GENERAL REPORT ON THE OUTCOME OF A SERIES OF MISSIONS CARRIED OUT IN ALL MEMBER STATES FROM 1998 TO 2003 IN THE FIELD OF CONTROL SYSTEMS ON PLACING ON THE MARKET OF PLANT PROTECTION PRODUCTS AND RESIDUES IN FOODSTUFFS OF PLANT ORIGIN
Table of Contents

1. EXECUTIVE SUMMARY ..........................................................................................3
2. INTRODUCTION ....................................................................................................4
3. BACKGROUND AND OBJECTIVES OF THE SERIES OF MISSIONS ............4
4. LEGAL BASIS .......................................................................................................5
5. MAIN FINDINGS AND CONCLUSIONS REGARDING CONTROL SYSTEMS FOR THE PLACING ON THE MARKET AND USE OF PLANT PROTECTION PRODUCTS ........................................................................5
   5.1. Legislation ..................................................................................................5
   5.2. Competent authorities .............................................................................6
   5.3. Control and inspection activities ............................................................7
   5.4. Laboratories for formulation analyses ...................................................9
6. MAIN FINDINGS AND CONCLUSIONS REGARDING CONTROL SYSTEMS FOR RESIDUES IN FOODSTUFFS OF PLANT ORIGIN .................10
   6.1. Legislation ................................................................................................10
   6.2. Competent authorities .............................................................................10
   6.3. Controls and inspection activities ............................................................11
   6.4. Laboratories .............................................................................................14
7. MAIN FINDINGS AND CONCLUSIONS REGARDING THE MISSIONS IN WHICH SPECIFIC PROBLEMS HAVE BEEN INVESTIGATED ................16
   7.1. Weaknesses in the control systems revealed by the crises .....................16
   7.2. Management of the situation .................................................................17
8. RECOMMENDATIONS .........................................................................................19
9. ACTION TAKEN BY THE COMMISSION SERVICES ......................................20
   9.1. Follow-up of mission recommendations ..............................................20
   9.2. Additional action by the Commission Services .....................................20
10. ANNEX I DETAILS OF MISSIONS UNDERTAKEN .....................................22
1. EXECUTIVE SUMMARY

During the period August 1998 till February 2003, missions were undertaken to the 15 Member States to evaluate the control systems in place for the marketing and use of plant protection products and for pesticide residues in foodstuffs of plant origin. Four missions were undertaken to investigate specific problems related to pesticides.

The main findings of these missions indicated that control systems vary considerably between Member States. The control system for pesticide residues was in general better developed than the control system for placing on the market and use of plant protection products.

For both control systems the relevant Community legislation was generally well transposed into national law. The fact that authorisations of plant protection products are not completely harmonised in the EU and that there are no harmonised maximum residue levels for all the pesticide-crop combinations caused some problems with infringements in Member States.

Competent authorities for the two control systems were designated. However, where the responsibilities were shared between different competent authorities these responsibilities were not always clearly defined, resulting in overlapping activities or gaps in the controls. Weaknesses were specifically found with regard to the communication between the different competent authorities in charge of controls of marketing and use and of residues, thus preventing an efficient follow up of infringements or forward planning of activities. In those Member States with a rather de-centralised structure the communication was often poor between the central and regional/local competent authorities, which led to an often incomplete overview of control activities at central level.

Controls/inspections on marketing and use were often incomplete and the importance given to them varied greatly between Member States. The result reporting to Commission was often incomplete or delayed. In the residue area there was great variance in planning, priorities and scope of monitoring programmes and deficiencies were found with regard to sampling. One of the weakest points in the residue area was the follow up and enforcement of infringements: in some Member States no or only limited enforcement action was taken. Enforcement action was further hampered by the absence of clear procedures (e.g. for the definition of exceeded MRLs, for dietary risk assessment) and by deficiencies in the proper functioning of the Rapid Alert System for Food and Feed at Member State level.

The situation of formulation laboratories was considered generally satisfactory, the legal requirements being less strict here than in the residue area. In the residue area the laboratories were a major problem, as a third of the Member States had not achieved accreditation in 2001. Most Member States had not fully implemented the EU Quality Control Procedures, however, progress in implementation was seen. While the methods used and the participation in proficiency tests were satisfactory, method validation was a weak point in both the control systems for marketing and use and for residues. The number of analytes sought for residue analysis varied greatly between Member States. The missions carried out with regard to specific problems revealed certain weaknesses or confirmed those already previously found. A number of recommendations were given to Member States in order to address those points identified as major weaknesses.
2. INTRODUCTION

The Food and Veterinary Office has carried out a series of missions to all 15 Member States to evaluate the control systems in place for the placing on the market of plant protection products and pesticide residues in foodstuffs of plant origin. The mission series started in August 1998 and was finalised in February 2003. Details of these missions are given in Annex I.

