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Monitoring of Pesticide Residues

in Products of Plant Origin

in the European Union, Norway, Iceland and Liechtenstein

2004

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

ADI	Acceptable Daily Intake
ARfD	Acute Reference Doses
EEA	European Economic Area
EFSA	European Food Safety Authority
EU	European Union
FAPAS	Food Analysis Proficiency Assessment Scheme
GAP	Good Agricultural Practice
LOD	Limit of Determination
MRL	Maximum Residue Level
RASFF	EU Rapid Alert System for Food and Feed

1. INTRODUCTION

This is a report on pesticide residues monitoring for the calendar year 2004 in the participating Member States of the EU and the three EFTA States who have signed the EEA agreement[1] (Norway, Iceland and Liechtenstein). This year, data from eight of the new Member States (Czech Republic, Cyprus, Lithuania, Hungary, Malta, Poland, Slovakia and Slovenia) are included in the report for the first time. Latvia provided a summary of the national monitoring programme, but no detailed data.

The report gives an overview of the monitoring data on pesticide residues. More detailed information about the situation in individual States is available from the respective national monitoring authorities. To complement the data, Member States and the EEA States contribute a short summary (two pages) for inclusion in this document (see Annex 2). Pesticide residues in foodstuffs of animal origin, as regulated in Council Directive 86/363/EEC[2], are not covered by this report.

2. LEGAL BASIS

In Council Directives 76/895/EEC[3], 86/362/EEC[4] and 90/642/EEC[5], as amended, maximum levels are fixed for pesticide residues in and on products of plant origin[6]. Directives 86/362 and 90/642 require Member States to check regularly the compliance of foodstuffs with maximum residue levels (MRLs). In 2004, inspections and monitoring had to be carried out in accordance with the provisions of Council Directive 89/397/EEC[7] on the official control of foodstuffs, and Council Directive 93/99/EC[8] on additional measures concerning the official control of foodstuffs[9]. Sampling methods have been specified in Commission Directive 2002/63/EC[10] establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC.

In addition to national monitoring programmes, the Commission recommended, via Commission Recommendation 2004/74/EC[11], the participation of each Member State in a specific EU co-ordinated monitoring programme. These programmes began in 1996. Their aim is to work towards a system which makes it possible to estimate actual dietary pesticide

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[1] Agreement on the European Economic Area

[2] Official Journal No L 221, 07/08/1986 p. 0043 - 0047

[3] Official Journal No L 340, 09/12/1976, p. 0026 - 0031

[4] Official Journal No L 221, 07/08/1986 p. 0037 - 0042

[5] Official Journal No L 350, 14/12/1990 p. 0071 - 0079

[6] Directives 76/895/EEC, 86/362/EEC, and 90/642/EEC were repealed by Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16/03/05, p. 0001 – 0016) with effect from six months from the publication of the last of the Regulations establishing Annexes I, II, III and IV of Regulation (EC) 396/2005.

[7] Official Journal No L 186, 30/06/1989 p. 0023 - 0026

[8] Official Journal No L 290, 24/11/1993 p. 0014 - 0017

[9] Directives 89/397/EEC and 93/99/EEC were repealed with effect from 1 January 2006 by Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30/04/2004. Corrected and re-published in OJ L 191, 28/05/2004 p. 0001 – 0052).

[10] Official Journal No L 187, 16/07/2002 p. 0030 - 0043

[11] Official Journal No L 016, 23/01/2004, p. 0060 – 0064

exposure throughout Europe. The monitoring programme was designed as a rolling programme covering major pesticide-commodity combinations in a series of cycles. A first 5-year cycle was completed in 2000. Subsequently, the time span of the cycles was reduced to 3 years in order to have a picture of the dietary intake situation after a shorter period of time. The first 3-year cycle was completed in 2003. This 2004 report is the first report of the second 3-year cycle. The choice of commodities includes the major components of the Standard European Diet of the World Health Organisation.

Article 7 of Council Directive 86/362/EEC and Article 4 of Council Directive 90/642/EEC, as amended by Council Directive 97/41/EC[12], require Member States to report to the Commission the results of the monitoring programme for pesticide residues carried out both under their national programme and under the EU co-ordinated programme. A common format for the reports on the Community programme was agreed in document SANCO/15001/2004. The Commission is required to compile and collate the information, annually.

Commission Regulation (EC) No 645/2000[13] provides for detailed implementing rules for the monitoring provisions of Directives 86/362/EEC and 90/642/EEC.

3. MAXIMUM RESIDUE LEVELS (MRL), ACCEPTABLE DAILY INTAKES (ADI) AND ACUTE REFERENCE DOSES (ARFD)

Pesticide residue levels in foodstuffs are generally regulated in order to:

- minimise the exposure of consumers to the harmful intake of pesticides;
- control the correct use of pesticides in terms of the authorisations or registrations granted (application rates and pre-harvest intervals);
- permit the free circulation within the EU of products treated with pesticides as long as they comply with the harmonised MRLs.

A maximum residue level (MRL) for pesticide residues is the maximum concentration of a pesticide residue (expressed in mg/kg) legally permitted in or on food commodities and animal feed. MRLs are based on Good Agricultural Practice (GAP) data. Foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable. Exceeded MRLs are indicators of violations of GAP. If MRLs are exceeded, comparison of the exposure with acceptable daily intake (ADI) and/or acute reference dose (acute RfD) will then indicate whether, or not, there are possible chronic or acute health risks, respectively.

The acceptable daily intake (ADI) is the estimate of the amount of a substance in food, expressed on a body-weight basis that can be ingested daily over a lifetime without appreciable health risk to the consumer. The ADI is based on the no observed adverse effect levels (NOAEL) in animal testing. A safety factor, that takes into consideration the type of effect, the severity or reversibility of the effect, and the inter- and intra-species variability, is applied to the NOAEL. The ADI therefore reflects chronic (long-term) toxicity.

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[12] Official Journal No L 184, 12/07/1997, p. 0033 - 0049
[13] Official Journal No L 78, 29/03/2000, p. 0007 - 0009

The acute Reference Dose (ARfD) is the estimate of the amount of a substance in food, expressed on a body-weight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer. It therefore reflects the acute (short-term) toxicity. At present, acute Reference Doses have been fixed for a limited number of pesticides.

4. NATIONAL MONITORING PROGRAMMES

4.1. Monitoring results for 2004

4.1.1. Overview

Table 1: Results of the national monitoring programmes for pesticide residues

	No. of samples analysed	No. of samples without detec-table residues	%	No. of samples with residues below or at MRL (national or EC MRLs)	%	No. of samples with residues above MRL (national or EC MRLs)	%	No. of samples with residues above EC-MRLs	%
Fruit and veg., *surveillance*	50428	26689	53	21232	42	2507	5.0	1519	3.0
Fruit and veg., *enforcement*	2211	963	44	1022	46	226	10.2	122	5.5
Cereals, *surveillance*	2719	1912	70	777	29	30	1.1	28	1.0
Processed products (excl. babyfood), *surveillance*	3678	2755	75	879	24	44	1.2	17	0.5
Babyfood, *surveillance*	1334	1221	92	77	6	36	2.7	36	2.7
Cereals, processed products incl. babyfood,	80	67	84	10	13	3	3.8	1	1.3
TOTAL (excl. processed)	55395	29595	53	23036	42	2764	5.0	1670	3.0
TOTAL (incl. processed)	**60450**	**33607**	**55.6**	**23997**	**39.7**	**2846**	**4.7**	**1723**	**2.9**

For the EU and EEA as a whole, the results of analysis of 60,450 samples of fruit and vegetables, cereals, and processed products including baby food are reported, of which 7,478 samples were provided by 8 of the 10 new Member States (12 % of all samples).

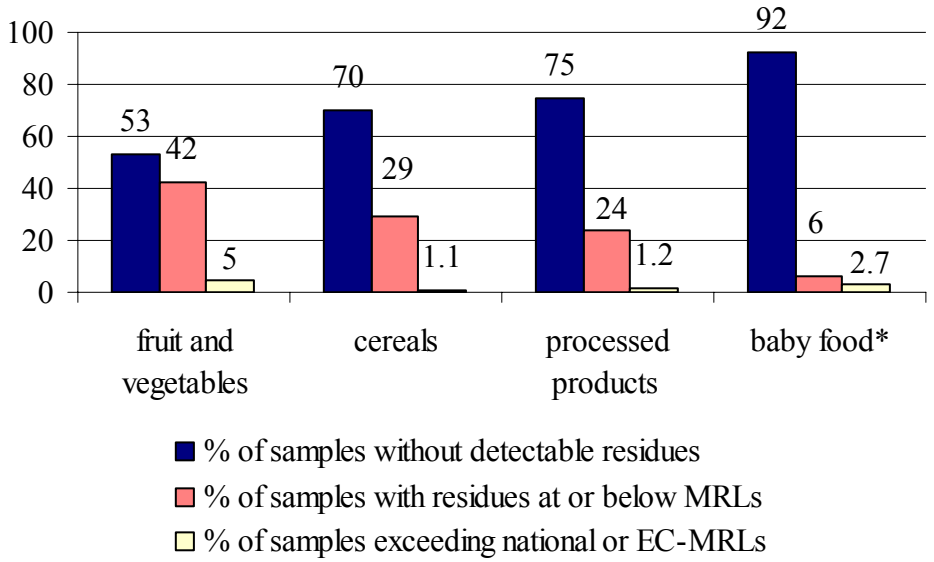
In total, 677 pesticides were sought in the surveillance samples of fruit and vegetables. The number of substances analysed in the individual States ranged from 41 to 595. A list of the substances, which were sought and detected, respectively, is provided in Annex 1, Table A.

