

Monitoring for Pesticide Residues in the European Union and Norway Report 1996

This report on “Monitoring for Pesticides Residues in the European Union and Norway – Report 1996” was forwarded to the Standing Committee on Plant Health on 29/30 July 1998. The Standing Committee agreed that publication of the report was desirable and noted that this was also the view of Norway during the Working Group discussions on the forwarded report.

Inquiries to this report should be addressed to the contact points listed in Annex I.

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1 Introduction

1.1 Maximum residue levels (MRLs) for pesticide residues in and on products of plant origin, including fruit and vegetables, were established by Directive 90/642/EEC¹ (as amended by Directives 93/58/EEC², 94/30/EC³, 95/38/EC⁴ et 95/61/EC⁵). The Directives were implemented by the Member States as well as being applied by Norway. In several cases the entry against a product in the list of MRLs in a Directive is blank except for an annotation signifying that insufficient data exist to set a harmonized MRL but that the data must be generated by a certain date to establish one, in default of which the MRL for that use will be set at the analytical limit of determination (LOD). These are the so-called open positions. In these cases, transitional arrangements apply whereby Member States may set a national MRL in their legislation as a transitional measure until a harmonized MRL, or the LOD, is established in a Directive concerned. Monitoring results pursuant to Directives 86/362/EEC⁶ on cereals, and 86/363/EEC⁷ on animal products are not covered by this document. The report covers the national situations in the 15 Community Member States and Norway for the calendar year 1996.

1.2 It is evident that this document can only give an overall view on monitoring of pesticide residues, particularly as national practices in reporting were not fully harmonised in 1996. Each Member State and Norway has been invited to contribute a short national statement for inclusion in this document. More detailed information about the situation in individual countries is available from the respective national monitoring authorities.

2 Background

2.1 Pesticide residue levels in foodstuffs are generally legislated for in order to respond to 3 principal concerns: to minimise the exposure of consumers to harmful or unnecessary intake of pesticides, to control the correct use of pesticides in terms of the authorizations or registrations granted (application rates and pre-harvest intervals), and to permit the free circulation of products treated with pesticides as long as they comply with the MRLs fixed. Individual European countries have historically taken different approaches to national controls on pesticide residues.

2.2 At Community level, the first legislative action in this area was the adoption of Council Directive 76/895/EEC⁸ of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables by which specific or group MRLs were set for a number of pesticides/crops in order to facilitate free circulation of these goods within the Community. Where Member States set MRLs they could not be at lower levels than those set out in the Directive but could be higher. This Directive established the Community principles that MRLs must reconcile the requirements of plant protection and the need to protect human and

¹ Official journal NO. L 350, 14/12/1990 p. 0071 - 0079

² Official journal NO. L 211, 23/08/1993 p. 0006 - 0039

³ Official journal NO. L 189, 23/07/1994 p. 0070 - 0083

⁴ Official journal NO. L 197, 22/08/1995 p. 0014 - 0028

⁵ Official journal NO. L 292, 07/12/1995 p. 0027 - 0030

⁶ Official Journal NO. L 221, 07/08/1986 p. 0037 - 0042

⁷ Official journal NO. L 221, 07/08/1986 p. 0043 - 0047

⁸ Official journal NO. L 340, 09/12/1976 p. 0026 - 0031

animal health, that MRLs must be fixed at the lowest possible levels and that Community action to harmonise MRLs is necessary to avoid the creation of trade barriers and thus assist the free circulation of goods within the Community.

2.3 The 1976 Directive also required Member States to take all necessary measures to ensure compliance with MRLs by carrying out random checks. While not providing for reporting of national checking activities or for a Community level of monitoring, the Directive does provide for the development of common sampling and analytical processes and methods.

2.4 Council Directive 90/642/EEC 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, sets out a new framework for establishing mandatory Community MRLs. This Directive reaffirmed the principles established in the 1976 Directive. In particular it restates the need to prevent risk to human or animal health, the principle that the mandatory MRLs should be set as low as is consistent with Good Agricultural Practice (GAP), and continued to recognize the need to avoid barriers to trade and the hindrance of the free movement of goods within the Community.