It is obvious that this General Report can only reflect the status observed at the time of the mission, although some systems may have improved in the meantime. One difficulty faced during preparation of this report was the long time span in which this series had been carried out. This hampers the comparability of the information received. In the missions to the first four Member States no recommendations to the competent authorities were made. In some cases the information obtained was not complete for all the Member States on every aspect. However, based on the findings in the individual mission reports, it is still possible to identify areas which are more problematic than others, to draw conclusions and to make recommendations.

By the time of this General Report all mission reports were finalised. In four cases missions were undertaken with regard to a specific problem. Since these reports are very good examples to demonstrate how efficient the control systems work in times of crisis, the main findings of these reports have been summarised in chapter 7. They are also mentioned in chapters 5 and 6 where they underlined weaknesses in the control systems.

Information is mainly taken from the mission reports. Where more updated information was available from the annual pesticide residues monitoring report 2001, this updated information has been used instead. This is clearly indicated in the relevant parts of the report.

The reports on the individual missions undertaken and the annual pesticides residue monitoring reports are available at the Directorate General's website:

http://europa.eu.int/comm/food/fs/inspections/index_en.html

3. BACKGROUND AND OBJECTIVES OF THE SERIES OF MISSIONS

Pesticide residues in foodstuffs of plant origin are an area of high consumer concern. In Council Directives 86/362/EEC\(^1\) of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals (as amended) and 90/642/EEC\(^2\) of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables (as amended), maximum levels have been fixed in order to minimise the exposure of consumers to harmful or unnecessary intake of pesticides. Member States are asked to check regularly the compliance of foodstuffs with these levels and to carry out national and European monitoring programmes.

---

\(^1\) OJ L 221, 07.08.1986, p. 0037 - 0042

The objective of the missions was to evaluate the control systems for pesticide residues in foodstuffs of plant origin within the framework of Council Directives 86/362/EEC (as amended) and 90/642/EEC (as amended).

As the residue monitoring is linked to the placing on the market and use of plant protection products, the control systems for these functions, in the framework of Council Directive 91/414/EEC\(^3\) of 15 July 1991 concerning the placing of plant protection products on the market (as amended), has also been evaluated.

In pursuit of these objectives visits to the central and regional competent authorities, the services in charge of inspections and sampling and to the laboratories in charge of formulation and residue analysis have been undertaken.

4. **LEGAL BASIS**

The missions were carried out under the general provisions of Community legislation and in agreement with the respective central competent authorities.

In particular, the missions were carried out under Article 5 of Commission Regulation (EC) No 645/2000\(^4\) of 28 March 2000 setting out detailed implementing rules necessary for the proper functioning of certain provisions of Article 7 of Council Directive 86/362/EEC and of Article 4 of Council Directive 90/642/EEC concerning the arrangements for monitoring the maximum levels of pesticide residues in and on cereals and products of plant origin, including fruit and vegetables, respectively.

5. **MAIN FINDINGS AND CONCLUSIONS REGARDING CONTROL SYSTEMS FOR THE PLACING ON THE MARKET AND USE OF PLANT PROTECTION PRODUCTS**

5.1. **Legislation**

5.1.1. **Transposition of legislation**

Transposition of the Community legislation has been carried out within the timeframe established in all Member States except one where there was a delay of 5 years in transposition of Council Directive 91/414/EEC. Completeness or accuracy checks of transposition were not part of the missions. Council Directive 78/631/EEC\(^5\) of 26 June 1978 on classification, packaging and labelling of dangerous preparations (pesticides) has also been transposed into national laws of Member States; although three Member States have been exempted for some of the provisions of this Directive. In some Member States, Council Directive 79/117/EEC\(^6\) of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances and its amendments were not formally transposed but the authorisation of the products concerned were withdrawn.

\(^3\) OJ L 230, 19.08.1991, p. 0001 - 0032
\(^4\) OJ L 78, 29.03.2000, p. 0007 - 0009
\(^6\) OJ L 33, 08.02.1979, p. 0036 - 0040
5.1.2. Number of authorisations

The number of authorised active substances and plant protection products varied greatly in the Member States, ranging from 147 to 500 active substances and from 300 to 7806 plant protection products. The different agricultural activities and conditions in the Member States can mainly explain these differences.

In some Member States, products authorised in another Member State were present on the national market although they were not authorised at national level. The resulting increasing number of infringements highlights the difficulties created by a national authorisation procedure in a common market.

5.1.3. Particular authorisation procedures

Extension of the field of application of an authorised plant protection product\(^7\) was granted for minor uses according to a simplified procedure in several Member States. In two Member States, the granted extension of use was not necessarily indicated on the label and in three Member States the competent authorities had recognised an increasing number of infringements regarding non-authorised minor uses.

Simplified procedures were in place for parallel imports in all Member States except one (authorisation of a product identical to an existing one and already authorised in another Member State). However, there was no harmonisation of the definition of an 'identical product'.

5.2. Competent authorities

In all Member States visited, there was one central competent authority for the authorisation of plant protection products. With one exception, this central competent authority was also responsible for the control of marketing and use; the extent of this responsibility varied considerably from one Member State to another.

