OVERVIEW REPORT OF A SERIES OF AUDITS IN MEMBER STATES
IN ORDER TO ASSESS THE OFFICIAL CONTROL SYSTEMS IN PLACE FOR
PESTICIDE RESIDUES IN FOOD OF PLANT ORIGIN
EXECUTIVE SUMMARY

This is an overview report on a series of audits undertaken between 2007 and 2011 by the European Commission's Food and Veterinary Office (FVO). The series consisted of 19 audits to 17 Member States (MSs) to assess the official control systems in place for pesticides residues in and on food of plant origin. Previously, two audit series on pesticide controls in MSs had taken place.

The outcome of this audit series was overall positive. Considerable progress has been made since the last audit series in the planning, performance and reporting of official controls for pesticide residues. The number of samples taken has increased. Sampling procedures followed the EU legislation and adequate enforcement measures were in place in the large majority of MSs, thus ensuring a high level of consumer protection. Effective procedures were in place for import controls of pesticide residues.

However, there were areas where controls can be organised more efficiently and effectively. Thus, controls would be more efficient with better consideration of all known risk factors: in particular, the reliability of Food Business Operators' (FBOs) auto-control systems and FBOs' past records regarding compliance were not sufficiently taken into account. National control programmes were aimed at assessing both consumer exposure and compliance with current legislation, often within the same programme. Although this is in line with Regulation (EC) No 396/2005, the best practice identified was to establish separate programmes for these differing objectives. The sampling points within the food chain varied considerably between MSs, and were not always adequately chosen.

Accreditation of laboratories has not been completed and LC-MS/MS equipment was not available in many regional laboratories, which resulted in an inadequate scope of analyses. This was practically the case in MSs where a relatively large number of laboratories were designated and analytical volumes were low. The inadequate allocation of the available laboratory resources had a negative impact on the effectiveness of controls.

There was progress in laboratories regarding the implementation of the SANCO Guidelines on Method Validation and Quality Control Procedures for pesticide residues analysis resulting in better quality and more reliable results. However, there was deviation of the Guidelines regarding the consideration of measurement uncertainty for decisions on compliance. Consequently, the thresholds for enforcement of MRLs varied between MSs.

This report identifies best practices for controls carried out, and provides a summary of recommendations made to MSs.
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1. INTRODUCTION

This series of audits was undertaken from 2007 to 2011 by the Food and Veterinary Office (FVO) of the European Commission's Directorate-General for Health and Consumers (DG SANCO). The series consisted of 19 audits to 17 Member States (MSs). Most audits were of one week and a half and usually consisted of a team of two auditors and one national expert from a MS authority. The programme involved meetings with central and regional/local Competent Authorities (CAs), visits to official laboratories undertaking analyses of pesticide residues in and on food of plant origin, and sampling points for pesticide residue analysis (wholesalers, supermarkets, markets, import points).

Reports on individual audits are available on DG SANCO's website: http://ec.europa.eu/food/fvo/index_en.htm

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

Obviously, this report can only reflect the status observed at the time of the audits, although some systems may have improved in the meantime. For some sections, the information was not complete for all MSs, as Regulations (EC) No 396/2005 and No 669/2009 became fully applicable during the period of the audit series.

2. OBJECTIVE OF THE SERIES OF AUDITS


3. LEGAL BASIS FOR THE AUDITS

The audits were carried out under the general provisions of European Union (EU) legislation, in particular Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council.

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

4. BACKGROUND

Prior to this audit series, the FVO carried out two series of audits to all MSs concerning pesticides in food of plant origin. During these previous audits, a number of deficiencies in control systems were identified. These included deficiencies in the planning and conduct of inspections to control the marketing and use of plant protection products (PPPs), sampling technique, assessment of risk to consumers, the operation of the EU
Rapid Alert System for Food and Feed (RASFF), the follow-up of infringements and the range of analysis in pesticide residue laboratories.