2.5 MRLs are fixed for crops for which authorized/registered uses exist. These should reflect minimum quantities of active substance necessary to achieve adequate pest control, applied in such a manner that the residues are as low as practicable, i.e. GAP. As indicators of GAP, MRLs are not toxicological limits but must be toxicologically acceptable. For reasons of environmental protection also, the use of plant protection products has to be limited to the minimum level compatible with effective crop protection. MRLs are also fixed at, or about, the limit of analytical determination (LOD) where there are no authorized uses, or where authorized use would not lead to detectable residues at, or above, the LOD.

2.6 The 1990 Directive makes greater provisions for control measures to guarantee compliance with MRLs. It requires Member States to check sample products for pesticide residues in compliance with Directive 89/397/EEC⁹ on the official control of foodstuffs, in which certain general requirements and conditions are set out for the taking of suitable control measures by the Member States. This Directive also foresees that provisions additional to those general requirements of Directive 89/397/EEC may be adopted in the context of more specific Community rules. This was subsequently done in Article 4 of the 1990 Directive which provided for:

- specific provisions on national inspection programmes to ensure compliance with pesticide MRLs
- provisions on the reporting to the Commission of their implementation
- the establishment of a Commission recommendation concerning a co-ordinated programme of inspections.

2.7 The conditions and requirements in Directive 89/397/EEC were augmented, with a general implementation date of 1 May 1995, by the provisions of Directive 93/99/EC¹⁰ on the subject of additional measures concerning the official control of foodstuffs. These include the requirement that Member States deploy sufficient

⁹ Official journal NO. L 186 , 30/06/1989 p. 0023 - 0026

¹⁰ Official journal NO. L 290, 24/11/1993 p. 0014 - 0017

numbers of suitably qualified and experienced staff to undertake controls, including sampling and analysis. The 1990 Directive provided for the forwarding to the Council five years after its adoption of a report on the application of Article 4 accompanied, if necessary, by any appropriate proposals.

3 Application of Article 4 of Directive 90/642/EEC

3.1 Article 4 of the Council Directive 90/642/EEC, before its modification by Article 4 (5) of the Council Directive 97/41/EC¹¹, required Member States to report the results of the monitoring exercise carried out both under their national programme and under the Community programme to the Commission. A format for the reports on the Community programme was agreed (Doc. 1609/VI/97). A diskette of the agreed format was also made available to all monitoring authorities. No format for national monitoring reports is set out in Article 4 of the 1990 Directive.

3.2 Detailed national reports were received from all Member States. There was variability in the reports, but most countries were able to report in diskette form. These reports are required to cover the monitoring of the harmonised MRLs fixed by Directive 90/642/EEC - see Annex I - and in some cases also cover the monitoring of national MRLs set in the absence of such harmonised levels.

3.3 Further information on the national monitoring exercises 1996 and national reports, where published, may be obtained from the national monitoring authorities - listed in Annex II.

4 Community Monitoring Exercise

4.1 Commission Recommendation 96/199/EC lays down the co-ordinated programme of inspections for 1996 to ensure compliance with MRLs in and on certain products of plant origin. Member States were recommended in point 5 to participate in a specific exercise set out in Annex I of that Recommendation. Seven pesticides (acephate, chlorpyrifos, chlorpyrifos-methyl, methamidophos, iprodione, procymidone, and chlorothalonil) and two groups of pesticides (benomyl group and maneb group (= dithiocarbamates)) were to be analysed in apples, tomatoes, lettuce, strawberries, and grapes. The summarized results are given in Table 1, more details can be found in Annex III and Annex IV where the complete results for all Member States are given.

4.2 An average of about 9700 samples has been analysed for each of the pesticides or pesticide groups listed in Table 1. For each pesticide or pesticide group, an average of about 500 samples were found to contain residues (5.2 %) of that specific pesticide and an average of 30 samples (0.31 %) had residues higher than the respective MRL for that specific pesticide.

4.3 The results were quite different for the various compounds and crops. Residues of pesticides from the maneb group (dithiocarbamates) were found most often, and also exceeded the respective MRLs most often, followed by the benomyl group (residues given as carbendazim). It has, however, to be kept in mind that these groups combine findings for several pesticides (five and three, respectively). Lettuce

¹¹ Official Journal NO. L 184, 12/07/1997 p. 0033 - 0049

was the crop with the highest number of positive results, residues in that crop also exceeded the MRLs more often than in any of the other crops investigated.

