD's role in approval is the same as described in the case of training for distributors.

In general, growers purchase and use pesticides according to the instructions received from certified advisers (*see section 5.2.4.4*). The presence of a Compliance certificate is checked during CC controls (*see section 5.2.5.2*).

#### *5.2.5.5 Application Equipment*

There are legal obligations in place in the UK requiring that equipment greater than 5 years old must not be in use after 26 November 2016 unless it has been inspected by then. It must thereafter pass inspection at the maximum intervals set out in Directive 2009/128/EC (at intervals of no greater than 5 years until 2020 and no greater than 3 years thereafter).

CRD informed the FVO team that the UK already has a voluntary annual equipment inspection regime in place for a number of years and the body which runs this scheme has been designated responsible for administering the statutory scheme.

The application equipment used by the growers visited by the FVO team was tested annually by a certified tester of the national sprayer testing scheme. Sprayers are tested to demonstrate compliance with Annex II of Directive 2009/128/EC and in addition some extra checks are also performed including a physical examination of the sprayer. The results of the inspection are summarised in a compliance certificate and a sticker is put on the equipment indicating the testing organisation and the duration of the certificate.

The certificate of the application equipment is checked in the framework of CC controls (*see section 5.2.5.2*).

#### *5.2.5.6 Handling, storage and safe disposal of Packaging and Remnants of PPPs at professional users*

According to the UK legislation in force, the professional user is responsible for the safe handling, storage and disposal of empty packages and remnants of PPPs. A range of hazardous waste management companies are licensed to dispose of revoked PPPs. The growers visited by the FVO team triple rinsed used containers and emptied the rinsate into the sprayer. Containers were stored under appropriate conditions until collection, usually once or twice per year.

Safe storage and appropriate disposal of empty PPP containers is checked during CC controls. The FVO team was informed that it is usually also checked in the framework of Quality Assurance Schemes.

#### **Conclusions**

Requirements are in place for growers to keep records on the application of PPPs for a period of three years as provided for in Article 4(1) of Regulation (EC) No 853/2004 and Article 67 of Regulation (EC) No 1107/2009. Evidence of record keeping was seen at the grower, subject to cross compliance check, met by the audit team.

Official controls on the use of PPP are only carried out in the framework of CC checks. As these checks do not cover the entire range of pesticide users, including fruit and vegetable growers with significant pesticide use, they do not provide sufficient guarantees that PPPs are applied in compliance with the conditions of use specified on the labels.

Growers are aware of, and implement IPM measures, driven by market demands, use of scientifically based advice and the requirements of Crop Quality Assurance schemes.

Requirements are in place with regard to handling, storage, transportation and safe disposal of packaging and remnants of PPPs, in line with Article 13 of Directive 2009/128/EC.

A system of initial and ongoing training within an officially designated and approved certification scheme is in place for pesticide users.

A scheme for the testing of application equipment is in place as required by Article 8 of Directive 2009/128/EC.

#### *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**

There are no regular, planned, risk based official controls on the marketing of PPPs (*see section 5.2.4.2*). HSE/CRD does not have a defined list of PPP distributors, packaging or formulation plants and importers at national level, which could be used for the risk based prioritisation of official controls. No information is available on any register kept by LAs on these type of stakeholders.

CRD stated that according to the general approach of the UK, HSE and LAs concentrate their official controls on areas, where there presence of a risk is clearly identified. In any other cases the official control is considered as an unnecessary burden for the stakeholder and does not justify the

use of budgetary resources. CRD also stated that according to the legal interpretation of the UK authorities, provisions of Regulation (EC) No 882/2004 do not apply for controls on the marketing and use of PPPs.

Investigations are carried out based on complaints from different stakeholders or based on information obtained about suspected non-compliances. Cases may be reported by the Wildlife Incident Investigation Scheme, the National Pesticide Residue Monitoring Program, by the Human Health Incident and Enquiry Survey and by the RPAs amongst others.

CC checks do not cover the entire range of professional users of PPP (*see chapter 5.2.5.2*). The RPA selects farms for CC control according to the risk criteria set by the EU legislation on CC. There are numerous criteria to be considered, of which pesticide usage is one. The National Pesticide Residue Monitoring program does not cover the entire production range of the UK, e.g. no samples are taken from cereals grown for animal feed.