The participating States reported a total of 6,783,859 analyses for the 50,428 surveillance samples of fruit and vegetables, and on average 135 substances were sought in these samples.

The overall results of the national monitoring programmes are shown in Table 1.

In 55.6 % of the samples, no pesticide residues were detected. Residues at or below the MRL were detected in 39.7 % of the samples. In 4.7 % of the samples, the residues exceeded MRLs (both national and EC-MRLs). There were confirmed exceedances of EC-MRLs in 2.9 % of all samples (sum of fresh, frozen and processed products). 324 different pesticides and metabolites were detected. Figure 1 illustrates the breakdown of the data for fruit and vegetables, cereals, processed products and baby food.

Figure 1: Monitoring results for fruit/vegetables, cereals, processed products (excl. babyfood) and baby food, surveillance samples only



*: different legislation on MRLs applies for baby food (see chapter 4.1.5)

A breakdown of the results of the different national programmes is provided in Annex 1, Tables B. It is noted that the results from the different States vary significantly. However, differences between the national monitoring programmes are very likely to account for an important part of the variation.

Several factors can cause these differences in the national monitoring programmes, such as:

- The choice of pesticides investigated in different commodities
- Sampling, e.g. more random or more targeted and the proportion of domestic and imported foodstuffs
- Methods used, e.g. the use of single methods to detect specific, often problematic pesticides
- Analytical capabilities of the laboratories (differences in reporting levels)
- Definition of exceeded levels (e.g. including or excluding analytical uncertainty)
- Differences in national MRLs, leading to differences in exceeded levels reported

4.1.2. Results for fresh fruit and vegetables

For fruit and vegetables 50,428 surveillance samples were analysed (see Table 1). No residues were detected in 53 % of the samples, the percentage of samples with residues at or below the MRL was 42 %, and the percentage of samples exceeding the MRL (national or EC) was 5.0 %. EC-MRLs were exceeded in 3 % of the samples. A breakdown of the results of the different national programmes is provided in Annex 1, Table C.

4.1.3. Results for cereals

For cereals, 2719 surveillance samples were analysed (see Table 1). No residues were detected in 70 % of the samples. The percentage of samples with residues at or below the MRL and exceeding the MRL (national or EC-MRL) was lower in cereals at 29 % and 1.1 %, respectively, compared to fruit and vegetables. A breakdown of the results of the different national programmes is provided in Annex 1, Table D.

4.1.4. Results for follow-up enforcement samples

In 2004, 96 % of the samples (58,159) were surveillance samples and 4 % (2,291) were follow-up enforcement samples. The more targeted nature of follow-up enforcement sampling leads to a higher percentage of MRL exceedances (national or EC-MRL) for these samples (10.2 % of fruit and vegetable samples compared to 5.0 % in the surveillance sampling, see Table 1). A breakdown of the results of the different national programmes is provided in Annex 1, Table E.

Surveillance and follow-up enforcement samples are distinguished, since a different sampling strategy (more or less targeted) can lead to considerably different results, due to the more targeted nature of the follow-up enforcement sampling.

Surveillance samples are collected without any particular suspicion towards a particular producer, consignment, etc. Surveillance sampling may also include more targeted samples, which are directed to a special problem, e.g. methamidophos in peppers or chlormequat in pears from States where problems were found previously.

Follow-up enforcement samples are taken in case of suspicion, as a follow-up for violations found previously. Follow-up enforcement sampling is directed to a specific grower/producer or to a specific consignment.

4.1.5. Results for processed products

As in 2003, 8 % of the samples (5,055) taken in the EU and the EEA States were processed products. Sampling and analyses of processed products were reported by 23 States.

The percentage of surveillance samples with residues at or below the MRL (national or EC-MRL) and with residues exceeding the MRL (national or EC-MRL) is significantly lower in processed products than in fresh products (see Table 1). Residues at or below the MRL were found in 24 % of the samples, and residues exceeding the MRL were found in 1.2 % of the samples. The percentage of samples with no residues detected was 75 %. A breakdown of the results of the different national programmes is provided in Annex 1, Table F.

Council Directives 86/362/EEC and 90/642/EEC contain general provisions for dried, processed and composite products, and specify that, in the absence of a specific MRL, the MRL for the fresh product shall be applied, taking into account concentration or dilution factors caused by processing. Specific MRLs for processed products may, or may not, have been set at the national level and the general provisions of Directives 86/362/EEC and 90/642/EEC are applied differently by Member States.

4.1.6. Results for baby food

Maximum levels for pesticide residues in baby food have been set by Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae[14] and Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children[15], as amended. An overall MRL has been set at 0.01 mg/kg, and for certain specified substances, specific MRLs (lower than 0.01 mg/kg) apply. This means that MRLs for pesticides in baby food are generally lower than MRLs specified in Council Directives 76/895/EEC, 86/362/EEC and 90/642/EEC.

In 2004, 18 States reported data on analyses of baby food. Overall, 1334 samples were analysed (see Table 1). No residues were found in 1221 samples (92%), residues at or below the MRLs were found in 77 samples (6 %), and exceedances of the MRLs specified in Directives 91/321/EEC and 96/5/EC, as amended, were found in 36 samples (2.7 %).

[14] Official Journal L 175, 04/07/1991, p. 0035 - 0049
[15] Official Journal L 49, 28/02/1996, p. 0017 - 0028

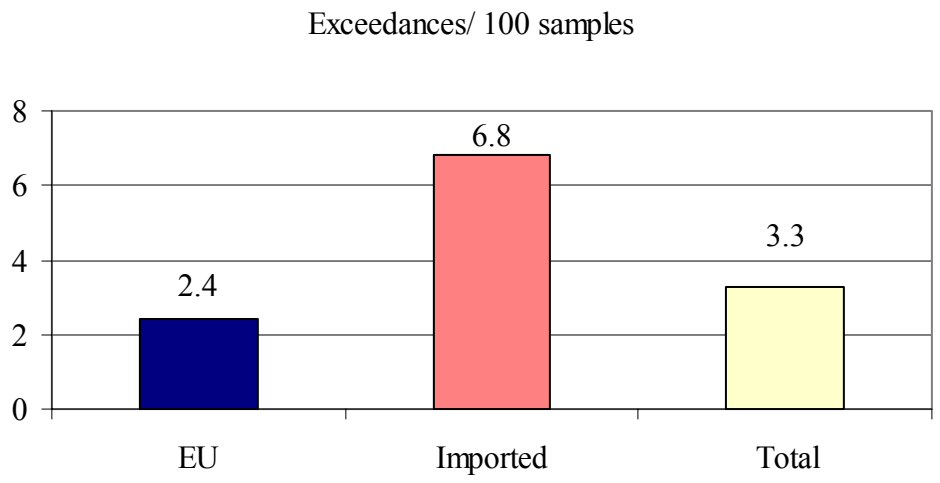
4.1.7. Origin of samples exceeding EC-MRLs

The participating States also report information on the origin of samples that exceeded MRLs. The data show that EC-MRLs are exceeded more often in samples of produce imported from Third Countries than in EU produce. Thus, 6.8 exceedances of EC-MRLs were reported per 100 samples of imported fruit, vegetables and cereals, compared to only 2.4 exceedances per 100 samples of produce from the EU (see Table 2 and Figure 2). Many of the MRL exceedances notified for imported food relate to commodity/pesticide combinations, where the MRL was set at the Limit of Determination (LOD)[16].

Table 2: Exceedances of EC- MRLs in relation to the origin of samples (surveillance samples of fruit, vegetables and cereals)

Origin	**No of samples**	**Exceedances of EC-MRLs**	**Exceedances/100 samples**
EU	42,359	1,020	2.4
Imported	9,523	650	6.8
Unknown	1,265	77	6.1
Total	53,147	1,747 *(in 1,537 samples[17])*	3.3 *(in 2.9 % of the samples)*

Figure 2: Exceedances of EC- MRLs in relation to the origin of samples (surveillance samples of fruit, vegetables and cereals)