In most of the Member States, the competence for the control was shared with some other authorities at the central and/or at the regional/local levels. These controls had generally distinct objectives and scopes but some of the checks performed were similar. In eight Member States the central authority could not get a complete overview of control results due to incomplete, delayed or even the absence of reports.

The relation between the competent authority for control of marketing and uses and the competent authority for control of pesticide residues are described in chapter 6.2.1.

In Member States with a rather de-centralised structure of control of marketing and uses, the scope and the checks performed varied from one region to another. In the larger Member States, the different competent authorities were not necessarily aware about activities and results of the inspections carried out by the other competent authorities.

\(^7\) Article 9 of Council Directive 91/414/EEC
5.3. Control and inspection activities

5.3.1. Planning and priorities of control activities

In some Member States there was no planning of the inspection activities at central level, sometimes the national plan was limited to the sampling of plant protection products only. The choice of active substances to be analysed was made according to different criteria (e.g. based on the rate of use, on toxicological characteristics of the products or on the size of premises where plant protection products were sold or used).

5.3.2. Scope of the control activities

The control measures for plant protection products required by the European legislation are laid down in Article 17 of Council Directive 91/414/EEC.

This Article leaves it up to the Member States to further specify how placing on the market and use, as well as authorisation and label should be checked. As a consequence, the importance and extent given by the Member States to the controls on marketing and use of plant protection products varied greatly.

The main control activities were done at the marketing level in retailers' premises. In some Member States, the manufacturers of plant protection products were also controlled. In one third of the Member States the users of plant protection products were not inspected.

Controls at user level

The control at user level (mainly at farmers' level) differed greatly, sometimes only a limited check of the storage conditions and the protective equipment or a verification of the user's license were carried out, in other cases the labels, the authorisation status of the products and spray records were also checked. Rarely, sprayer equipment was inspected. In some countries samples of soil, water and/or plants were taken in order to check which plant protection products had been used.

---

8 Text of Art. 17: Member States shall make the necessary arrangements for plant protection products which have been placed on the market and for their use to be officially checked to see whether they comply with the requirements of this Directive and in particular with the requirements of the authorisation and information appearing on the label.

The Member States shall report annually before 1 August to the other Member States and the Commission on the results of the inspection measures taken in the previous year.
Controls at market level

The controls on market level (at retailers' premises mainly) usually included some checks of the label, the authorisation of the product, the storage conditions and sampling for formulation analysis. However, label and/or authorisation checks of the plant protection products present on the market were limited in several Member States.

- The control of the label ranged from a check of the products taken for formulation analysis only, verification of expiry date and presence of batch or registration number only, to an extensive check of all information on a limited number of labels.

- The authorisation of the plant protection products on the market was not checked at all in two countries. In other Member States the lists of non-authorised/authorised plant protection products, an essential tool for the inspector to carry out authorisation checks, were sometimes not available or not updated.

- Sampling of plant protection products at retail level was generally carried out with the exception of three Member States.

Licenses, training and qualifications required for retailers and users

National rules concerning licence, training and qualifications of retailers and users of plant protection products were variable. With the exception of two Member States, the retailers needed a licence (permit) to sell plant protection products, which were classified as toxic. This licence was generally given following a check of the knowledge and/or qualification of the retailer and/or the suitability of the storage conditions. In five Member States retailers had to participate in specific training. Apart from four Member States, the users needed also to have a licence, especially when they used toxic plant protection products. Training for users of plant protection products was organised in nine Member States.

5.3.3. Performance of inspection

The inspections were carried out by official representatives of a central competent authority or its regional services in the majority of the Member States and/or representatives of a regional/local competent authority. The staff was usually trained and had the power to enter retailers' premises. In four Member States, the human resources were considered limited to perform the controls efficiently.

Check-lists were present in eight Member States. Inspections reports were not always drawn up in two Member States, especially when there was no suspicion of infringements.

5.3.4. Follow up of infringements

In all Member States, provisions in the legislation exist to define the sanctions following an infringement. According to the type of the infringement, various sanctions can be taken from a verbal warning, a warning letter, an administrative fine, to a court case, which could lead to fine and/or imprisonment.
Adequate follow up activities were observed in some Member States. However, the Member States' follow up activities were not evaluated by the FVO during all inspections. Considering all Member States, the main infringements reported concerned unauthorised use\(^9\) of plant protection products and use of unauthorised plant protection products.

5.3.5. **Overview over Member States' reports to the Commission on the inspection results**

Several Member States did not send the annual reports on the results of the inspection measures taken in the previous year or this report was sent with long delays. This is not in compliance with Article 17 of Council Directive 91/414/EEC (see chapter 5.3.2). Following FVO missions, the situation has slightly improved but on 1 June 2003, there were still three Member States which had not yet sent the report for the year 2001 (this should have been sent on 1 August 2002). These reports were often incomplete and unclear and only eight Member States followed approximately the report format laid down in a non-approved EC Working Document. Due to these differences in format, completeness and content, these reports cannot be used to evaluate the situation in the European Union regarding control of marketing and use of plant protection products.