4.4 The highest value found for chlorpyrifos was 0.79 mg/kg in apples and 0.59 mg/kg for chlorpyrifos-methyl in strawberries. For the benomyl-group, the highest concentration measured was 8.87 mg/kg in a sample of grapes. For all other compounds, the highest values were found in lettuce, such as 11.2 mg/kg for acephate, 1.8 mg/kg for methamidophos, 32 mg/kg for iprodione, 6.6 mg/kg for procymidone, and 28 mg/kg for chlorothalonil.

4.5 From all pesticides investigated in the Community exercise, the highest value was found for a compound of the maneb group (dithiocarbamates) in lettuce with 63 mg/kg, expressed as carbon disulfid (CS₂) according to the legal definition. This amount corresponds e.g. to a residue of 118 mg/kg for e.g. the compound mancozeb. Taking into account an average consumption of 22.5 g lettuce a day (European diet, WHO, 1994) this leads to a potential intake of 2.65 mg for a person of 60 kg body weight, corresponding to 0.044 g/kg b.w. (calculated according to the “Guidelines of predicting dietary intake of pesticide residues of the WHO, 1997). This crude overestimation leads to an exceedence of the ADI (acceptable daily intake) of 0.03 mg/kg b.w. for mancozeb. The ADI is based on a safety level of 100 deriving from the no observed adverse effect level (NOAEL) in an animal testing. Therefore, for the intake of 0.044 mg/kg b.w. there will be a remaining safety level of 70 % to the NOAEL. Furthermore, this calculation does not take into account the considerable reduction of residues during preparation of the food for consumption (e.g. washing).

Table 1: Results from the Community monitoring exercise for each pesticide or pesticide group analysed for in apples, strawberries, tomatoes, lettuce and grapes (the percentages are calculated from the sum of the total number of samples)

Pesticide	Sum of the total no. of samples	Sum of the no. of samples without residues	Sum of the no. of samples with residues	Samples with residues exceeding the MRLs
Acephate	9514	9367	117 (1.23 %)	22 (0.23 %)
Chlorpyrifos	11924	11614	310 (2.60 %)	10 (0.08 %)
Chlorpyrifos-methyl	11464	11372	92 (0.80 %)	3 (0.03 %)
Methamidophos	9691	9598	93 (0.96 %)	28 (0.29 %)
Iprodione	11905	10394	1511 (12.69 %)	13 (0.11 %)
Procymidone	12044	10892	1152 (9.56 %)	30 (0.25 %)
Chlorothalonil	11633	11444	189 (1.62 %)	34 (0.29 %)
Benomyl group	4258	3908	350 (8.22 %)	50 (1.17 %)
Maneb group ¹⁾	4464	3831	687 (15.39 %)	82 (1.84 %)

¹⁾The compounds of the maneb-group are dithiocarbamates

The residue of 63 mg/kg CS₂ in lettuce was found in the framework of check sampling, therefore no immediate action could be taken. The official body, however, was immediately requested to trace more lettuce samples. During this enforcement sampling, no such values were found.

4.6 A realistic intake calculation should not be carried out with the highest residues found, but more correctly on the 90th percentile (= the value below which 90 % of the non-zero values are) of the amount of residues found in the monitoring. An example is given in Table 2. It shows explicitly that the real exposure of the consumers is much lower and is a more solid basis for a sound scientific risk evaluation. Nevertheless, these evaluations are still an overestimation, as they also do not take into consideration the reduction of residues during processing or preparation of the food. These evaluations only have regard to chronic exposure, corresponding to the definition of the ADI. At the time being, there is no universally accepted methodology for the evaluation of risks from an acute exposure.

Statistical evaluation of the sampling design applied in the co-ordinated monitoring programme

4.7 The results of the co-ordinated monitoring programme can be used as a sound basis for an intake study related to the pesticides under investigation. This is achieved by taking samples and subjecting these samples to analysis. The main constraints on gaining a precise estimation of the intake of pesticides are the reporting level of the respective compound and the specific properties of the sampling design.

4.8 The reporting level indicates the limit of detection of the respective compound while the sampling design determines the chance to detect a certain portion of items in the population (European market) exceeding the reporting level. In order to estimate the portion of items above this level, the statistical methodology described in the Codex Alimentarius¹² was applied. The evaluation is based on the principle that a sample containing a certain number of items is analysed and the results of these samples are then used to characterise the whole of those food items of the European market. If at least *one* item exceeding the reporting level is found, the corresponding portion of items above this level in the population can be estimated. This estimation can be done by taking into account the number of items in the sample, since the sample size is an important characteristic of the sampling design applied in the respective monitoring program. A confidence level also has to be fixed. The confidence level determines the accuracy of the test and should be in the range of 95 %. This level indicates the chance to detect the estimated portion of items exceeding the reporting level is 95 % as shown in Table 3. As a coarse rule of thumb one can say that the lower the expected portion of items in the population above the reporting level is, the higher is the required number of samples to get a precise estimation of this portion.