Findings during audits to Third Countries (TCs) have shown deficiencies in control systems for pesticide residues in plant produce exported to the EU. As a result, the assessment of controls at the point of import from TCs was included in this current series of audits.

The Overview reports of previous audits in MSs and in TCs can be found on DG SANCO's Internet site: [http://ec.europa.eu/food/fvo/specialreports/index_en.htm](http://ec.europa.eu/food/fvo/specialreports/index_en.htm).

The final reports of the individual audits can be found at: [http://ec.europa.eu/food/fvo/ir_search_en.cfm](http://ec.europa.eu/food/fvo/ir_search_en.cfm).

In accordance with the requirements of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) drafts an Annual Report on Pesticide Residues. The Annual reports are to be found on EFSA's website at the following address: [http://www.efsa.europa.eu/en/publications.htm](http://www.efsa.europa.eu/en/publications.htm).

5. **FINDINGS AND CONCLUSIONS**

5.1. **Relevant national legislation**

**Legal Requirements**

The relevant EU legislation is listed in Annex I.

**Findings**

The visited MSs adopted national legislation to implement Regulations (EC) No 396/2005 and 882/2004. The scope of this legislation varied from rules for imposition of fines to detailed instruction for planning and performance of and reporting on official controls.

**Conclusions**

Adequate national legislation was in place to implement EU legislation within the scope of the audits.

5.2. **Competent Authorities**

5.2.1. **Designation of Competent Authorities**

**Legal Requirements**
Article 4(1) of Regulation (EC) No 882/2004 requires MS(s) to designate the CA responsible for official controls.

**Findings**
Designation of the CAs in seven of the seventeen visited countries has changed since the previous series of audits. All changes are described in updated Country Profiles (CPs) which can be found at following website:

http://ec.europa.eu/food/fvo/country_profiles_en.cfm

The number of national reference laboratories (NRLs) designated for pesticide residue controls ranged from one to three laboratories per MS. In general, the NRLs acted as specified in Article 33 of Regulation (EC) No 882/2004. The NRLs in some MSs also acted as official control laboratories.

**Conclusions**
The CAs responsible for official controls of pesticide residues were clearly designated in all visited MSs.

5.2.2. *Resources for Performance of Controls*

**Legal Requirements**
Article 4 of Regulation (EC) No 882/2004 requires the CA to ensure that they have access to a sufficient number of suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available.

Article 6 of Regulation (EC) No 882/2004 requires CAs to ensure that staff receives appropriate training, and are kept up-to-date in their competencies.

**Findings**
The number and qualification of staff designated for pesticide residue controls were adequate. Job requirements were clearly defined, and satisfactory training was available in almost all of the visited MSs with the exception of one MS.

Staff members were kept up-to-date in various ways, including regular meetings, participation in external and internal trainings, national and international events, and several staff also participated in training under the Better Training for Safer Food (BTSF) programme.

The visited laboratories in several MSs, in particular regional laboratories, did not have LC-MS/MS equipment. Consequently, they could not analyse for a sufficiently broad range of pesticides with the sensitivity required by EU legislation. On the other hand, some of these laboratories stated that they were in the process of purchasing LC-MS/MS equipment.
Conclusions

A sufficient number of experienced staff was appointed for official controls. The staff members received adequate training within the scope of their responsibilities. The main shortcoming identified was related to laboratory equipment, as several laboratories did not have LC-MS/MS, which is essential for effective pesticide residue control.

5.3. Organisation and implementation of official controls

5.3.1. Control programmes for pesticide residues

Legal Requirements

Article 26 of Regulation (EC) No 396/2005 requires MSs to carry out official controls on pesticide residues in order to enforce the compliance with the Regulation. Article 27 requires MSs to take a sufficient number and range of samples to ensure that the results are representative of the market, and the point of sampling shall allow subsequent enforcement action to be taken. Article 30 requires MSs to establish multi-annual control programmes for pesticide residues. It specifies the requirements of the control programme.