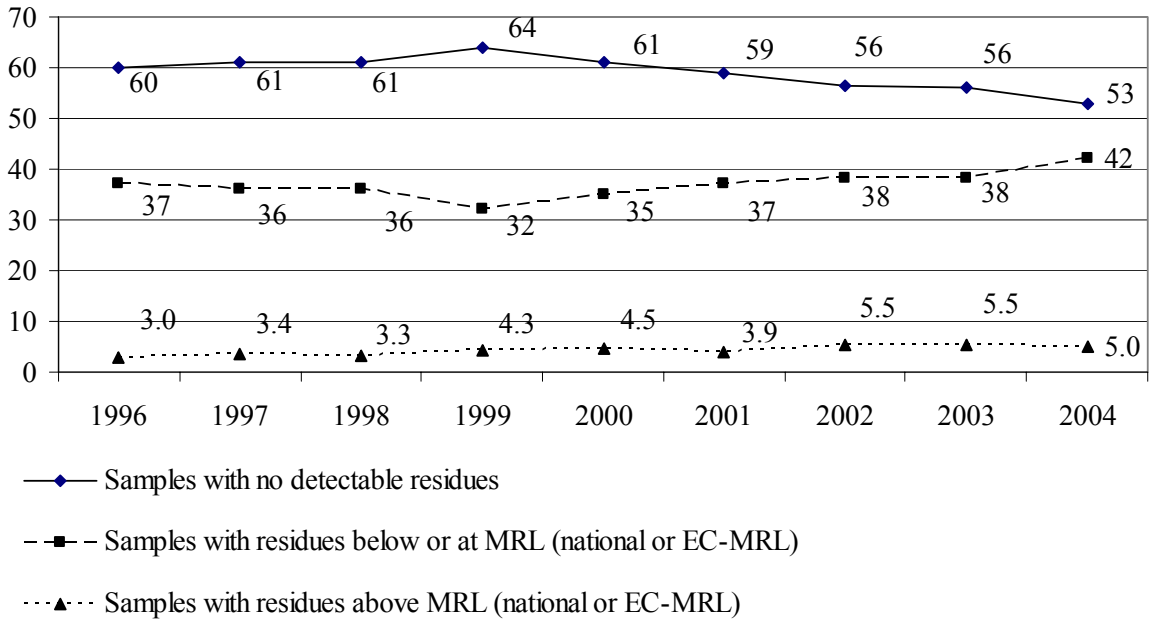
[16] LOD (limit of determination) means the validated lowest residue concentration which can be quantified and reported by routine monitoring with validated control methods. It is also known as limit of quantification (LOQ).

[17] In some samples, more than one MRL exceedance was found.

4.2.Results of the 2004 national monitoring programmes compared to the previous years

Figure 3 provides an overview of the overall trend in the data on presence of pesticide residues in or on fruit, vegetables and cereals. The percentage of samples with no residues detected has steadily decreased from 64 % in 1999 to 53 % in 2004. Similarly, the percentage of samples with residues below or at the MRL (national or EC-MRL) has increased from 32 % in 1999 to 42 % in 2004. The percentage of samples with residues above the MRL varied from 3.0 % in 1996 up to 5.5 % in 2002/2003. In 2004 at 5.0 %, it is slightly lower than in the previous two years.

Figure 3: National monitoring results 1996 – 2004 for fruit, vegetables and cereals: percentage of samples with no residues detected, with residues below and above MRLs (national or EC-MRL)



A number of factors may have contributed to the findings shown in Figure 3. Firstly, the quality of the analytical laboratories is constantly moving towards lower detection limits and lower reporting levels, and towards enhanced capability to analyse more substances. The development is shown in Figure 4. In 1997, the analytical capabilities of laboratories varied between the participating States from 66 to 281 detectable pesticides, and an average of 126 pesticides and metabolites were analysed by the different States[18]. In 2004, the average was 169 (ranging from 41 to 595 detectable pesticides, see Table C of Annex 1). If only the EU 15 and EEA States are taken into account (which analysed 88 % of the samples), an average of 197 substances was analysed for in 2004.

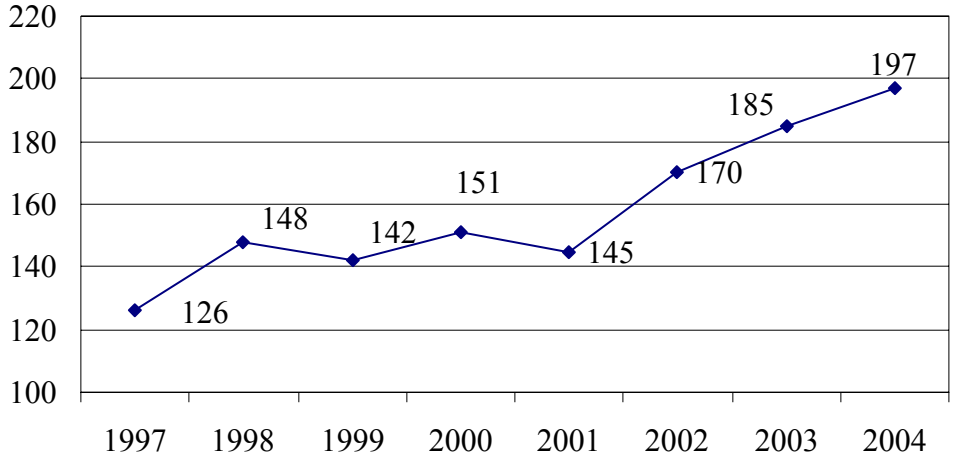
Secondly, as outlined in chapter 4.1.1, the national monitoring programmes differ considerably from year to year. In most States, priorities for the monitoring programmes are set annually at national level and are often targeted at specific problems, such as the information received on infringements in the EU (e.g. disseminated via the EU Rapid Alert System for Food and Feed (RASFF)) and/or infringements detected in their national territory during previous years.

[18] Value is not identical to the average number of analytes per sample.

Thirdly, the legislative situation has changed rapidly in recent years, and will continue to change in future, with more MRLs set at the LOD.

Finally, comparability of the data is limited by the fact that the number of States included in the reports has increased from 16 in 1996 to 26 in 2004.

Figure 4: Average number of pesticides analysed for in the participating States from 1997 to 2004 (EU 15 and EEA States), surveillance samples of fruit and vegetables



4.3. Samples with multiple residues

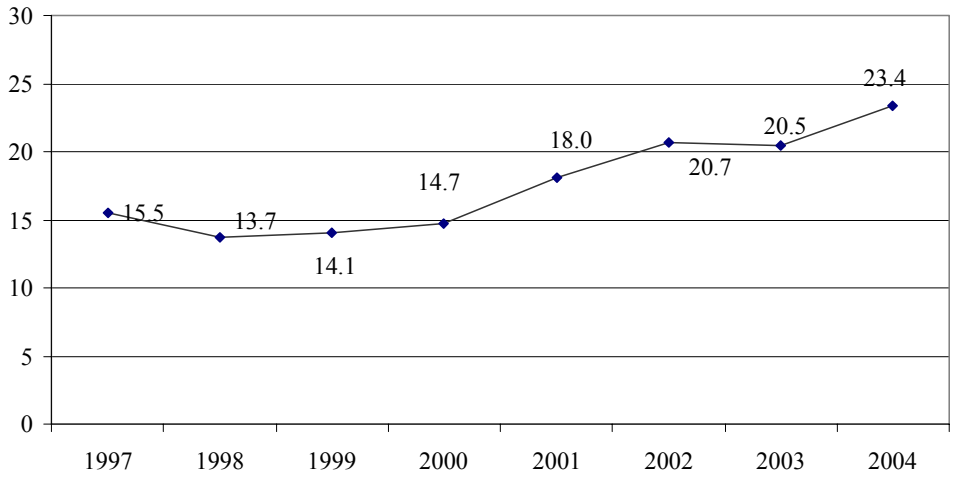
Residues of two or more pesticides were found in 23.4 % of the analysed samples. In most of these cases (10.3 %, see Table 3), residues of two pesticides were found, while 5.8 % of samples contained residues of three pesticides. The percentage of samples with four or more residues (7.3 %) is higher than in previous years (2 % in 1998, 2.8 % in 2000, 5.4 % in 2002, and 5.6 % in 2003). In 2004, the highest reported number of different residues in one sample was 18, detected in samples of sweet pepper and table grapes. More than 10 different pesticide residues were detected most frequently in sweet peppers and table grapes, but also in strawberries, tomatoes, pears, lettuce, apples, peaches, oranges, aubergines, rocket, bananas and wheat. A breakdown for the results of the different national programmes is provided in Annex 1, Table G.

Table 3: Samples with residues of more than one pesticide in fresh (incl. frozen) fruit, vegetables and cereals

	Samples analysed	**Samples with 2 or more pesticides**	2 pesti-cides	3 pesti-cides	4 pesti-cides	5 pesti-cides	6 pesti-cides	7 pesti-cides	8 or more pesticides
No.	**55395**	**12986**	5695	3220	1850	955	544	283	439
%	**100**	**23.4**	10.3	5.8	3.3	1.72	0.98	0.51	0.79

Figure 5 gives an overview of the percentage of samples with multiple residues in the years from 1997 to 2004 (fresh fruit, vegetables and cereals). The chart shows that the proportion of samples with multiple residues has increased since 1998. When evaluating these data, the factors outlined in chapter 4.2, in particular the improvement of the analytical laboratories, are relevant.

Figure 5: Percentage of samples with multiple residues from 1997 to 2004, fruit, vegetables and cereals



4.4. Most frequently found pesticides

The participating States were asked to prepare a list of the ten most frequently found pesticides in decreasing order of frequency. This list was established by calculating the percentages of the findings of each pesticide in relation to the total number of samples analysed for this specific pesticide. The results from all reporting States were combined and are summarised in Table 4, ranked in decreasing order. A breakdown of the results from each State is provided in Annex 1, Table H.