¹² Codex Alimentarius, Volume 2, p. 367

Table 2: Estimation of the dietary intake of pesticide residues for commodities based on the 90th percentile for the residues

Compound	Food item	90th percent. (mg/kg)	ADI (µg/kg b.w.)	Average consumption (g/d) ¹⁾	Intake µg/person (60 kg)	Intake (µg/kg b.w.)	Intake in % of the ADI
Acephate	Lettuce	< 0.06	30	22.5	1.35	0.023	0.08
Chlorpyrifos	Apples	< 0.03	10	40	1.2	0.02	0.20
Chlorpyrifos-methyl	Strawberries	< 0.03	10	5.3	0.159	0.003	0.03
Methamidophos	Lettuce	< 0.04	4	22.5	0.9	0.015	0.38
Iprodione	Lettuce	< 1	60	22.5	22.5	0.375	0.63
Procymidone	Lettuce	< 0.03	100	22.5	0.675	0.011	0.01
Chlorothalonil	Lettuce	< 0.02	30	22.5	0.45	0.008	0.03
Benomyl-group (Thiophanat-methyl)	Grapes	< 0.184	20	13.8	2.54	0.042	0.21
Maneb-group ²⁾ (Mancozeb)	Lettuce	< 9	30	22.5	202.5	3.375	11.25

¹⁾ WHO European diet

²⁾ The compounds of the maneb-group are dithiocarbamates

4.9 A simple statistical model as proposed in the Codex Alimentarius is employed in order to estimate the real portion of items in the population exceeding the reporting level. The whole population is divided into two classes. The first class contains food items not exceeding the reporting level and the second class represents the items, which do exceed this level. The chance to find one or more items in the sample belonging to class 2 is calculated by making use of the binomial distribution.

4.10 The results of the evaluation shown in Table 3 indicate that the detectable portion of food items above the reporting level is quite low. An exact portion rather than a range could not be calculated in all cases since for the nine pesticides under investigation a different number of samples has been analysed.

Table 3: Detectable portion of food items exceeding the reporting level (%) (results from Norway are not included in this calculation)

Food Item	Number of analysis	Detectable portion (%)
Apples	1035-2904	0.10-0.29
Strawberries	642-1939	0.15-0.47
Tomatoes	734-1957	0.15-0.41
Lettuce	686-2811	0.11-0.44
Grapes	543-1274	0.23-0.55

4.11 Conclusion: In the co-ordinated monitoring program a high number of samples were taken allowing a good estimation of residues of certain pesticides of vegetable and fruits in the European market. The good precision of the sampling design applied in the co-ordinated programme is indicated by the fact that for almost every pesticide a sufficient number of samples exceeding the reporting level are found. Therefore, further calculations using the observed pesticide concentration are on a sound data basis.

5 National Monitoring

5.1 The results of all national monitoring exercises are shown in Annex V. They can be summarized as follows:

5.2 Out of about 41,000 samples analysed, usually by multi-methods capable of detecting up to 100 or more pesticides - meaning that a calculated 4.1 million analyses were conducted - no detectable residues were found in 60 % of the samples, meaning that 40 % of samples contained pesticide residues.

5.3 The rate of exceedences of MRLs in products sampled was about 3 % throughout the European Union and Norway, but varied significantly between the different countries. It is important to note that the differences in percentage of samples exceeding the MRLs between the Member States can be caused mostly by differences in the monitoring programmes rather than differences in the presence of pesticide residues in food. Several factors can be mentioned:

- 1 The choice of products sampled and the choice of pesticides investigated:
Some national programmes focus more on crops that have problems of exceedences than others, which put more weight on e.g. consumption figures. For example, the proportion of winter lettuce can influence the final exceedence rate significantly.
Adding single residue methods to the list of methods of analysis to be applied on a sample increases the probability of finding exceedences.