Findings

Article 30 of Regulation (EC) No 396/2005 requires MSs to establish multi-annual control programmes for pesticide residues, and specifies the requirements of the control programme. The programmes shall be aimed at assessing consumer exposure and compliance with current legislation. Germany and France have established separate programmes, one "consumer basket" programme with random samples in order to assess consumer exposure, and further risk based programmes with samples targeted to the risks identified. This is seen as a best practice. Conversely, the majority of MSs include in their national programmes both elements of a programme for dietary risk assessment and risk-based elements. Thus, the national programmes always considered the main commodities of the national diets, but also risk-based factors such as results from previous years, volume of imports, production, RASFF notifications, and the available laboratory resources. Based on these parameters, among others, the number of samples for the different commodities was established, and samples of these commodities were then taken in many cases randomly. However, some MSs included instructions regarding the country of origin for some consignments to be sampled. Some small MSs implemented only the EU control programmes with random samples, or implemented a risk based programme in addition to the EU programme. Some MSs took a small number of "enforcement samples" in case of suspicion or to follow-up infringements identified (2.1 % of all samples according to the 2009 European Union Report on Pesticide Residues in Food1 of the European Food Safety Authority (EFSA)).

The 2009 EFSA report also indicated that 67 000 official samples were analysed for pesticide residues. This is a very high number of samples compared to non-EU countries (see FVO overview report of a series of missions carried out in third countries between

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2004 and 2010 to evaluate controls of pesticides in food of plant origin intended for export to the EU\(^2\).

All MSs sent their national programmes to the European Commission, and only few shortcomings were identified for these programmes, e.g. it was not specified which pesticides should be analysed for, or the programmes were not multi-annual as required by Regulation (EC) No 396/2005. Annual reports about the controls performed were communicated to EFSA, European Commission and published on the websites of CAs as required by EU legislation. One MS had published only summary reports, but stated however, that detailed data were available on request.

Article 27(1) of Regulation (EC) No 396/2005 requires that sampling shall be carried out as close to the point of supply as is reasonable, to allow for any subsequent enforcement action to be taken. Article 26(2) of the same Regulation specifies that such controls shall also be carried out at the point of supply to the consumer. The points of sampling varied considerably between the MSs. Generally, samples were taken at various points, including growers, pack houses, wholesalers, distributors, supermarkets, retailers and import points. However, only in two of the visited MSs samples were taken at warehouses of growers and traders. In two other MSs samples were taken predominantly at retail level, e.g. supermarkets. This latter practice was not in line with Article 27(1) of Regulation (EC) No 396/2005, as the food had been consumed when the analytical results became available, and enforcement action was generally not possible.

Four MSs visited had additional programmes for pre-market samples in place. As the samples have not entered the market at the time of sampling, the MRLs do not apply. Nevertheless, enforcement action can be taken in case of illegal use of pesticides detected, and the programmes were considered useful to achieve additional control of pesticides used.

**Conclusions**

The high number of official samples taken in the EU overall ensures a high level of consumer protection.

The national control programmes for pesticide residues were aimed at assessing consumer exposure and compliance with current legislation, in line with Regulation (EC) No 396/2005. However, as these two objectives were often followed by the same national programmes, neither objective could be fully achieved: the data were not fully representative for a dietary exposure assessment and not sufficiently risk-based to cover all risks identified, e.g. minor commodities such as fresh herbs. The best practice identified was to establish separate programmes.

Sampling points in the food chain varied considerably between MSs, with some MSs sampling close to the farm gate and others close to the supply to the consumer. For dietary risk assessment it would be more suitable to sample close to the consumer to enable a more realistic assessment of exposure. For risk-based enforcement sampling, however, sampling close to the farm gate is required by Regulation (EC) No 396/2005.

As the objectives of the MS control programmes were not fully clear, the sampling points were not always adequately chosen.