Although there is a formulation analysis programme, the number of samples are limited, and it is not ensured that samples analysed accurately represent the product placed on the market. (*see section 5.2.4.6*).

Results of all samples tested as part of the annual monitoring programme for PPP residues in food are published on the CRD website, including details of the commodity, sampling location (typically a retailer), packer/manufacturer, pesticides found (name and level) and the relevant MRLs. Results above the MRL and detected residues of unauthorised uses are highlighted. In the case of MRL breaches publication of the results on the website is the sole enforcement action where no specific health concerns are identified. However, the name and address of the grower is usually not indicated.

## **Conclusions**

Controls on the marketing of PPPs are not carried out regularly, on a basis of risk and with appropriate frequency. They take into consideration only external information that might indicate non-compliance. Furthermore, the lack of a register of pesticide distributors does not allow Competent Authorities to identify all operators under the scope of the legislation. CC controls do not cover the entire scope of PPP users and farms are selected using multiple risk criteria, involving numerous elements other than related to PPP use. In particular due to the sampling method applied the formulation analysis survey is not considered to be effective to verify the compliance of the PPPs on the market with requirements of the authorisation. Steps taken in the case of MRL exceedances and unauthorised uses identified in the framework of the annual pesticide residue monitoring program are not considered as sufficient, especially because the cause is usually not investigated.

### *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**

HSE has developed detailed written instructions and flow charts to assist follow-up investigations and decision making in the case of official controls for enforcement purposes. However, these are general instructions to be applied by HSE inspectors for all areas of responsibility and are not specifically designed for controls related to pesticides. As there are no systematic controls on pesticide distributors and professional users, there are no written guidelines for performance of these type of controls and there are no standard templates for reporting of results. HSE and NPET inspectors use their standard, general report templates in the case of their controls related to PPPs

There are general operational guidelines available for LA inspectors for supporting their inspection activity on marketing of PPPs. LA inspectors use general templates for reporting PPP inspections.

RPA developed very detailed and comprehensive instructions for CC checks. During these inspections, standard inspection reports are drafted in electronic format. There is one specific chapter of the report related to the storage and use of PPPs where all the findings are recorded and recommendations are made for enforcement steps if necessary.

Although they are obliged, LAs do not routinely report their inspection results on PPPs to CRD. Therefore, CRD does not have an overview of the total number of pesticide related inspections in England and Wales and of their outcome. CRD stated that the situation is the same in Scotland and Northern Ireland. Due to difficulties in compiling data, no annual report was submitted to the Commission for 2011 or 2012.

CRD stated that Article 68 of Regulation (EC) No 1107/2009 does not specify the requirements of the report. In their opinion an implementing regulation detailing the specific requirements is necessary for the preparation of comprehensive reports.

## **Conclusions**

Written instructions are in place for HSE, LA and CC controls which is in line with the requirements laid down in Article 8 of Regulation (EC) No 882/2004.

Reports are drawn up on individual inspections using standard templates, as required by Article 9 of Regulation (EC) No 882/2004. Standard inspection report templates do not exist for controls carried out by HSE/CRD and local authority controls.

Annual reports on the scope and results of controls under Article 68 of Regulation (EC) No 1107/2009 are not submitted to the Commission which is in breach of the requirements of the same article.

### *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**

In the case of PPP authorisation, CRD ensures the necessary coordination between the UK and other MS authorities involved in this activity. CRD provides sufficient guidance for the work of the NPET and HSE inspectors. CRD stated that they also implement certain measures to guide and coordinate relevant activities of the LAs.

Although they are legally obliged, in general LAs do not inform HSE/CRD about the number, scope and result of controls, unless they require specific assistance in certain cases.

The FVO team could not obtain evidence of cooperation between HSE/CRD and CAs involved in controls of marketing of PPPs in Scotland and Northern Ireland or of cooperation among the four RPAs of the UK.

RPA regularly informs CRD about non-compliances related to use of pesticides identified during CC checks. Concerning follow-up cases, where information was received on a breach or suspected breach from external sources, there is effective and efficient cooperation of the authorities involved. LAs occasionally inform CRD about the cases they deal with. CRD makes efforts in order to collect comprehensive information from different official, semi-governmental and private pesticide use monitoring systems.