5.4. **Laboratories for formulation analyses**

The situation of the official laboratories in charge of formulation analyses of plant protection products varied greatly particularly regarding the number and scope of analyses.

In most of the Member States, there was one laboratory in charge of the official analyses of formulations of plant protection products. In three Member States, there were several official laboratories for this task. However, in three Member States there was no official laboratory and no analyses were carried out. The number of samples analysed per year varied from 30 to 250 per Member State. In the European Union, around 1,300 samples are analysed per year in total.

The visited laboratories were at various stages in the participation in proficiency tests and the development of Standard Operating Procedures. Although the European legislation does not require it, two visited laboratories were accredited for formulation analyses according to EN/ISO 17025. All the visited laboratories used methods established by CIPAC\(^{10}\) or by manufacturers and some of them also developed in-house methods. However, validations of methods were often incomplete or absent. The human resources and the equipment were considered adequate with the exception of two Member States' laboratories where human resources were considered to be low.

With one exception, the content and the identity of the active substance were analysed in all the laboratories visited and in a few cases the impurities and the co-formulant, too. The physico-chemical properties were also analysed in eight Member States.

---

\(^{9}\) use of an authorised product on a crop for which this product is not authorised  
\(^{10}\) Collaborative International Pesticides Analytical Council
6. MAIN FINDINGS AND CONCLUSIONS REGARDING CONTROL SYSTEMS FOR RESIDUES IN FOODSTUFFS OF PLANT ORIGIN

6.1. Legislation

6.1.1. Transposition of legislation

Generally, timely transposition of the Community legislation was not a problem in the Member States. In two Member States, Council Directive 93/99/EEC\textsuperscript{11} of 29 October 1993 on additional measures concerning the official control of foodstuffs was not formally transposed. Nevertheless, in one of them the regional administrations were bound to act according to this Directive. One of these Member States had also a considerable delay with the transposition of Commission Directive 98/82/EC\textsuperscript{12} of 27 October 1998 amending the Annexes to Council Directives 86/362/EEC and 90/642/EEC. Completeness or accuracy checks of transposition were not part of the missions.

6.1.2. MRL setting procedures

Currently, many possible pesticide-commodity combinations are not yet covered by Community MRLs. In this non-harmonised area, Member States proceed very differently.

Most Member States set national MRLs when no Community MRLs exist. This often includes provisional MRLs for new substances. In some Member States import tolerances are included, two Member States reported they did not set national MRLs. In setting national MRLs most Member States took into consideration existing Codex\textsuperscript{13} limits or national MRLs set in other Member States. In one Member State, Codex MRLs were directly applicable and enforceable when no EU MRLs existed.

Information on setting of MRLs for unauthorised uses was only available for eight Member States. Of them, five Member States did not set MRLs for non-authorised uses, whereas the other three Member States did.

6.2. Competent authorities

6.2.1. Structure and performance

The structure of the residues control systems varies between Member States. Four Member States have a rather de-centralised system. The central level is in charge of co-ordinating the activities of the various regions, drafting the national residue legislation and representing the Member State at international level. Implementation of the legislation and enforcement is the responsibility of the regions.

The remaining Member States have a rather centralised control system for pesticide residues, some with a distinct government agency for the controls of foodstuffs, including pesticide residues.

\textsuperscript{11} OJ L 290, 24.11.1993, p. 0014 - 0017
\textsuperscript{12} OJ L 290, 29.10.1998, p. 0025 - 0054
\textsuperscript{13} Codex Alimentarius Commission, established by FAO and WHO
The controls of pesticide residues were the responsibility of different Ministries. Often the Ministry of Agriculture, the Ministry of Health or both were involved.

**Co-ordination and communication between competent authorities**

Main weaknesses of the competent authorities' performance related to a) communication and co-ordination between central and regional competent authorities and b) between the different authorities in charge of marketing and use and residues.

a) Co-ordination and communication between central and regional/local authorities was more difficult in Member States with a de-centralised system than in the ones with a more centralised system. In several Member States regions failed to deliver complete monitoring results to the central level within the deadlines specified by EU legislation. In other Member States the central level had no clear overview of inspection and enforcement actions taken on regional level. In most Member States communication was based on informal procedures.

b) The main area of concern was the lack of communication between different control systems for marketing and uses and for residues in several Member States. In six Member States a different Ministry was responsible for the control system on marketing and uses and for the control system on pesticide residues. In most of the Member States the services responsible for sampling had no legal power to also inspect the premises of users of plant protection products, so that misuse could only be followed up through the competent authorities for marketing and use. Vice versa, the input of the marketing and use authorities in the planning of sampling programmes is important to detect possible residue problems. Lack of communication was one important factor for the problems with chlormequat and methamidophos (see chapter 7).