5.3.2. Import controls for pesticide residues

Legal Requirements

Article 15(1) and (2) of Regulation (EC) No 882/2004 require official controls on the introduction of feed and food of non-animal origin from TCs to be carried out regularly, in the light of potential risks, and at an appropriate place, including the point of entry of the goods, the point of release for free circulation, warehouses, the premises of the importing Food Business Operators (FBOs), or other points of the food chain.

Findings

For imported food of non-animal origin, no approval of exporting countries or export certification is required by EU legislation, and the main responsibility for compliance with EU MRLs lies with the importer in the EU. FVO audits in exporting countries have shown that authorisations of PPPs are very different from the EU, and therefore import controls were assessed in this audit series. Regulation (EC) No 669/2009 has established harmonised levels of import controls for products with known or emerging risks. The controls under this Regulation were audited by a separate audit series (Overview report SANCO/2011-6577, http://ec.europa.eu/food/fvo/specialreports/index_en.htm). This audit series for pesticide residue control only covered import controls, which are not harmonised at EU level.

In all visited MSs, import controls were carried out at the point of entry. In the Mediterranean MSs visited, the CAs must approve all consignments of food of non-animal origin submitted for import. In other MSs, however, only Customs are routinely involved in imports and CAs are informed of imported consignments on a voluntary basis.

All visited MSs took samples based on identified risks, although the risk assessment was not clear in two MSs. In five of the visited MSs, the sampled consignments were always detained during the analysis. In one MS, consignments were never detained, and always cleared by Customs before the analytical result became available. In the remaining visited MSs, consignments were detained in the case of suspicion, in particular if previous consignments of the same origin had been found to be non-compliant.

Conclusions

Effective procedures for import controls were found in the visited MSs. Consignments were detained during analysis, at least in the case of suspicion, in line with EU legislation and ensuring that suspicious consignments are not released by Customs without adequate checks. However, in the majority of MSs, the CAs were not always informed of imported consignments, which was a weakness in the control systems.

5.3.3. 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
The control programmes for pesticide residues of MSs usually took into account the risks identified for different commodities in previous years or through the RASFF system, e.g. more samples are taken for mandarins if a high rate of non-compliance had been identified for mandarins in previous years. Some MSs had additional enforcement programmes, where they target the commodity and origin due to identified risks, e.g. mandarins from a specific country. Only five of the visited MSs also took into account the past compliance record of individual FBOs, or types of FBOs. This is a requirement of Article 3(1)(b) of Regulation (EC) No 882/2004. One MS took the large majority of samples in the big supermarket chains, which generally have a lower non-compliance rate than other types of retail.

Only one MS took into account the reliability of auto-controls that have already been carried out, as required by Article 3(1)(c) of Regulation (EC) No 882/2004. In France, such a system was being developed at the time of the audit. The CA, together with the professional organisations of importers, packers and wholesalers were involved in a project on the implementation of agreed auto-control procedures for food safety. At the time of the mission, a total of 63 companies were in different stages of implementation. Member companies have to notify non-compliant auto-control samples to the CA, which stated that they plan to take into account the reliability of the auto-controls for the frequency of their official controls.

Conclusions
While MS control programmes for pesticide residues took into account the risk identified for certain commodities, and to some extent also their origin, they did not sufficiently take into account the FBO's past record as regards compliance. The reliability of any own checks that have already been carried out, was not taken into account by the large majority of the MSs, contrary to Article 3(1) of Regulation (EC) No 882/2004.

5.3.4. Sampling

Legal Requirements

Findings
The requirements of the EU sampling legislation regarding identification of the lot, the weight and unit numbers of the laboratory sample, and sealing and labelling of the sample, were generally followed. Only in one MS the lot was not correctly identified and in two MSs the number of primary samples was too small. A lack of traceability
data in the sample records attached to RASFF notifications had been noted during the audits in TCs, see FVO overview report (DG(SANCO)/2010-6140). However, the sampling records evaluated during the audits of this series contained all information to trace back the samples in all but one MS, where the sampling form required entering the relevant bar code and batch number but the sampling officer failed to complete it. In several MSs, photos were taken of the labels of sampled lots.