## **Conclusions**

Concerning official controls on marketing and use, including enforcement there is sufficient cooperation between CRD and RPA and between CRD and NPET members. There is no clear evidence of systematic cooperation between CRD and LAs, between CRD and RPAs of other countries of the UK and between CRD and HSE of Scotland and Northern Ireland.

### *5.2.9 Enforcement Measures*

## **Legal Requirements**

Article 72 of Regulation (EC) No 1197/2009 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**

Legal authorities and powers are in place allowing staff of the relevant CAs to enter premises of operators and to undertake enforcement measures, as required. Enforcement measures are undertaken by CRD/HSE based on complaints or breaches reported from external sources, pesticide residues found in food samples, non-compliances identified in the framework of post authorisation monitoring of PPPs or poisonings of wildlife reported. In order to determine the need for further investigation, the line manager at CRD takes account of all the information available with regard to the specific case. Then the individual cases are allocated to the specialists of CRD, to the FOD or to NPET.

It was stated by the CAs, that pesticide related complaints or suspected cases are, in general further investigated due to the high public interest. In relation to investigation of complaints received by FOD, these generally relate to allegations of ill health caused by overspray or general complaints (e.g. spray drift, damage to plants in garden, storage, etc). These are dealt with in accordance with HSE's complaints procedure. The majority of complaints are dealt with by HSE's Complaints and Advisory Teams. Serious complaints that are selected for investigation are passed to a FOD inspector. LAs follow similar approach in enforcement cases within their region.

Once the investigation has been completed and depending on the findings, the main enforcement tools to be applied include either informal or formal written advice, notice, regulatory action or prosecution. Decisions on administrative sanctions are taken on case-by-case basis by CRD or local authorities. Fines are always determined a Court. The Court of magistrates can impose a maximum fine of 5 000 GBP for each offence of a case. When cases are brought to the Crown Court, there is no limit for the fines to be imposed.

In 2012/2013 CRD investigated about 70 cases reported by the Wildlife Impact Investigation Scheme and about 40 cases related to maximum residue limits breaches or otherwise to the use of PPPs. In the majority of the cases no further action was implemented. In 2012/13 FOD and HSE's Complaints and Advisory Teams investigated 45 incidents and issued 14 enforcement notices.

No information is available on the enforcement actions implemented by LAs.

Irregularities identified during CC checks are described in an Annex to the individual inspection report. The file then is submitted to the RPA's headquarters to determine the final measure. Different factors are taken into account in the decision making process such as the severity, extent, permanence and repetition of the non-compliance and the character of the non-compliance (negligence or intentional). In the case of negligence, the reduction of the single payment is one, three or five percent. In cases where non-compliances are considered to be intentional, this percentage may vary from 15 up to 100%. In all cases when non-compliances are related to the storage and/or use of PPPs, these are communicated to CRD for further action if necessary. The RPA identified non-compliances related to use of PPPs in about 3% of CC checks (25 and 42 cases in 2011 and 2012, respectively).

CRD/HSE representatives stated that, in the case of enforcement, they are consistent and undertake a common approach in similar cases to ensure that measures are proportionate and appropriate.

CRD demonstrated two enforcement dossiers to the FVO team. In the first case investigation was carried out at a grower, following identification of residues of an unauthorised PPP in the framework of the National Pesticide Monitoring Program. The inspection identified severe non-compliances concerning PPPs stored at the premises of the grower (non-identifiable, or illegal PPPs). CRD required the removal of the non-compliant products and initiated prosecution at the relevant magistrates court. The grower pleaded guilty to the charges was fined 3 000 GBP and ordered to pay costs of 3 500 GBP.

The second case referred to a parallel import. CRD received complaints, accompanied by photographic evidence, that the appearance of a product authorised under a parallel import permit was different to the likely reference product.

Upon investigation, it was determined by analysis that the parallel import permit product was not identical to the reference product. Furthermore some of the parallel import permit product was a completely different product, containing a different active substance. As a result, the investigating officer of CRD recommended the withdrawal of the parallel import permit. At this stage, the parallel import permit had been revoked for routine procedural reasons allowing 24 months to use or dispose of existing product. Despite the serious findings, these deadlines were not immediately revised following the investigation.