**6.2.2. Human and financial resources**

It is difficult to compare human and financial resources between Member States. Some Member States reported constraints with regard to financial resources or personnel in parts of their control system.

However, in two Member States the competent authorities were not in a position to efficiently run their control system with the human resources available.

The specific situation with regard to the laboratory resources is mentioned in chapter 6.4.2.

**6.3. Controls and inspection activities**

**6.3.1. Planning and design of monitoring programmes**

Planning, priorities and scope of monitoring programmes varied considerably between Member States. Planning and reporting frequency for the monitoring programmes was annually in most Member States. Consultation during the planning process was mostly done on an unofficial basis, e.g. meetings, phone calls, etc. In one Member State there was a (non-binding) manual in place to give guidance to the regions on how to perform the monitoring.
Monitoring programmes were designed either as rolling programmes or as a fixed programme for main commodities or as combination of both.

In all Member States except one, where three separate programmes existed, the co-ordinated programme was included in the national programme. In some cases a separate food monitoring programme existed beside the pesticide residues monitoring programme.

6.3.2. Priorities and scope of the programmes

Priorities for the monitoring programmes are not harmonised in the EU. They are set by Member States according to the characteristics of their country. However, most Member States took into account consumption of the foodstuffs, domestic production and imports, previously detected or expected infringements and analytical possibilities and budget.

Numbers of samples taken

One main difference existed in the numbers of samples taken per year, ranging from 171 to 9365. The samples per 100,000 inhabitants ranged from 5 samples/100,000 habitants to 65 samples/100000 habitants, the EU average being 11 samples per 100,000 habitants (data from the 2001 EU annual monitoring report on pesticide residues, compiled by the European Commission).

However, the pure samples number was not the only criterion to assess the quality of the programmes. Laboratory standards in general and the variety of different compounds, which could be analysed also contributed to the quality.

Products sampled

Five out of 15 Member States sampled predominantly domestic products. These are mainly the Southern Member States, which are important producers of fresh fruit and vegetables. Six Member States, who are mainly importers of fresh fruit and vegetables, sampled pre-dominantly imported products. In three Member States the share of domestic and imported produce was more or less balanced. In this overview imported samples comprise samples from Third Countries and other EU Member States.

In all Member States fresh produce was sampled, whereas only eight Member States also sampled processed products in significant amounts.

Surveillance and follow up enforcement sampling

More than half of the Member States did not take any or only very few follow up enforcement samples, most samples were taken as surveillance samples.\textsuperscript{14}

\textsuperscript{14} Definition as given in the 2001 EU annual monitoring report on pesticide residues: **Surveillance sampling** means that samples are collected without any particular suspicion towards a particular producer, consignment, etc. It may also include more targeted samples, which are directed to a special problem, e.g. methamidophos in peppers or chlormequat in pears from countries where previously problems were found. Samples directed to a special producer or consignment, however, fall within the category follow-up enforcement sampling.

**Follow-up enforcement sampling** means that samples are taken in case of suspicion as a follow-up for previously found violations. Follow-up enforcement sampling is directed to a specific grower/producer
Significant amounts of follow-up enforcement samples were only taken by three Member States (2001 monitoring data).

6.3.3. Sampling

Sampling personnel and level at which samples were taken

Sampling was carried out on regional or local level in most Member States. In three Member States sampling was organised on a contract basis, but the services carrying out the sampling were still part of the same or another competent authority. In one Member State sampling was contracted to a private market research company. In two other Member States laboratory staff were involved in sampling.

All Member States sampled at distribution level. In some Member States some samples were also taken at production level, e.g. farms. Sampling at farm level was in most cases the responsibility of a different service (often a different competent authority) since the food inspectors had in most cases no legal power to sample at farms.

In one Member State four different competent authorities were empowered by law for sampling. There was a considerable lack of co-ordination between the competent authorities, leading to a certain overlap of activities.

Sampling procedure

In ten Member States sampling was carried out according to Commission Directive 79/700/EEC of 24 July 1979 establishing Community methods of sampling for the official control of pesticide residues in and on fruit and vegetables. Some Member States used the Codex procedure and others a combination between Commission Directive 79/700/EEC and Codex. One Member State had an own sampling procedure, modifying Commission Directive 79/700/EEC.

In more than half of the Member States deficiencies in sampling were found, regardless whether Commission Directive 79/700/EEC or the Codex procedure was used. Very often samples were not completely taken at random or not properly sealed.

In one Member States sampling was assessed against the new sampling procedure laid down in Commission Directive 2002/63/EC, which was applicable from 1 January 2003 only.

Counter samples were regularly taken in eight Member States, in the remainder of Member States counter samples were not usually taken.

Training of sampling personnel

Although deficiencies were frequently encountered in the way samples were taken, this could not be directly linked to a lack of training. In most Member States

or to a specific consignment. Samples directed to a specific problem, but not to a specific producer/consignment fall within the category of surveillance sampling.