Table 4: Pesticides found most often in the national (incl. co-ordinated) monitoring programmes in the European Union, Norway, Iceland and Liechtenstein for **a) fruit and vegetables** and **b) cereals**, as reported

Fruit and vegetables	**Cereals**
Maneb group, Chlorpyriphos, Imazalil, Procymidone, Benomyl group, Iprodione, Thiabendazole, Chlormequat, Bromides and ortho-Phenylphenol	Pirimiphos-methyl, Malathion, Chlorpyriphos-methyl, Chlormequat, Deltamethrin, Chlorpyriphos, Glyphosate, Bromides, Dichlorvos and Mepiquat

The Table shows that the most frequently found pesticides on fruit and vegetables were mainly fungicides. On cereals, the pesticides found were mainly insecticides. In both cases, this confirms the findings of previous years.

Of the 677 pesticides and metabolites analysed for (see Table A in Annex 1), a total of 324 substances (48 %) were detected. 117 of these substances were only detected in 1 to 4 samples.

5. THE EU CO-ORDINATED MONITORING PROGRAMME

As an EU co-ordinated monitoring programme, the Commission recommended in 2004 via Commission Recommendation 2004/74/EC that eight commodities should be tested (apples, tomatoes, lettuce, strawberries, leek, orange juice, head cabbage and rye/oats) for 47 pesticides. The list of pesticides analysed in 2004 includes all 42 substances analysed in 2003, with five additions – cyprodinil, diphenylamine, fenhexamide, myclobutanil, and spiroxamine. For diphenylamine, only results for apples were requested.

The list of pesticides has been extended substantially over the previous years. In 1996, only analyses of nine pesticides were reported.

The benomyl-group comprises three different compounds (benomyl, carbendazim, thiophanate-methyl), which are analysed with the same analytical method and determined as sum of residues expressed as carbendazim. The maneb-group, by legal definition, comprises five different dithiocarbamates, which are also determined as a sum, expressed as CS_2.

Twenty-two Member States (all except Estonia, Latvia and Malta), and the three EEA States participated in the EU co-ordinated programme. Overall, 13,953 samples were analysed (3133 samples of apples, 2665 of tomatoes, 2301 of lettuce, 2668 of strawberries, 769 of leek, 704 of orange juice, 918 of head cabbage and 795 of rye/oats). This is an increase of 58 % compared to 2003, when 8579 samples were reported. A total of 155 laboratories were involved in the analyses.

Table 5 shows the numbers of samples taken for each commodity. A breakdown for the different participating States is provided in Table I of Annex 1. Table K of Annex 1 provides a breakdown of the results for the participating States.

Table 5: Numbers of samples taken for each commodity

Recommended number of samples (for each commodity)	Number of samples taken by commodity							
	Apples	Tomatoes	Lettuce	Strawberries	Leek	Orange juice	Head cabbage	Rye/ Oats
649	3133	2665	2301	2668	769	704	918	795

5.1. Sampling design applied in the 2004 EU co-ordinated monitoring programme

5.1.1. Description of the sampling design

In order to achieve reliable information concerning the concentration of pesticides in fruit, vegetables and cereals on the European market a suitable sampling plan is required.

The sampling design of the co-ordinated programme is based on a statistical method proposed by Codex Alimentarius[19]. Based on a binomial probability distribution, it can be calculated that examination of 613 samples gives a confidence of more than 99 % detecting one sample containing pesticide residues above the LOD, where less than 1 % of products of plant origin contain residues above the LOD.

The minimum numbers of samples to be taken of each commodity were fixed at a different level for each State, according to their population and consumer numbers, since adjusting the sample size to the size of the national markets improves the precision of the sampling design. As specified by Commission Recommendation 2004/74/EC, the required number of samples varied from 12 to 93, resulting in a recommended total of 613 samples for all Member States and 649 samples for all participating States (i.e. incl. EEA States). As in previous years, more samples were analysed from all commodities than recommended.

5.1.2. Statistical evaluation of the results of the co-ordinated programme

As described in section 5.1.1. the statistical approach of Codex Alimentarius requires that at least one sample of the whole number of samples must contain a specific concentration of a certain pesticide (e.g. above the reporting level or above the MRL) in order to assess the lowest portion of food items containing pesticides above this specific level in the whole population. In the following section this lowest portion shall be estimated on a 95 % confidence level for each of the pesticides.

The portion of samples with residues below or at the MRL (grey columns) or exceeding the MRL (white columns) of the respective pesticide are shown in Figures 6, 7, 8 and 9. The results are presented in a logarithmic scale in order to accommodate a broad range of data in the figures. In addition, the corresponding confidence interval on the 95 % level is shown, reflecting the sampling error. The sampling error, in this context, reflects the variability of the data due to the different numbers of samples taken for the determination of the respective pesticide. Other error sources, such as the way how and when the samples were taken are not included in this estimation.

The impact of the sampling error on the final result is illustrated using the reported concentrations of the maneb-group in the food items. 6149 samples have been analysed and 852 of them showed residues below or at the MRL. The number of 6149 samples represents only a part of the whole European market, therefore the calculated fraction of samples with residues below or at the MRL (852/6149 = 13.9 %) is only an estimate for the true but unknown value. The variability of this value can be calculated and is expressed in terms of % samples shown as error bars in the above mentioned figures. For the example of the maneb-group this means that the true value of the number of samples with residues at or below the MRL would vary between 796 and 911 samples which corresponds to a range of 12.9 % to 14.8 %.

The relative sampling error increases with decreasing numbers of samples of a certain category. For cases where no samples with exceeding MRLs have been found, those error bars reflect the actual percentage of the specific commodity in the whole population which still could contain residues above the MRL. For example no sample with residues exceeding the MRL for folpet was found in the co-ordinated monitoring programme, but the upper limit

[19] Codex Alimentarius, Pesticide Residues in Foodstuffs, Rome 1994, ISBN 92-5-20372271-1; Vol. 2, p. 372

of the error range is 0.03 %. This upper limit of the error range for the other pesticides, for which no residues exceeding the MRL have been found (azinphos-methyl, chlorpyriphos-methyl, dichlofluanid, diphenylamine, fenhexamid, folpet, malathion, mecarbam, omethoate, phorate, spiroxamine, triazophos) varied from 0.03 % to 0.17 %. The exact value depended on the number of samples included, but the indicated error range was considered as very low. This ensures sufficient precision of the results and allows for subsequent risk analysis calculations to be carried out.

In Figures 6, 7, 8 and 9 the percentage of samples with residues at or below MRL (national or EC-MRL) and exceeding the MRL (national or EC-MRL) for a specific pesticide with the corresponding error bars is shown.

Figure 6: Statistical evaluation of results from the EU co-ordinated programme (I)

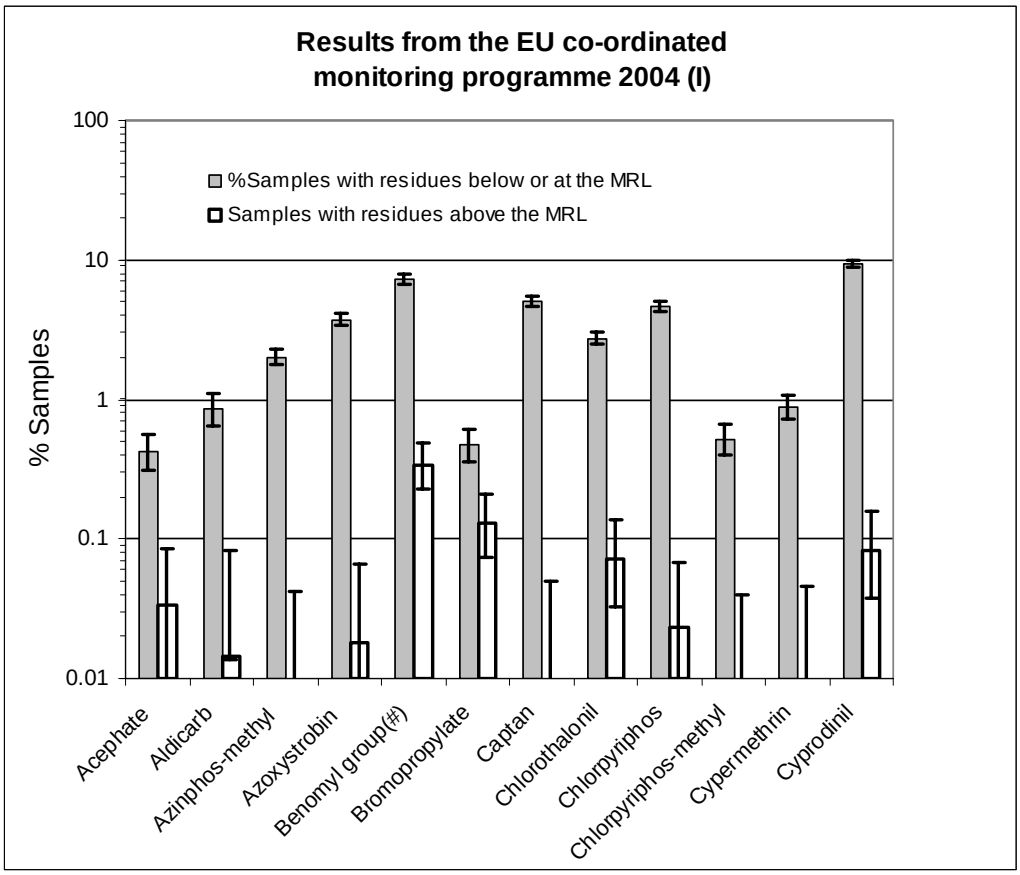


Figure 7: Statistical evaluation of results from the EU co-ordinated programme (II)