MSs had different approaches for the number of primary samples in lots which have been mixed, e.g. through washing and grading. Some MSs only took one primary sample in such case. However, although such lots will be well mixed, they cannot be proven to be fully homogenised. Best practice observed was not to consider such lots as homogenous, and to take the numbers of primary samples required by the Directive.

Conclusions
The sampling procedures followed the requirements of EU legislation that allows samples to be analysed which are representative of the lot, as well as tracing back in the case of non-compliance. The taking of photographs of sampled lots is seen as a best practice.

5.3.5. Laboratory performance

Legal Requirements
Article 12 of Regulation (EC) No 882/2004 requires that CAs designate only laboratories that operate and are assessed and accredited in accordance with the standards EN ISO/IEC 17025 and EN ISO/IEC 17011. Article 33 of the Regulation requires MSs to designate NRLs for each Community reference laboratory, and specifies tasks for the NRL.

Article 28 of Regulation (EC) No 396/2005 requires that the methods of analysis of pesticide residues shall comply with the criteria set out in the relevant provisions of Community law relating to official controls for food and feed, and that all laboratories analysing samples for the official controls on pesticide residues participate in the EU proficiency tests (PTs) for pesticide residues organised by the Commission.

Findings
In all MSs visited at least one NRL for pesticides residues was nominated as required by Article 33 of Regulation (EC) No 882/2004. In three MSs, where more than one NRL was appointed, deficiencies in effective and clear co-ordination between NRLs were identified. Some, but not all NRLs, analysed official control samples in addition to their responsibilities specified in Article 33 of Regulation (EC) No 882/2004. NRLs in two MSs were not accredited to ISO 17025.

A combination of LC-MS/MS and GC-MS/MS equipment is necessary to analyse pesticide residues with the required sensitivity, analytical scope and identification. However, LC-MS/MS equipment was not available in all laboratories of ten visited
MSs, and GC-MS/MS was not available in all laboratories of eleven MSs. In several visited laboratories, however, such equipment was recently received and was in the process of becoming operational. Notably, a lack of instrumentation was normally observed in laboratories analysing less than 500 samples per year. Such laboratories were found in MSs, which have designated analyses to a high number of laboratories compared to the number of inhabitants. In one MS with 11 million inhabitants, a total of ten laboratories were designated of which eight did not have the required instrumentation. In two MSs, a new laboratory building had been completed, but due to the lack of staff and/or equipment, analyses were only performed for one residue (dithiocarbamates).

Best practices observed were to concentrate laboratory resources in one or few adequately equipped laboratories, e.g. one laboratory in the Netherlands with 16 million inhabitants or four laboratories in the UK with 60 million inhabitants. Belgium has delegated some of the official analyses to a well performing laboratory in another MS, and Sweden has designated a private laboratory for pesticide residue analyses (audit DG(SANCO) 2010-8574 on import controls).

A long time lapse between sampling and submission of the analytical report was noted in only four of the seventeen visited MSs, where in individual cases analyses were delayed for six weeks or even six months.

In nine of the visited MSs, not all designated laboratories were accredited to ISO 17025. The SANCO Guidance Document on Method Validation and Quality Control Procedures for pesticide residues analysis in food and feed (SANCO/12495/2011 or its previous versions) has generally been implemented and was known in all but one of the laboratories. However, full implementation of this document was observed only in less than half of the laboratories visited. The audit teams noted deviations from the Guidance document regarding validation data, matrix-matched calibration and recovery checks. In particular, five MSs did not follow the Guidance (point 91) to apply a 50% factor for expanded measurement uncertainty for decisions on compliance, based on the laboratory calculation on expanded uncertainty to be less than 50%. However, in the action plans submitted after the audits, Member States stated that they have aligned their procedures with the Guideline. The vast majority of official laboratories for pesticide residues in the MSs visited participate in EU PTs on a regular basis. The EURLs also organise regular workshops for NRLs discussing *inter alia* the SANCO Guidance Document, but in larger MSs with a number of official control laboratories, the discussions at EU level are not always passed on by NRLs to all regional laboratories.