16 ALINORM 99/24, Appendix III
training given to the sampling personnel was satisfactory, apart from three Member States, where deficiencies with regard to training were observed.

6.3.4. Follow up action

Follow up and enforcement of infringements was one of the weakest points in more than half of the Member States’ control systems. In some Member States no or only limited follow up enforcement action was taken. The enforcement systems were considered not satisfactory in four Member States, in another six Member States deficiencies were identified.

Responsibility for follow up

In Member States with a de-centralised system follow up to MRL exceedances, e.g. enforcement, was normally carried out by the (autonomous) regions or provinces, whereas in the more centralised Member States enforcement was carried out most often by the regional or local branches of the central competent authorities or by the central competent authority itself (see chapter 6.2.1). Sampling and follow up was often done by the same service.

Weaknesses in follow up enforcement action

Follow up action varied greatly between Member States, ranging from administrative sanctions (i.e. oral or written warnings, fines) to penalties imposed by the public prosecutor or (rarely) seizure of the products concerned. The following main weaknesses were observed:

- Deficiencies in laboratory action: in case of MRL exceedances confirmatory repetition of analysis in real matrix, recovery and identity checks were not carried out systematically in all Member States.

- Monitoring results did not always lead to any enforcement action, especially when programmes were designed for surveillance purposes only. Enforcement procedures were very slow in some cases.

- Lack of standard procedures for the definition of MRL exceedances and for dietary risk assessment: in only a few Member States were clear standard procedures in place to define MRL exceedances and action limits set for enforcement based on the analytical uncertainty. In most Member States standard procedures describing when and how to carry out dietary risk assessment were also lacking.

- Deficiencies in the functioning of the Rapid Alert System for Food and Feed (RASFF) at Member State level related mainly to poor communication between competent authorities and long delays in transmission of information. Absence of a standard procedure at Member State level of when to notify a critical result to the Commission often weakened the efficiency of the systems.

6.4. Laboratories

6.4.1. Organisation

The situation of laboratories varied greatly from Member State to Member State. Some Member States had only one laboratory in charge of pesticide residue
analysis, whereas in other Member States there were several with a maximum of 61 in one Member State. In most of the Member States with a high number of specialised laboratories, difficulties were observed to achieve satisfactory quality standards for all of them.

Almost all of the laboratories used were official ones, apart from two Member States, where private laboratories were used under official supervision.

6.4.2. Resources and training

Most Member States reported some constraints due to staff shortage. In one Member State where the laboratory had also the function as competent authority the staff was insufficient for the tasks.

All Member States had an acceptable standard of equipment to properly perform residues analysis.

Training for laboratory staff was satisfactory in all Member States but one, where not all staff had regular and sufficient access to training.

6.4.3. Analytical spectrum and methods

All Member States used a multi-residue method (MRM) to analyse for pesticide residues in products of plant origin. The number of analytes sought in this multi-residue methods varied considerably: from 52 analytes to 320 analytes. The EU average was 161 (data from the 2001 EU monitoring report).

Apart from the MRM a varying degree of single residue methods (SRM) were used besides. It is difficult to compare these data, as not every Member State may have given the whole list of SRMs used, but there was a tendency that those Member States who analysed for a higher number of active substances in the MRM also tended to apply more different SRMs.

6.4.4. Quality Assurance Systems

Laboratory Accreditation

The situation of laboratory accreditation is still very unsatisfactory, since in more than a third of the Member States (data from the 2001 monitoring report) not all residue monitoring laboratories are accredited. This is a legal requirement since 1 January 1999 (Council Directives 86/362/EEC).

Approaches to accreditation and criteria used by the national accreditation bodies vary greatly in the Member States and often Member States’ representatives commented that it was easier to achieve accreditation in some Member States than in others.

Quality Control Procedures and proficiency tests

The degree of implementation of the EU Quality Control Procedures varied between the Member States. Most Member States had not fully implemented them, however, progress in implementation was seen. It was recognised that the EU QC procedures for pesticide residues laboratories play an important role in the quality assurance systems of pesticide residues laboratories besides accreditation.
Participation in proficiency tests was generally satisfactory, although it was observed that in three Member States not all of the laboratories had taken part in the proficiency tests organised by the European Commission. Frequently, method validations were either absent, incomplete or just in the process of being carried out. Some deficiencies with regard to the relevant SOPs (Standard Operating Procedures) (e.g. method SOPs) were also found.

7. MAIN FINDINGS AND CONCLUSIONS REGARDING THE MISSIONS IN WHICH SPECIFIC PROBLEMS HAVE BEEN INVESTIGATED

In four Member States missions were carried out with regard to a specific problem. In three, the mission was related to residues of chlormequat in different commodities. In one Member State the subject of methamidophos residues in peppers was investigated.

The following summary distinguishes 1) some weaknesses in the control systems which were revealed by the crises and 2) examples of mistakes in management of the specific situation.