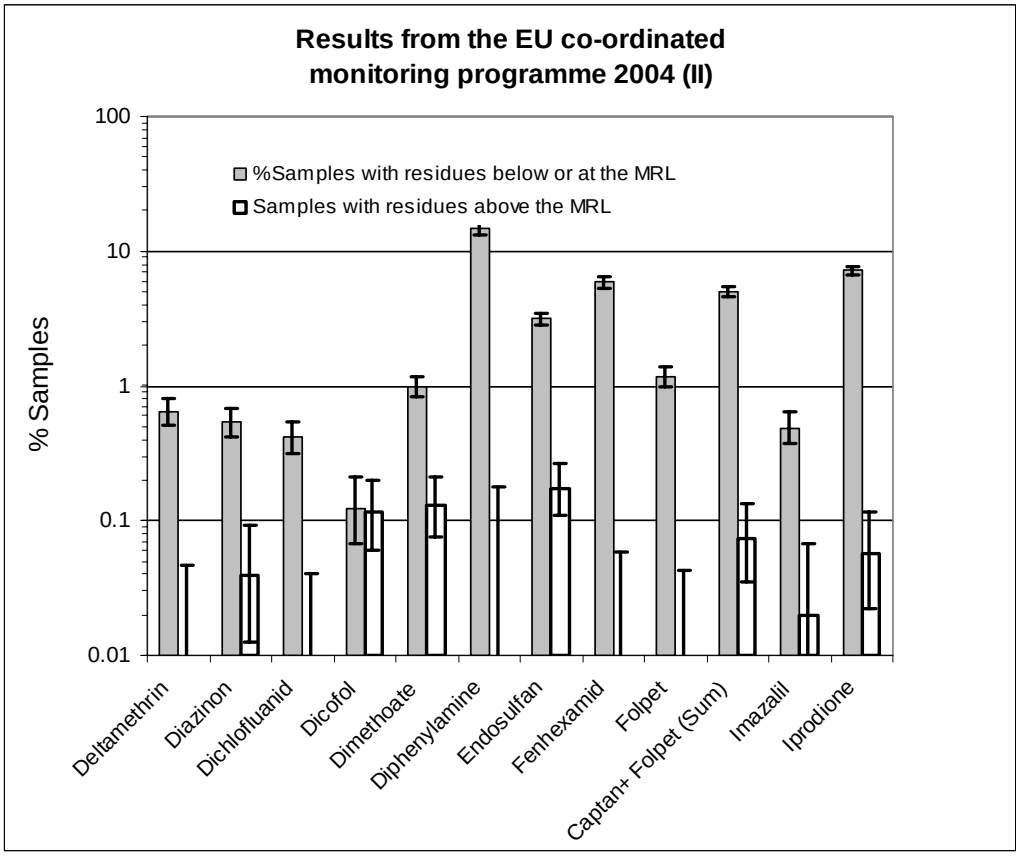


Figure 8: Statistical evaluation of results from the EU co-ordinated programme (III)

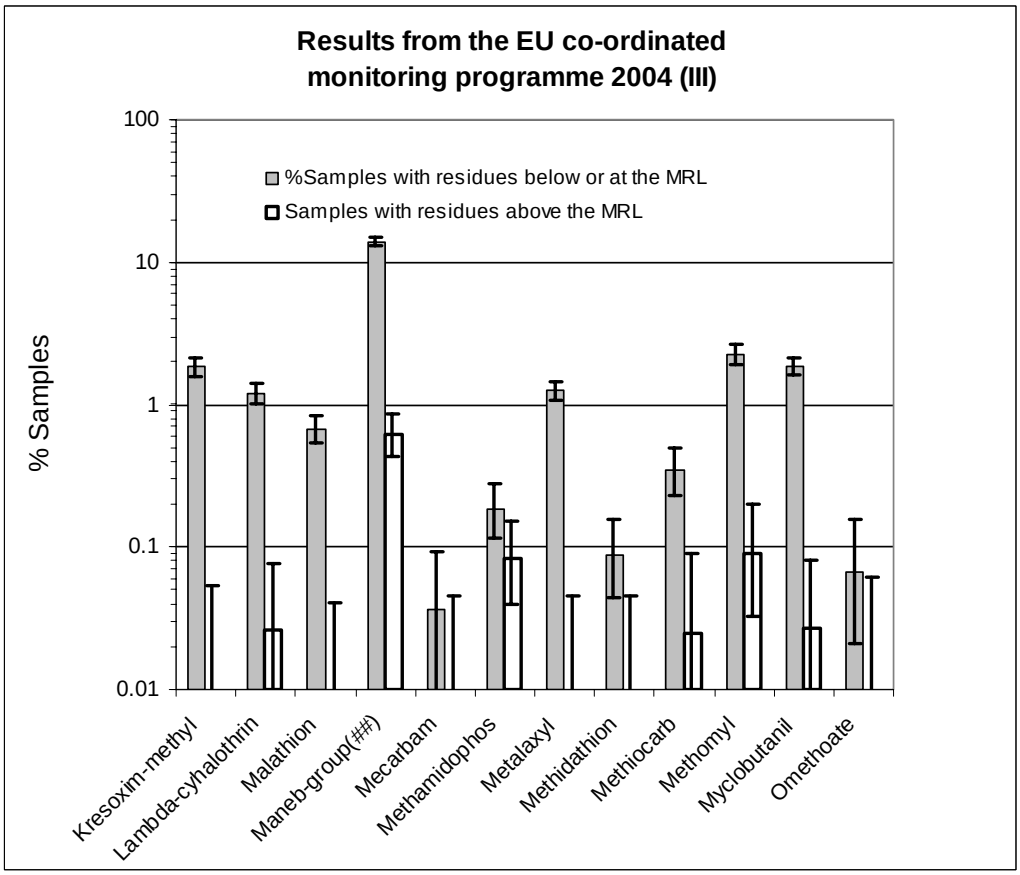
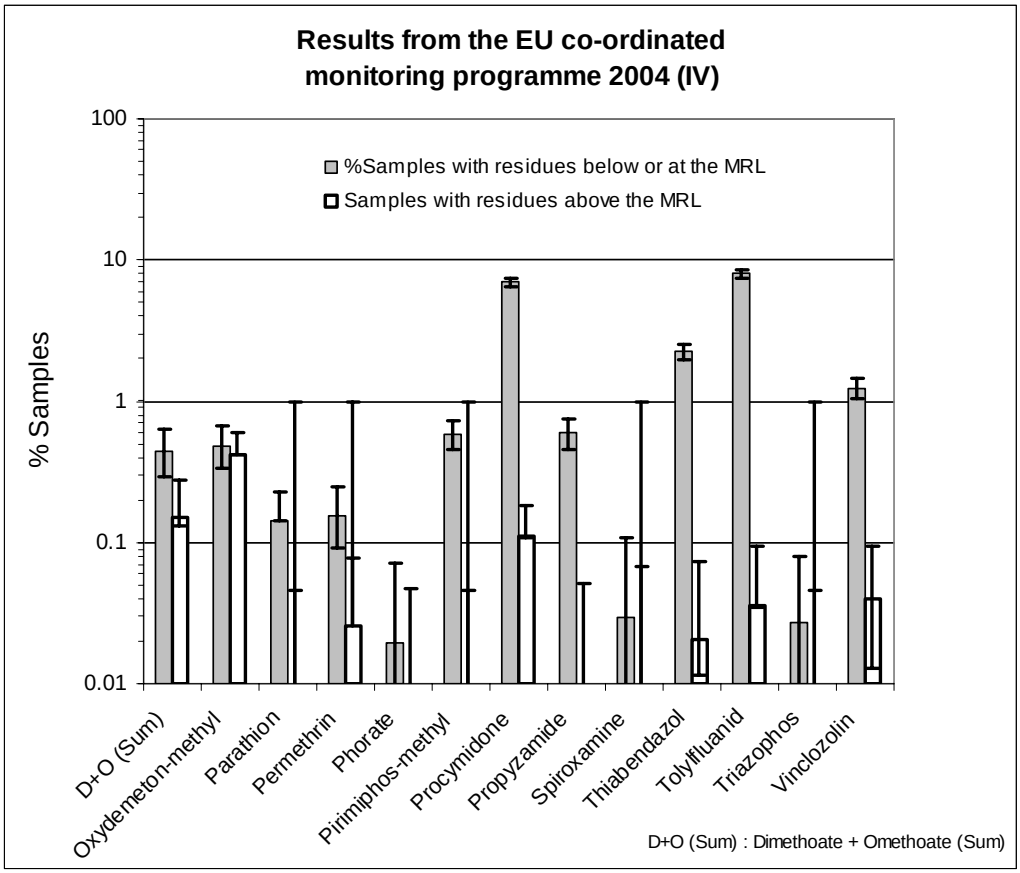


Figure 9: Statistical evaluation of results from the EU co-ordinated programme (IV)



5.2. Evaluation by pesticide

Figures 10 and 11 show the most significant pesticide detections at or below the MRL and exceedances of MRLs. More details can be found in Table L of Annex 1, and in Annex 3, where the complete results for all reporting States and all commodities are given.