**Conclusions**

A lack of the required instrumentation did not allow effective control of pesticides in many laboratories. This was because in the MSs concerned resources were inefficiently allocated to an excessive number of laboratories. The identified best practices include the concentration of laboratory resources and, where relevant, the designation of private laboratories and laboratories in neighbouring MSs.

While the implementation of the SANCO Guidance Document (SANCO/10684/2009) has overall ensured good quality control in the laboratories, the process of accreditation had not been completed in all MSs. Due to deviating approaches of some MSs regarding
the consideration of uncertainty data for compliance decisions at the time of the audits, the enforcement of MRLs was in practice not harmonised between all visited MSs.

In two MSs, the NRLs designated were not accredited to ISO 17025 which was not in line with the requirements of Article 12(2) and (3) and Article 33(3) of regulation (EC) No 882/2004.

5.3.6. 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 30(3) of Regulation (EC) No 396/2005 requires MSs to publish, on an annual basis, all results of national residue monitoring on the Internet. Article 31 of the Regulation requires MSs to submit the results of official controls on pesticide residues to the Commission, the EFSA and the other MSs.

Findings

In all visited MSs, there were documented procedures in place and written instructions for official controls of pesticide residues. Instructions were mostly developed by the central CAs, and, only in one MS, by regional CAs. In three MSs, further more detailed guidance documents were developed by staff members involved in routine controls for pesticide residues.

All MSs have developed standard templates e.g. sampling records, checklists and/or audit reports. In most MSs, inspection reports and sampling records are uploaded to and further processed in electronic databases.

In all but one MS, FBOs who are the subject of inspection receive a copy of the inspection report, at least in the case of non-compliance, as required by Article 9 of Regulation (EC) No 882/2004.

Conclusions

Procedures for performance of and reporting on official controls were established and applied in all MSs visited as required by Articles 8 and 9 of Regulation (EC) No 882/2004.
5.4. Co-operation, enforcement and verification

5.4.1. 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 and co-operation 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 MSs visited, the exchange of information was secured by both formal (meetings, circulars, letters) and informal means (phone calls, e-mails). Moreover, in many MSs communication was supported by official agreements and standardised procedures between and within CAs.

Minor shortcomings regarding communication were observed in two MSs, and a lack of communication between two CAs was observed in only one MS.

Conclusions

Effective communication, co-operation and co-ordination between and within CA was generally in place.

5.4.2. Enforcement Measures

Legal Requirements

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 Community 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 the majority of MSs visited, there is a legal requirement and procedure in place for administrative sanctions to be applied by the CA. In most cases, this allows for quick and effective enforcement actions to be undertaken. In two of the MSs visited, the administrative sanctions were applied by a different authority. In one MS, administrative sanctions could only be applied if a risk to the consumer was identified. Only in two
MSs visited, non-compliances had to be referred to the public prosecutor. In addition to administrative sanctions, financial sanctions (fines and/or penalties) were applied, which were found to be proportionate and dissuasive. Moreover, CAs of the MSs were empowered to apply further enforcement measures, including warning letters, seizure, withdrawal from the market and/or destruction of non-compliant produce.

Adequate enforcement measures were taken in the large majority of MSs, including the measures described above, but also follow-up inspections to trace back the produce, and/or to take additional samples.