7.1. Weaknesses in the control systems revealed by the crises

Among the weaknesses in the control systems lack of communication between the competent authorities for marketing and use and for residues was one of the most important factors, alongside with structural and organisational problems, lack of procedures at Member State level for risk assessment and notification of critical results to the Commission, weak controls at user level and problems with the laboratories.

Communication

Communication problems were a major issue in all of the specific situations investigated (see also chapter 6.2.1). Often they were related to poor information flow between regional and central level and vice versa.

In all of the four cases investigated unauthorised use was involved, but in three cases the co-operation between the services responsible for residues and for marketing and use was not considered sufficient to ensure an efficient follow up at farmer level and to ensure an appropriately targeted sampling for residue analysis.

Organisational and structural problems

Structural and organisational problems in the competent authorities partly contributed to the problems encountered in twoMember States.

Lack of procedures

One Member State considered the lack of an agreed methodology for dietary risk assessment and the absence of an internationally fixed Acute Reference Dosis for chlormequat as major obstacle for carrying out a detailed risk assessment and hesitated to take action based on this risk assessment.
Controls on marketing and use

Controls at marketing and user level were seen as insufficient in three of the four Member States visited for a specific purpose. More powerful controls could have prevented at least part of the problems. The main issues were limited controls at user level and a lack of proper controls of labels and authorisation status at market level.

Laboratory performance in emergency situations

In crisis situations the laboratory capacities were usually a weak point. Most of the Member States, however, coped well with this problem, e.g. by hiring temporary staff for a certain time, seeking help from other laboratories which had to pass a small inter-laboratory test, and other measures.

More problematic was the fact that when a specific problem came up the official laboratories often did not have the equipment, method and expertise available to immediately perform the required analyses. This was the case especially for chlormequat, as the analyte was not routinely analysed before and required specific equipment.

Once the method was established, appropriate and complete validation data could not be always obtained in time, nor could the method be accredited before official analysis was carried out, which led to considerable delays in reaction and a weak basis for enforcement.

7.2. Management of the situation

In addition to the above mentioned weaknesses, a considerable degree of problems resulted from poor management of the situation in all of the cases investigated. The following main points were identified:

Underestimation of the situation and delays

Generally, the seriousness of the situation tended to be initially under-estimated in all cases. This led to late reactions, sometimes only months after the initial problem had become known. Often appropriate action was only taken when the first RASFF was notified.

Handling of changes of GAP (Good Agricultural Practice) and withdrawal decisions

In two cases GAP had been changed at some stage in the past, but no new trials were carried out to confirm that the new GAP still complied with the residue limits. When it became clear that the GAP was not appropriate for the residue limit in force, decisions on withdrawal of authorisations were only slowly taken. In one case the residue limit was set to the limit of determination, but the necessary withdrawal decisions were taken much too late. After the withdrawal decisions had finally been taken and authorisations had been changed, products on the market were not inspected sufficiently, so that products with incorrect use instructions on the label were still sold and applied.
Responsibilities attributed to producers' organisations

In two Member States too much responsibility for sampling and analyses was left to producers' organisations. This opened the door for fraudulent practices. In both Member States significant amounts of the crop concerned had disappeared at the time of official inspection, their destination could not be traced. Since a private laboratory carried out the analyses for the producer’s organisations the competent authority had no access to the results and therefore no clear overview.

Communication to users and traders

Where authorisations had been changed or withdrawn, this was not properly communicated to users and retailers in two Member States. It was left up to the product manufacturers to inform about the changes. Appropriate action was taken in one Member State where the Ministry of Agriculture issued a press release to inform the public and in another Member State where the farmers’ and manufacturers' organisations were informed about the withdrawal of use by the Ministry of Health. However, the Ministry left it up to the manufacturer’s associations to inform distributors and retailers.
8. RECOMMENDATIONS

The following is a list of the main recommendations made in individual mission reports. It should be noted that not every recommendation has been made to each Member State.

The Member State authorities should:

(1) Ensure that the competence to control marketing and uses are clearly defined and that a clear overview of the situation can be established at central level.

(2) Ensure that the label and the status of the authorisation of the plant protection products are adequately checked at user and retail level.

(3) Ensure that at central level there is a complete overview of monitoring data, data on marketing and use inspections and on enforcement action taken at regional level.

(4) Encourage communication between the authorities for marketing and use and for residues, in order to ensure appropriate follow up of infringements in both the area of marketing/use and residues, and in order to develop appropriately targeted sampling plans for residue analysis.

(5) Ensure that monitoring data are complete and representative for the country, that the sample number taken is appropriate to guarantee consumer protection and that samples are taken at random and according to EU legislation.

(6) Ensure that in case of MRL exceedances appropriate enforcement action is taken. Strengthen enforcement systems by developing standard procedures for
   - enforcement action to be taken based on the analytical uncertainty of results,
   - for dietary risk assessment and
   - for notification of critical results to the Commission.