Residues at or below the MRL were found most frequently of diphenylamine (14.8 % of the samples analysed for the substance). Only results from apples are reported for this pesticide. Of the pesticides analysed in samples from all commodities, residues of the maneb group were found most often (13.9 %), followed by cyprodinil (9.3 %), tolylfluanid (8 %), iprodione (7.3 %), the benomyl group (7.2 %), procymidone (7 %) and fenhexamid (5.9 %). All these substances are fungicides. For 24 of the pesticides, the frequency of samples with residues corresponded to less than 1 %.

The frequencies of MRL exceedances for single pesticide detections are all below 1 %. The highest frequency was found for the maneb group, where 0.62 % of all samples exceeded MRLs. The main other exceedances, in decreasing order, are oxydemeton-methyl (0.42 %), benomyl group (0.34 %) endosulfan (0.17 %) , bromopropylate (0.13 %), dicofol (0.12 %) and procymidone (0.11 %). The majority of these substances are insecticides or acaricides. For 11 substances no exceedance has been reported.

Figure 10: Percentage of samples with residues at or below MRL (national or EC-MRL); results by pesticide (24 pesticides where less than 1 % of samples had residues at or below the MRL are not included in the chart.)

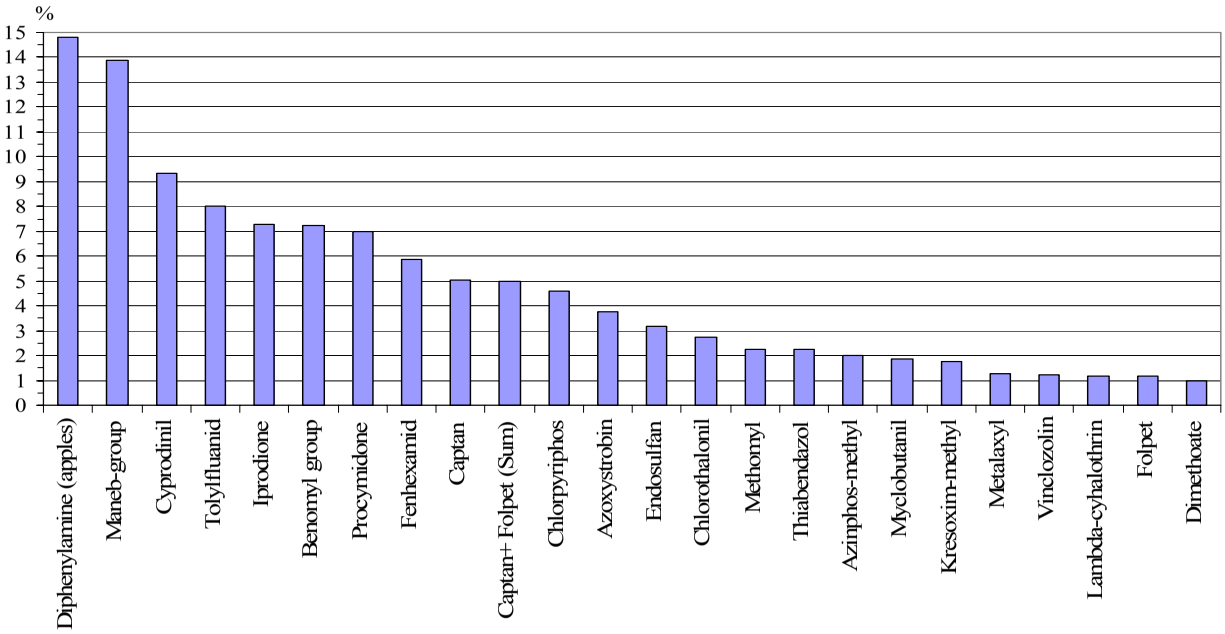
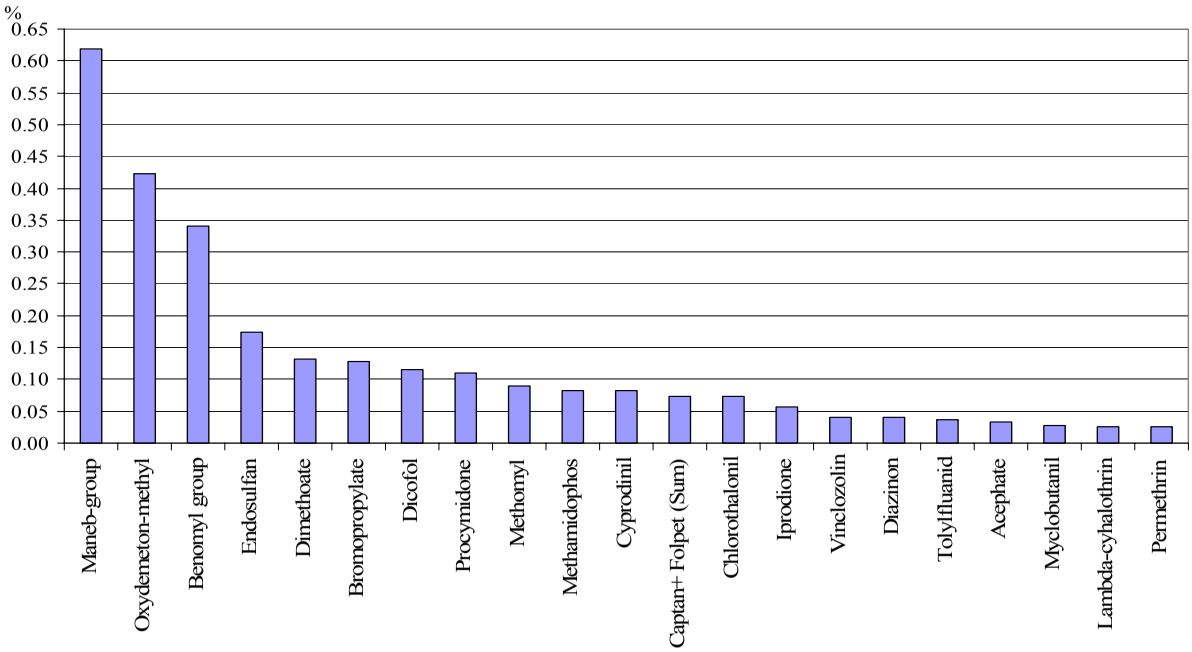


Figure 11: Percentage of samples with residues exceeding the MRL (national or EC-MRL); results by pesticide (27 pesticides where less than 0.03 % of samples had residues above the MRL are not included in the chart.)



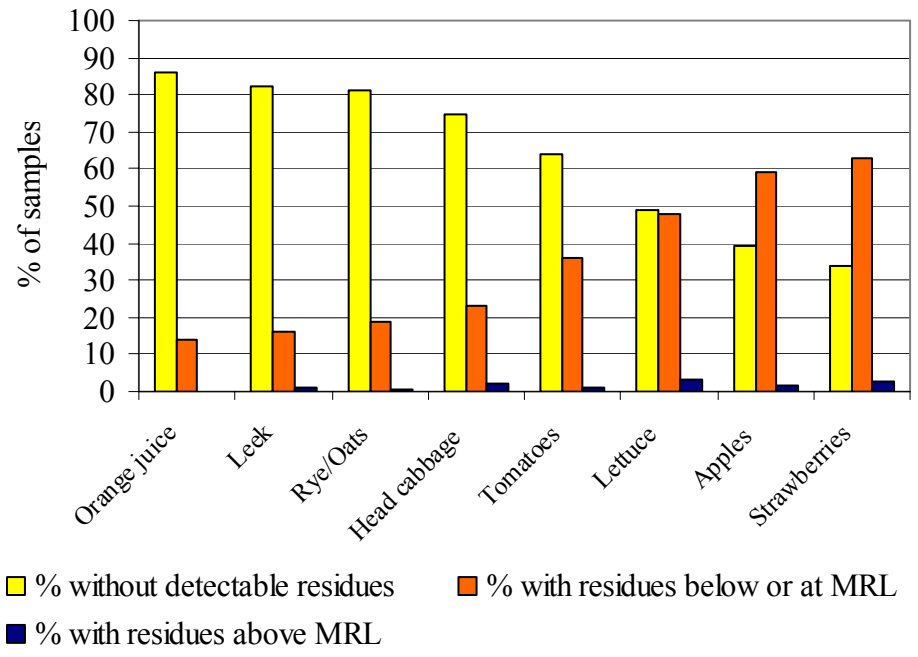
5.3. Evaluation by commodity

Tables 6 gives an overview of the findings in the different commodities. With regard to all eight commodities investigated, no residues were detected in 54 % of the samples, 44 % of the samples contained residues of pesticides at or below the MRL (national or EC-MRL), and 1.9 % above the MRL. However, these percentages vary significantly between the analysed commodities, as the illustrated data in Figure 12 show.