In two of the MSs, however, there was no legal requirement for sanctions to be applied where samples were taken as "surveillance samples". In one of these MSs, a letter was sent to the FBO concerned and, in addition, the FBO was publicly named on the CA's website. The audit team considered this enforcement action as effective for large retail chains, where the majority of samples in this MS were taken. However, for small FBOs like corner shops or market stalls this action does not have the same impact and effectiveness is not guaranteed.

In three MSs, analyses and follow-up actions were slow, so that the non-compliant products had been consumed before any actions could have been taken.

Conclusions

Adequate enforcement measures were in place in the large majority of MSs.

5.5. Rapid Alert System for Food and Feed

Legal Requirements

Article 50 of Regulation (EC) No 178/2002 requires MSs to immediately notify any information relating to the existence of a serious direct or indirect risk to human health deriving from food, to the Commission under the RASFF.

Findings

The national contact point for the RASFF was clearly defined in all MS visited. Written guidelines for RASFF operation were well established. As MRLs for pesticides found to be in excess do not always represent a risk to the consumer, a systematic risk assessment has to be performed for all non-compliant samples in order to ensure adequate follow-up actions. Only in one MS, a risk assessment was not conducted for non-compliant samples and, in a second MS, the procedures applied were unclear and risk assessment was not performed for all non-compliant samples. However, in four MSs delays of up to two months and more were noted regarding the time span between availability of laboratory results and notifying the non-compliance identified via the EU RASFF. The delays in these MSs did not ensure swift information to other MSs.

Conclusions
In the large majority of MSs, the operation of RASFF regarding pesticide residues was well organised. Only in a small number of MSs some problems were identified with unclear procedures for risk assessment and delays in drafting and submission of RASFF notifications.

6. **RECOMMENDATIONS**

The following is a summary of the main recommendations made in individual audit reports. It should be noted that not every recommendation applies to each MS:

**Resources**

1. Ensure that all laboratories responsible for pesticide residue analysis in food of plant origin have appropriate and properly maintained equipment to ensure that staff can perform official controls effectively and efficiently as required by Article 4 (1)(d) of Regulation (EC) No 882/2004.

2. In accordance with Article 6 of Regulation (EC) No 882/2004, the CAs should ensure that staff receive appropriate training so that samples are taken in accordance with Commission Directive 2002/63/EC.

**Co-operation**

3. Ensure that efficient and effective co-ordination takes place between all CAs carrying out official controls for pesticide residues, in accordance with Article 4 (3) of Regulation (EC) No 882/2004.

**Control programmes for pesticide residues**

4. Ensure that the national control programme for pesticide residues contains all the details required by Article 30 of Regulation (EC) No 396/2005.

5. Ensure that official controls are carried out at all appropriate stages of production, processing and distribution, as required by Article 3 (3) of Regulation (EC) 882/2004

6. Ensure that taking samples within the national control programme for pesticide residues is performed as close to the point of supply as is reasonable to allow for any subsequent enforcement action to be taken, as required by Article 27(1) of Regulation (EC) No 396/2005.

7. Ensure that all control results are routinely reported to the Commission. This should include results of surveys.

**Import controls for pesticide residues**
Ensure that official controls on imported food of plant origin, including controls at points of entry, are risk-based and the frequency of controls is considered in accordance with the requirements laid down in Article 15 and Article 16 (2) of Regulation (EC) No 882/2004.

Prioritisation of official controls

(9) Take account of the reliability of FBOs own checks, as stipulated in Article 3 (1) (c) of Regulation (EC) No 882/2004.

(10) Ensure that auto-control systems in place at FBOs are evaluated for the purposes of the official controls as stipulated in Article 10 (2) (a) of Regulation (EC) No 882/2004.

Procedures for performance and reporting of controls

(11) Ensure that a documented procedure is in place in the case of sampling for pesticide residues as laid down in Article 8 (1) of Regulation (EC) No 882/2004. Consider providing all the necessary details in the written instructions on sampling for pesticide residues to ensure that a uniform approach is followed by all the inspectors.