(7) Ensure that the Rapid Alert System for Food and Feed works efficiently.

(8) Ensure that all laboratories contributing to the national and European monitoring programmes are accredited, use validated methods only and take regularly part in proficiency tests. Fully implement the EU QC procedures in all laboratories.
9. ACTION TAKEN BY THE COMMISSION SERVICES

9.1. Follow-up of mission recommendations

For each mission a copy of the Final Report was sent to the national competent authorities with a request for an action plan, indicating the steps taken to address the report's recommendations.

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

9.2. Additional action by the Commission Services

Control systems for the placing on the market and use of plant protection products

With regard to the increasing problem in some Member States with the use of non authorised plant protection products which are authorised in some other Member States, the Commission is considering the possibility, in the context of an amendment of Council Directive 91/414/EEC (see below) proposing a move to a zonal or regional type of authorisation system within which disparities between Member States should be minimised (Section 5.1.2). This would also entail addressing the further harmonisation of authorisation procedures and requirements for minor uses.

Guidance is being developed for Member States on the definition of 'identical products' and a guidance document has been finalised for the handling of parallel imports of plant protection products (Section 5.1.3).

A proposal to the Council and the Parliament to amend Council Directive 91/414/EEC is in preparation. Among the provisions will be a strengthening of its Article 17 concerning control measures (Section 5.3). In addition, the Commission Strategy on Sustainable Use of Pesticides will address issues such as training, certification of users and equipment, the keeping of records etc. Infringements of MRLs in the residues legislation is now also being used as a tool in the detection of unauthorised uses of plant protection products. With regard to reporting under Art. 17 of the Directive, work is now in progress to develop an electronic system within which a harmonisation of requirements and of formatting would fit.

Control systems for residues in foodstuffs of plant origin

The Commission submitted in March 2003 to the European Parliament and the Council a proposal for a Regulation on the setting of maximum residue levels for pesticide residues in food. The proposal addresses many issues, including those referred to in this report.

In addition the Commission is working with the Member States to develop guidance on which bases national monitoring programmes should be developed. This should help to reduce the variation in sampling, analysis and enforcement currently seen in Member States and may include criteria for
target sample numbers and sampling frequencies, number of analyses and may take into account population, dietary habits, production, imports or other factors.
### 10. ANNEX I  DETAILS OF MISSIONS UNDERTAKEN

<table>
<thead>
<tr>
<th>Mission reference number</th>
<th>Member State</th>
<th>Dates of mission</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>XXIV/1476/98</td>
<td>Ireland</td>
<td>21. - 23.10.1998</td>
<td>See above</td>
</tr>
<tr>
<td>XXIV/1073/99</td>
<td>Denmark</td>
<td>06. - 09.4.1999</td>
<td>See above</td>
</tr>
<tr>
<td>XXIV/1104/1999</td>
<td>Portugal</td>
<td>03. - 07.5.1999</td>
<td>See above</td>
</tr>
<tr>
<td>1239/1999</td>
<td>Belgium</td>
<td>20. - 22.10.1999</td>
<td>Chlormequat on pears</td>
</tr>
<tr>
<td>1139/2000</td>
<td>Netherlands</td>
<td>05. - 09.6.2000</td>
<td>Marketing and use of plant protection products and residues of pesticides in foodstuffs of plant origin AND Chlormequat on pears and carrots</td>
</tr>
<tr>
<td>3319/2001</td>
<td>Luxembourg</td>
<td>26. - 28.03.2001</td>
<td>See above</td>
</tr>
<tr>
<td>Mission reference number</td>
<td>Member State</td>
<td>Dates of mission</td>
<td>Scope</td>
</tr>
<tr>
<td>--------------------------</td>
<td>--------------</td>
<td>------------------</td>
<td>-------</td>
</tr>
<tr>
<td>3227/2001</td>
<td>Germany</td>
<td>09. - 13.07.2001</td>
<td>Marketing and use of plant protection products and residues of pesticides in foodstuffs of plant origin</td>
</tr>
<tr>
<td>3397/2001</td>
<td>United Kingdom</td>
<td>12. - 16.11.2001</td>
<td>See above</td>
</tr>
<tr>
<td>8599/2002</td>
<td>France</td>
<td>15.02. - 1.3.2002</td>
<td>See above</td>
</tr>
<tr>
<td>8639/2002</td>
<td>Italy</td>
<td>04. - 07.6.2002</td>
<td>Follow up on mission 1113/2000 AND Chlormequat in carrots</td>
</tr>
<tr>
<td>8702/2002</td>
<td>Finland</td>
<td>30.9. - 4.10.2002</td>
<td>Marketing and use of plant protection products and residues of pesticides in foodstuffs of plant origin</td>
</tr>
<tr>
<td>8711/2002</td>
<td>Greece</td>
<td>04. - 8.11.2002</td>
<td>Marketing and use of plant protection products and residues of pesticides in foodstuffs of plant origin</td>
</tr>
</tbody>
</table>