2 The proportion of domestic and imported foodstuffs analysed:

National MRLs can be set in cases where no harmonised EC MRLs have been set. These national MRLs can be very different, as some Member States take the limit of analytical determination, others fix national MRLs from their national authorised use; others follow Codex MRLs or fix import tolerances. These differences in legislation are the reason that often more imported foods than domestic foodstuffs do not comply with national legislation.

3 Definition of exceedence:

The guidelines for the preparation of the national reports leave the definition of exceedence up to the Member States. This may include:

- cases where the analytical laboratory has certified an exceedence within the application of the quality assurance applicable to the analysis;
- cases where official warnings have been issued to the holders of the products inspected and sampled;
- cases where legal or administrative consequences have followed, e. g. prosecution, the levying of penalties or fines.

4 Analytical capabilities:

Residues of some pesticides can only be detected by using specific and specialized analytical methods. These can be different in the Member States.

5 Sampling:

Sampling can be more or less at random or targeted. This would influence the findings.

5.4 In many cases, more than one pesticide residue can be found in a product. This can be of particular concern due to possible additive and synergistic effects. Member States were therefore asked to provide information on the samples with residues of more than one pesticide. These results are given in Table 4. In order to relate this to the national monitoring programmes, Table 4 also contains the total number of samples taken. An overall of 13 % of the samples contained residues of more than one pesticide. Residues from more than four different pesticides could be found in about 2 %. These results demonstrate the importance to further address this problem.

Table 4: Number of samples with residues of more than one pesticide

Country	Total no. of samples	³ 2	³ 3	³ 4	³ 5	³ 6	³ 7	³ 8	³ 9	³ 10
B	932	231	129	66	28	12	3	1	1	
DK	1273	110	38	15	4	2	1	1		
D	4257		84	19	3	1				
EL	1132	60	30	11	2					
F		984	410	141	55	10	2			
IRL	505	120	53	24	8	1				
I	7194	246	52	4						
L	212	40	16	4						
NL	11015	1374	540	181	60	32	8	4		
P	600	79	31	6						
A		69	45	20	11	5	2			
S	3908	759	358	165	67	23	9	4	2	1
UK	878	101	36	13	1					
N	2936	895	334	132	52	17	2			
EU(10)¹+ N	30585	4015	1617	621	222	87	23	10	3	1
%		13.1	5.3	2.0	0.72	0.28	0.07	0.03	0.01	0.003

¹⁾ Data from A, D and F were not complete and are therefore not included in the summary and also not into the calculations, data from FIN and E were not available at all

5.5 Pesticides found most often were mainly fungicides and are shown in Table 5. Although the report format was not harmonized for this information, it is evident that products most often found were similar in many cases. With the exception of captan, MRLs have been fixed for the 12 compounds found most often in the European Union and Norway (results from 14 countries).

Table 5: Pesticides found most often during the national monitoring programmes of the Member States and Norway (number of pesticides given may vary due to missing harmonization of the report format, pesticides are listed in alphabetical order for the single countries and in descending order of times mentioned for EU(14)+ N.