(12) Ensure that a copy of the inspection report is provided to the FBOs concerned, at least in case of non-compliance, as set out in Article 9 (3) of Regulation (EC) No 882/2004.

Laboratories

(13) Ensure that the NRLs work closely together to ensure efficient coordination between them, with other national laboratories and with the EURLs, in accordance with Article 33(5) of Regulation (EC) No 882/2004.

(14) Ensure that the NRLs and all designated laboratories are accredited, as required by Articles 12 and 33 of Regulation (EC) No 882/2004.

(15) All laboratories analysing samples for the official controls on pesticide residues should participate in the Community proficiency tests for pesticide residues as required by Article 28(3) of Regulation (EC) No 396/2005.

(16) Consider to fully implement the SANCO Guidelines on method validation and quality control procedures for pesticide residues analysis in food and feed.

(17) Consider to apply, for the decision on compliance of a sample containing pesticide residues, the default value of 50 % for expanded analytical uncertainty, as specified in the SANCO Guidelines on Method Validation and Quality Control Procedures for Pesticide Residues Analysis in Food and Feed.

(18) Ensure access to rapid laboratory analysis, so that official control can be carried out effectively, in accordance with Article 4(2) of Regulation (EC) No 882/2004.

Enforcement measures
(19) Where control identifies non-compliance, ensure that appropriate enforcement actions are taken in accordance with Article 54 of Regulation (EC) No 882/2004.

RASFF

(20) Consider taking into account the Draft Guidance document on notification criteria for pesticide residues findings to the Rapid Alert System for Food and Feed (SANCO/3346/2001, rev. 7), including systematic consumer risk assessments for adults and children.

(21) Ensure that any information relating to MRLs or pesticide residues in food of non-animal origin considered as a serious direct or indirect risk to human health is immediately notified to the Commission under the RASFF as required by Article 50(2) of Regulation (EC) No 178/2002.

7. ACTION TAKEN BY COMMISSION SERVICES

7.1. Follow-up of audit recommendations

For each audit a copy of the final report was sent to the national CAs with a request for an action plan indicating the steps envisaged to address the recommendations made in the audit report.

A deadline was set for the receipt of these plans and the response of the CAs was analysed. Where it was considered that a response did not address the issues raised, the Commission's services actively pursued the matter with the authorities concerned.

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

7.2. Additional action by Commission Services

Before the audit series started, an information meeting was organised at the FVO with the relevant national experts from different MSs who would be involved in future audits on pesticide controls. At this meeting, an overview of the findings of the previous mission series was presented, and an update on the relevant legislation was given. Information on FVO procedures was also provided.

Since September 2008, Regulation (EC) No 396/2005 has been fully applicable with the result of establishing harmonised EU MRLs for all agricultural products.

In the period 2007 – 2011, when the current audit series was on-going, the SANCO Guidelines on Method Validation and Quality Control Procedures for pesticide residues analysis in food and feed was up-dated twice (SANCO Documents No 3131/2007 and 10684/2009). These Guidelines were discussed and reviewed by representatives from
the EU RLs and official laboratories for pesticide residue analysis of different MSs. In addition, EU RLs continued to organise PTs and to provide support to MSs' laboratories in terms of quality control procedures, development and validation of new analytical methods as well as providing technical and scientific advice to the Commission.

Based on the findings described in individual audit reports, a review of the Draft Guidance Document on notification criteria for pesticide residue findings to the RASFF (Document No SANCO/3346/01 rev. 7) is currently in progress with a view to ensuring that a uniform approach is followed by the CAs of all 27 MSs in the case of non-compliant plant produce notified via the EU RASFF.
ANNEX I

DETAILS OF AUDITS UNDERTAKEN

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<th>Member State</th>
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The reports on individual missions are available on the Directorate General’s Website:

http://ec.europa.eu/food/fvo/ir_search_en.cfm
## Annex II

### Table of legislation

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