Table 6: Residues found in the eight commodities analysed in the EU co-ordinated monitoring programme

	Number of samples analysed	Without detectable residues	%	With residues below or at MRL (national or EC-MRL)	%	With residues above MRL (national or EC-MRL)	%
Apples	3133	1229	39	1848	59	56	1.8
Tomatoes	2665	1693	64	947	36	25	0.9
Lettuce	2301	1129	49	1096	48	76	3.3
Strawberries	2668	900	34	1694	63	74	2.8
Leek	769	634	82	125	16	10	1.3
Orange juice	704	602	86	101	14	1	0.1
Head cabbage	918	689	75	208	23	21	2.3
Rye/Oats	795	641	81	149	19	5	0.6
SUM	13953	7517	54	6168	44	268	1.9

Figure 12: Residues found in the eight commodities analysed in the EU co-ordinated monitoring programme



Strawberries had the highest percentage of samples with pesticide residues (63 %) below or at MRLs, and 59 % of the apple samples and 48 % of the lettuce samples contained residues at or below the MRL. Samples of tomatoes and head cabbage contained residues at or below the MRL less frequently (36 % and 23 %, respectively). Orange juice, leek and rye/oats had the lowest percentage of samples containing residues (< 20 %).

In all commodities, the vast majority of samples did not exceed the MRLs. The highest percentage of MRL exceedances was found in lettuce (3.3 %), followed by strawberries (2.8 %), head cabbage (2.3 %) and apples (1.8 %).

In these results, no differentiation is made with regard to findings of several pesticides in the same sample. This means that a sample where two different pesticides were found would be counted as just one finding with detectable residues. To provide a complementary picture, Table 7 shows the residues found in individual determinations, which means the findings with regard to every single pesticide. In this table, a sample where two different pesticides were found would be counted as two findings with detectable residues. In this evaluation, residues of a specific pesticide at or below the MRL (national or EC-MRL) were found most often in strawberries, followed by apples and lettuce. This is consistent with the results in Table 6. Regarding MRL exceedance, the highest frequency was found in lettuce, followed by strawberries and head cabbage. This is also consistent with the results in Table 6.

It can be concluded that strawberries and apples were the commodities on which pesticide residues were most often detected, whereas MRLs (national or EC-MRLs) were most often exceeded in lettuce and strawberries.

Table 7: Residues found in individual determinations (ind. det.) in the eight commodities analysed in the EU co-ordinated monitoring programme

	Total number of ind. det.	**Number of ind. det. without residues**	**Number of ind. det. with residues below or at MRL (national or EC)**	**%**	**Number of ind. det. where a residue exceeded the MRL (national or EC)**	**%**
Apples	122902	119158	3686	3.0	58	0.05
Tomatoes	99195	97630	1540	1.6	25	0.03
Lettuce	86347	84044	2213	2.6	90	0.10
Strawberries	103152	99534	3539	3.4	79	0.08
Leek	29970	29727	233	0.8	10	0.03
Orange juice	27931	27802	128	0.5	1	0.01
Head cabbage	34545	34260	263	0.8	22	0.06
Rye/Oats	27422	27216	201	0.7	5	0.02
SUM	531464	519371	11803	2.2	291	0.05

5.4. Evaluation by pesticide-commodity combinations

The main pesticide-commodity combination where detectable residues were found most frequently (including those at or below the MRL and exceeding the MRL) was cyprodinil/strawberries, and residues of cyprodinil were detected in 33.92 % of strawberry samples (Table 8). This is followed by iprodione/lettuce (22.72 %), fenhexamid/strawberries (22.37 %), and the maneb group/lettuce (22.03 %). The pesticides in the main pesticide-commodity combinations are all fungicides, except the insecticide chlorpyriphos.

Table M of Annex 1 gives a more detailed overview of the most important pesticide-commodity combinations for all pesticides included in the EU co-ordinated programme. It also lists the maximum concentrations found for each of the pesticides.

Table 8: Most frequent detections of particular pesticide/commodity combinations

Pesticide	**Commodity**	**% samples with detectable residues**
Cyprodinil	Strawberries	33.92
Iprodione	Lettuce	22.72
Fenhexamid	Strawberries	22.37
Maneb-group	Lettuce	22.03
Tolylfluanid	Strawberries	20.61
Benomyl group	Apples	20.42
Chlorpyriphos	Apples	16.38
Diphenylamine	Apples	14.80
Procymidone	Tomatoes	14.76
Captan+ Folpet (Sum)	Apples	14.64
Azoxystrobin	Strawberries	12.84

There were eight combinations with MRL exceedances above 0.5 % (see Table 9). The highest percentages were found for the maneb group, which exceeded MRLs most often in head cabbage (3.66 % of all samples), followed by oxydemeton-methyl in lettuce (1.50 % of all samples), the benomyl group in strawberries (1.49 % of all samples), the maneb group in lettuce (1.42 %), and oxdemeton-methyl in apples (0.90 %). All the other exceedances of pesticides for specific commodities were below 0.7 %. It is noted that, due to the residue definition of the maneb group (CS_2), the analysis for these substances in head cabbage may lead to false positive results. The MRL exceedances of oxydemeton-methyl in lettuce and apples are of particular relevance, due to the high acute toxicity of this pesticide.

Table 9: Most frequent MRL exceedances of pesticide/commodity combinations

Pesticide	**Commodity**	**% MRL exceedances**
Maneb group	Head Cabbage	3.66 %[20]
Oxydemeton-methyl	Lettuce	1.50 %
Benomyl group	Strawberries	1.49 %
Maneb group	Lettuce	1.42 %
Oxydemeton-methyl	Apples	0.90 %
Benomyl group	Rye/Oats	0.67 %
Endosulfan	Strawberries	0.66 %
Iprodione	Leek	0.56 %

5.5. Homogeneity exercise

As in previous years, a special exercise was carried out to determine the distribution of pesticide residues in the individual sample units taken from commercial trade, which form part of the analytical sample (composite sample). The residue contents in the individual sample units can differ. This is partly due to the variability of results for single units from the same field or producer, but can also be due to the fact that different units from the sampled lot do not originate from the same producer and therefore do not have the same sample treatment history. In order to get an idea of the variability of the single units (and therefore of the homogeneity of the composite monitoring sample) the participating States were recommended to sample apples, tomatoes, lettuce, leek and head cabbage and preferably analyse for pesticides posing an acute risk. It was recommended to take two samples of an appropriate number of items, analyse the first sample as a composite sample after mixing the items and, if there were residues detected in the composite sample, to analyse the single items of the second sample. The participating States were also asked to give information on whether the single units of a sample were taken from a single producer.

The homogeneity of the composite monitoring sample is expressed by calculating a factor, which is called the homogeneity factor. The homogeneity factor indicates the variability of the single items' results of a composite monitoring sample, taken in commercial trade. It is calculated by dividing the maximum value by the mean value of the single items' results. Thus, a high homogeneity factor indicates low homogeneity of a sample.

In 2004, ten of the participating States provided data for the homogeneity of a total of 111 samples. Results are available for 47 samples of apples, 39 samples of lettuce, 19 samples of tomatoes, 4 samples of peaches, and one sample each for head cabbage and leek. Out of the 111 samples, 56 were taken of lot originating from single producers. For 55 samples, the participating States could not confirm that the sampled lots originated from single producers, and multiple producers were probable. The samples contained a total of 44 different pesticides.

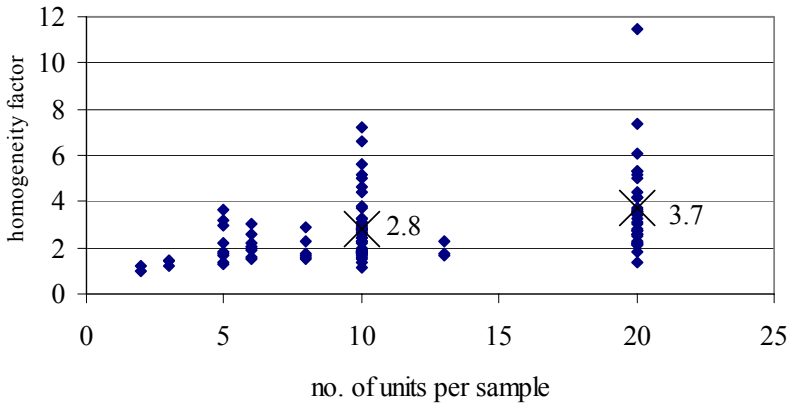
[20] It is noted that due to the residue definition of the maneb group (CS_2), the analysis for these substances in head cabbage may lead to false positive results.

The samples contained between 2 and 20 single units. The identified homogeneity factors were between 1 and 11.5. In five cases, no homogeneity factor could be calculated, because the residues, which had been identified in the homogenised sample, were below the reporting limits in each of the single units. A summary of the results for all samples is shown in Table N of Annex 1.

In an opinion of February 2005 on the appropriate variability factor(s) to be used for acute dietary exposure assessment of pesticide residues in fruit and vegetables[21], the EFSA demonstrated that the performance of variability factor estimation degrades rapidly for samples with less than 50 units, especially in terms of bias and skewness. For this reason, EFSA decided to use only datasets having 50 or more single units for their main analyses, and therefore did not use the available data from the EU coordinated monitoring programmes.