Country	Pesticides
B	Inorganic bromide, carbendazim, dithiocarbamates, iprodione, pirimicarb, procymidone, propamocarb, tolclophos-methyl, tolylfluanid, vinclozolin
DK	Carbendazim, chlorpyrifos, dithiocarbamates, endosulfan, folpet, procymidone, thiabendazole
D	Carbendazim, chlorpyrifos, chlorpyrifos-methyl, chlorothalonil, dithiocarbamates, imazalil, iprodione, metalaxyl, methamidophos, procymidone, vinclozolin
EL	Captan, chlorothalonil, chlorpyrifos, dithiocarbamates, endosulfan, phosalone, parathion-methyl, pyrazophos, vinclozolin
E	Chlorpyrifos, chlorothalonil, fenitrothion, malathion, metalaxyl, methamidophos, pirimiphos-methyl, triazophos
F	Carbendazim, captan, chlorpropham, dithiocarbamates, imazalil, iprodione, oxadixyl, phosalone, procymidone, propham, thiabendazole, vinclozolin
IRL	Bromopropylate, captan, chlorothalonil, chlorpyrifos, dichlofluanid, endosulfan, iprodione, methidathion, phosalone, tolclophos-methyl, vinclozolin
I	Acephate, carbendazim, chlorpyrifos, chlorpyrifos-methyl, chlorothalonil, methidathion, metalaxyl, procymidone, thiabendazole, vinclozolin
L	No information available
NL	Bromopropylate, captan, endosulfan, imazalil, iprodione, pirimicarb, procymidone, thiabendazole, tolclophos-methyl, tolylfluanid, vinclozolin
P	Carbendazim, captan, dimethoate, dithiocarbamates, endosulfan, iprodione, methamidophos, pirimiphos-methyl, procymidone, thiabendazole, vinclozolin
A	Captan, chlorpyrifos, dithiocarbamates, endosulfan, iprodione, procymidone, vinclozolin
FIN	Chlorpyrifos, endosulfan, imazalil, iprodione, methamidophos, methidathion, procymidone, thiabendazole, vinclozolin
S	Azinphos-methyl, captan, chlorothalonil, dimethoate, dithiocarbamates, endosulfan, imazalil, methamidophos, methidathion, thiabendazole
UK	Carbendazim, chlorpyrifos, dithiocarbamates, imazalil, iprodione, procymidone, thiabendazole, chlorpropham, technazene, pirimiphos-methyl, inorganic bromide, tolclofos-methyl.
N	Chlorpyrifos, dephenylamin, imazalil, iprodione, metalaxyl, methidathion, ortho-phenylphenol, thiabendazole, tolylfluanid, vinclozolin
EU(14) + N	Vinclozolin, iprodione, procymidone, dithiocarbamates, endosulfan, thiabendazole, chlorpyrifos, carbendazim, imazalil, captan, chlorothalonil, methamidophos

6 Sampling

6.1 Commission Decision 79/700/EEC¹³ established sampling methods for the official control of pesticide residues in and on fruit and vegetables. More details on the sampling done in the Member States are given in Annex VI (summaries of the Member State reports). Table 6 shows a summary of the information given in these summaries on sampling. In most cases, sampling followed national plans that were often established taking into consideration consumption, production, imported and exported products and risks (e.g. results from previous years).

6.2 Samples were taken at different points, such as wholesalers, local and central markets, points of entry (for imported products), and processing industries. As the report format on sampling has not been harmonized, it is not possible to draw a conclusion about the overall situation. From the data provided in the national reports, sampling by the different national authorities has obviously been very heterogeneous.

Table 6: Summary on sampling by the national authorities (information taken from the national reports)

Country	Summary on sampling
B	The sampling plan took account of the average consumption, production figures, results of previous years, and analytical and budgetary possibilities
DK	The sampling plan took account of dietary consumption, production data, results of the previous year; the samples are taken at random, from consignments for consumption and working up in production, size 1 kg or 10 items
D	The sampling plan took account of the production, the turnover and the import of goods, the risk orientation, and a basket of goods; the requirements of Com. Dir. 79/700/EEC were followed
EL	Samples were taken at central markets and entry points
F	Sampling plans took account of consumption and results in the previous years, the samples were taken at wholesaler markets
IRL	The sampling plan took account of the dietary importance, the sampling was done primarily at wholesale level
L	Samples were taken at central markets and imported products at wholesalers level, the sampling plan was based on a rolling plan
NL	Sampling was done at auctions, importers, wholesalers, and processing industries, Com. Dir. 79/700/EEC was followed
P	Sampling was done at wholesaler markets, generally following Com. Dir. 79/700/EEC
FIN	Sampling plans took account of consumption and risks, organically grown products and vegetarian food were monitored in special exercises, the sampling was done in accordance with Com. Dir. 79/700/EEC
S	The sampling plan took account of the food consumption rate; the sampling was done at wholesalers, milling plants, and ports for imported products.
UK	The sampling plan took account of the level of consumption, the level of residues, and ensured a wide range of products were included, CAC guidelines were followed
N	Samples were taken at wholesalers warehouses
A, E, I	No information provided

¹³ Official journal NO. L 207, 15/08/1979 p. 0026 - 0028

7 Quality assurance

7.1 Article 3 of Directive 93/99/EEC requires laboratories undertaking pesticide residue analyses to be accredited in accordance with the relevant European Standards by 1 November 1998. It follows that from that date Member States should only submit monitoring results from national laboratories with a respective accreditation.