The investigation took seven months to conclude. It took a further ten months for instructions to issue for a recall of the product. A two month period was given to collect existing stocks for disposal. The FVO team received no evidence that the precise quantity and batch numbers of the material in question was determined at any point in the investigation. No evidence was provided of any verification of the recall or disposal of the product. No prosecution was initiated.

## **Conclusions**

The CAs have the necessary legal power for enforcement. General procedures of the UK legal system on enforcement and penalties are followed in the cases, related to the marketing and use of pesticides.

Based on the information received during the audit it can be concludes that CAs do not always take appropriate actions to ensure that the operator remedies the situation and CAs do not always apply effective, proportionate and dissuasive sanctions as required by Regulation (EC) 882/2004.

## **6 OVERALL CONCLUSION**

A comprehensive system is in place in the UK for the authorisation of pesticides. Authorisation procedures are fully in line with EU requirements. However, the deadlines prescribed in EU legislation for authorisation and re-registration of pesticides are not met in about ten percent of the cases.

There are no systematic, risk-based controls on the marketing of pesticides. Compliance of pesticides with requirements of the authorisation, including labels are not checked at distributors. Instead, investigations are only initiated in response to complaints or information on potential non-compliances obtained from external sources. There are certain initiatives for coordinated controls by the relevant authorities in order to combat illegal pesticides.

Although the formulation laboratory has the necessary capability for comprehensive controls, the number of pesticide samples analysed and the method of sampling does not provide adequate assurance for detection of non-compliances.

Although there are regular risk based controls on the use of pesticides at growers, in the framework of the cross compliance controls, the system does not cover about 10-15% of professional users in the UK, including numerous large and medium size fruit and vegetable farms.

Different central competent authorities are responsible for official controls in the different countries of the UK. The central competent authorities have no information about the controls carried out by the local authorities. Therefore the UK does not provide an annual report to the Commission on the scope and results of official controls on the marketing and use of pesticides, as required by the EU legislation.

There are detailed procedures in place for enforcement in the case of non-compliances, including prosecution and application of penalties. However, CAs do not always take appropriate actions to ensure that the operator remedies the situation and the sanctions are not always effective, proportionate and dissuasive.

## **7 CLOSING MEETING**

A closing meeting was held on 22 October 2013 with representatives of CRD. At this meeting, the FVO team presented the main findings and preliminary conclusions of the audit. CRD made preliminary comments and provided clarifications and legal explanations to the FVO team.

## 8 RECOMMENDATIONS

The CAs 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:

N°.	Recommendation
1.	Ensure the re-evaluation and authorisation of PPPs within the deadlines specified in the relevant EU legislation approving the individual substances.
2.	Ensure that regular and risk based official controls are carried out on the marketing of PPPs, in order to provide guarantees that PPPs placed on the market comply with the requirements of Regulation (EC) No 1107/2009, in particular Article 28 of this Regulation.
3.	Ensure that formulation analysis provides for sufficient verification that PPPs placed on the market meet the requirements laid down in Article 29(1)(a), (c), (d) and (h) of Regulation (EC) No 1107/2009 specifically concerning the number of samples and the method of sampling, taking into account the number of authorised active substances, authorised PPPs and registered parallel trade PPPs.
4.	Ensure that all professional users of PPPs are included in the scope of official controls to ensure that PPPs are applied in accordance with the conditions specified on the labels as required by Article 55 of Regulation (EC) No 1107/2009
5.	Ensure that annual reports on the scope of and results from official controls under Regulation (EC) No 1107/2009 are transmitted to the Commission within the deadlines indicated in Article 68 of the Regulation.
6.	Ensure that the planning of controls on the use of PPPs takes into account all identified risks as required by Article 3 (1) of Regulation (EC) No 882/2004.
7.	Ensure that efficient and effective coordination between all CAs involved in official controls takes place as laid down in Article 4(3) of Regulation (EC) No 882/2004.
8.	Ensure that appropriate actions are taken in the case of non-compliances identified in order to guarantee that the operator remedies the situation and that sanctions are effective, proportionate and dissuasive as required by Article 54 and 55 of Regulation (EC) No 882/2004.

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=2013-6643](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6643)

## 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

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
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
	FAO Pesticide Storage and Stock Control Manual	<a href="http://www.fao.org/docrep/v8966e/v8966e00.HTM">http://www.fao.org/docrep/v8966e/v8966e00.HTM</a>