7.2 The Commission Recommendation 96/199/EC suggests that Member States make (short) general reports on the application of national quality assurance measures applied to sampling and analysis in their 1996 monitoring programmes. At the time of sampling and analyses, work was in hand on assessing and developing quality assurance measures applicable to sampling and analyses of pesticide residues. In 1996/97, an initial European analytical proficiency test programme was instituted, in which some 87 laboratories analysing pesticide residues as part of the official monitoring activities of the Member States and Norway participated. A workshop on Analytical Quality Control was also held in September 1997, in Portugal, at which the laboratory practice aspects in particular were intensively discussed. However, information from these two events was not available to the Member States when they undertook sampling and made analyses in 1996. Table 7 gives an overview on the situation of accreditation and proficiency tests.

Table 7: Accreditation and proficiency tests (information taken from the national reports 1996)

Country	No. of Laboratories	Accreditation (refer to Council Directive 93/99/EC)	Participation in proficiency tests
B	2	In preparatory phase	No information
DK	3	Accredited	Yes
D	No information	Accreditation bodies are currently set up	Performance testing has been specified
E	6	In preparatory phase	Participation in 2 proficiency tests
EL	>1	Not yet	No information
F	6	1 accredited, 1 partially	Yes, in 3-4 ring test/year (BIPEA)
IRL	No information	No information provided	No information
I	95	In preparatory phase	15 laboratories participated in Italian or regional ring tests, some on FAPAS
L	1	In preparatory phase	No information
NL	11	QAS complies with EN 45001	5 laboratories FAPAS, 11 laboratories CHEK
P	4	SOPs are in the process of preparation	Participation in external quality control measures
FIN	2	Accredited (FINAS)	1 laboratory participated in 2 interlaboratory comparison tests
S	4	All accredited by SWEDAC	Participation in three proficiency tests
N	1	Accredited (EN 45001, GLP according OECD)	Regular participation in international tests
UK	5	Most laboratories are accredited by UKAS or meet requirements of GLP	Laboratories participated in different international tests

7.3 Table 7 shows the status quo of accreditation of the laboratories and their participation in proficiency tests for 1996. As the report format was not harmonized for this, the information provided was very heterogeneous. Where “no information provided” is shown in Table 7, it does not mean the lack of respective quality procedures. Details on quality assurance measures and quality control in the laboratories can be obtained from the summaries of the national reports.

8 Summary

National Monitoring

8.1 All Member States submitted reports on their national monitoring programmes. Results differed significantly between the Member States, reflecting differences in monitoring programmes rather than differences in the presence of pesticide residues in foodstuffs. The overall situation indicates that about 40 % of the samples contained residues. MRLs were exceeded in 3 % of the cases (1 % for confirmed exceedences of harmonized EC MRLs). In about 13 % of the positive samples, residues of more than one pesticide were found. Residues most often found were from vinclozolin, iprodione, procymidone, dithiocarbamates, endosulfan, thiabendazole, chlorpyrifos, carbendazim, imazalil, captan, chlorothalonil, and methamidophos.

Community Monitoring Exercise

8.2 The Community monitoring exercises allow for a more detailed statistical analysis for a selected number of product/pesticide combinations. The results vary significantly with the different products and pesticides. For the pesticides investigated, MRLs were most often exceeded for dithiocarbamates, especially in lettuce, followed by compounds of the benomyl group. Lettuce was the product, in which exceedences of the MRLs were found most often, followed by grapes, strawberries and apples, and tomatoes. The detectable portions of food items exceeding the reporting level for the whole monitoring exercise were calculated to be between 0.10 % and 0.50 %, depending on the different products, indicating a good precision of the sampling design.

8.3 Calculations show that the acceptable daily intakes (ADIs) were exceeded for dithiocarbamates (e.g. mancozeb) if products with the highest residue found would be consumed regularly. A more realistic calculation, based on the 90th percentile of the amount of residues, demonstrates that the real exposure for the consumer is much lower. The results, however, demonstrate the importance of monitoring exercises, and in particular the necessity for the responsible national authorities to take appropriate action.

Quality Assurance and Sampling

8.4 Quality assurance of the analyses and representability of the sampling protocols are essential to the usefulness of the work of monitoring pesticide residues. The report format for 1996 was not harmonized on sampling and Quality Assurances and the situations in the Member States were different. It has to be stressed that sampling should follow Commission Decision 79/700/EEC, and laboratories should

be accredited according to Council Directives 93/99/EEC and 97/41/EC by 1 November 1998.

8.5 The report indicates that Member States have taken steps to apply Quality Assurance measures.