Taking into consideration the opinion of EFSA, the results of the 2004 homogeneity exercise were compared to the number of units per sample (Figure 13). It was found that the average homogeneity factor was higher for samples with 20 units (3.7) than for samples with 10 units (2.8). This shows that the sample size has an influence on the homogeneity factor. Therefore, since the number of units in the samples was too small, it does not appear appropriate to conclude on the homogeneity of the sampled lots. The data provide only information on the homogeneity of the samples.

Figure 13: Homogeneity of samples in relation to the number of units per sample (single or multiple producers)



X: average homogeneity factor for 10 and 20 units/sample, respectively

In a further analysis, the average homogeneity factors were compared between samples from single producers and samples from probable multiple producers. Figures 14 and 15 show that the homogeneity factors were higher in those samples from probable multiple producers (on

[21] Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from Commission related to the appropriate variability factor(s) to be used for acute dietary exposure assessment of pesticide residues in fruit and vegetables (Question N° EFSA-Q-2004-124) adopted on 16 February 2005; The EFSA Journal (2005) 177, 1-61.

average 3.9 for samples with 20 units) than in samples taken from produce of single producers (on average 3.3 for samples with 20 units).

Figure 14: Homogeneity of samples in relation to the number of units per sample (single producers)

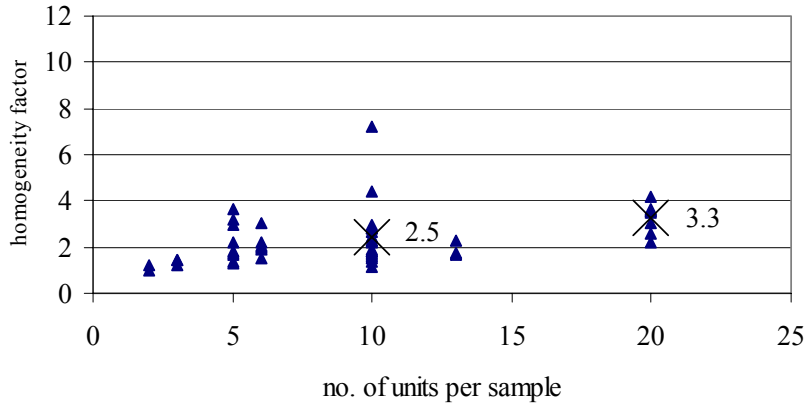
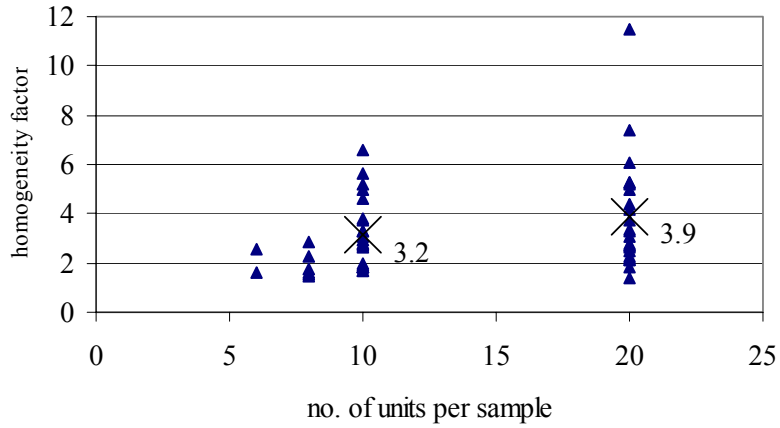


Figure 15: Homogeneity of samples in relation to the number of units per sample (multiple producers probable)



The data show that where the sampled lots do not clearly originate from single producers, there is a higher variability of results for individual units. Data for mixed lots were submitted in the 2004 homogeneity exercise by one participating State, who analysed the samples in this exercise for several pesticides. As an example, Table 10 shows the homogeneity of a lettuce sample containing 10 single heads. Two heads of lettuce contained residues of dichlofluanid, but not of other pesticides. Four heads of lettuce contained residues of endosulfan, metalaxyl, pirimicarb and acephate (but not of dichlofluanid), and in further four heads no residues were detected. Captan and methamidophos were detected in one and three heads of lettuce, respectively, but the concentrations were below the reporting limit of the homogenised sample.

There are several possible explanations, why lots contain produce with different pesticide patterns. In particular, lots may be mixed by grading, washing, packaging, at retailing, or other processing steps.

Table 10: Example for the homogeneity of a lettuce sample from multiple producers, results for homogenised sample and single units in mg/kg

	captan	dichlo-fluanid	endosulfan	metalaxyl	pirimicarb	acephate	methamidophos
Result of homogenised sample	*< reporting limit*	*0.06*	*0.25*	*0.04*	*0.14*	*0.12*	*< reporting limit*
Result of unit 1	0.14		0.09	0.14	0.11	0.380	0.04
Result of unit 2			0.14	0.16	0.50	0.66	0.05
Result of unit 3							
Result of unit 4			0.14	0.09	0.16	0.21	0.03
Result of unit 5			0.09	0.10	0.15	0.12	
Result of unit 6		0.03					
Result of unit 7							
Result of unit 8							
Result of unit 9		0.05					
Result of unit 10							
Homogeneity factor	**3.8**	**1.8**	**2.9**	**2.8**	**5.0**	**4.6**	**2.6**

5.6. Exposure assessment

5.6.1. Chronic risk

To estimate the chronic risk to the consumer for the commodities investigated in the EU co-ordinated programme, calculations can be done based on consumption figures from the World Health Organisation (Standard European Diet). As in previous EU monitoring reports, the assessment of the chronic risk was carried out, to consider worst case conditions, on the basis of the 90th percentile[22]. For 42 of the 47 pesticides of the co-ordinated programme the 90th percentile was below 0.01 mg/kg. For these pesticides, only insignificant intakes are expected. For five pesticides (diphenylamine, fenhexamide, iprodione, the maneb group and procymidone) the 90th percentile was above 0.01 mg/kg. An indicative risk assessment was carried out for an adult with an average bodyweight of 60 kg for these pesticides. The intake of the pesticide was calculated for those commodities, in which the highest residues were found, and compared with the acceptable daily intake (ADI).

As shown by the results in Table 11, the intake of pesticide residues remains clearly below the ADI in every case. The exposure ranges from 0.009 % of the ADI for fenhexamide on strawberries, to 0.75 %- 5.36 % of the ADI for the maneb group on lettuce.

[22] WHO/FSF/FOS/97.7, p. 14. The 90th percentile of the amount of residues found in the monitoring exercise is the value below which 90 % of the values are situated, including those samples with no detectable residues. Example: the 90th percentile for the content of residues of diphenylamine in apples is to be determined: 2,331 samples were analysed in total, out of which 1,986 samples contained no detectable residues. 345 samples showed different residue contents, categorised in 9 categories (from "up to 0.01 mg/kg" to "2.1-5mg/kg". 90 % of all values would comprise 2,331*0.9= 2,097.9 samples. The 2097/2098th sample falls within the samples of the category "0.11-0.2 mg/kg". Because of the categorised reporting format the exact 90th percentile value can not be given, but the 90th percentile can be given as ≤ 0.2 mg/kg

Table 11: Indicative exposure assessment for **chronic** risk for those 5 of the 47 pesticides, where the 90th percentile was above 0.01 mg/kg

Compound	Commo-dity	90th percentile (mg pesticide / kg commodity)	ADI (mg pesticide / kg body weight/day) 23	Average consumption (g commodity / day)[24]	Intake via specific commodity (mg pesticide / d / kg bw)	Intake in % of the ADI
Diphenylamine	apples	≤ 0.2	0.08	40	0.00013	0.17
Fenhexamide	straw-berries	≤ 0.2	0.2	5.3	0.00002	0.009
Iprodione	lettuce	≤ 1.0	0.06	22.5	0.00038	0.63
Maneb-group[25]	lettuce	≤ 1.0		22.5	0.00038	
Metiram, Zineb			0.03			0.75
Maneb, Mancozeb			0.05			1.25
Propineb			0.007			5.36
Procymidone	lettuce	≤ 0.05	0.1	22.5	0.00002	0.02

5.6.2. Acute risk

There is no unique model for evaluating risks from acute exposure in the EU. As an example, the acute risk can be evaluated by using the UK Consumer Exposure Model, where an exposure assessment is carried out based on the 97.5th percentile of consumption[26]. This means, that in order to include consumers with a high consumption of specific commodities, a large portion value is used. The 97.5th percentile is the value below which the consumption of 97.5 % of all consumers is situated. The model enables the intakes of ten consumer categories to be determined. The consumer categories used are: adult; infant; toddler; 4-6 year old child; 7-10 year old child; 11-14 year old child;15-18 year old child; vegetarian; elderly (own home); elderly (residential). Other models, reflecting the situation within different Member States of the EU, are based on alternative consumption data and body weights. For this report, as in previous EU monitoring reports, the data from the United Kingdom were used. Since no assessment has been made on the basis of data from other Member States, these calculations are only indicative. They were performed to identify possible pesticide/commodity combinations, which raise potential concern to consumer health.

The evaluation of the acute risk was carried out for each of those 18 of the 47 pesticides of the EU co-ordinated programme, for which acute Reference Doses (ARfDs) have been set. The highest residue found for each pesticide was used in this calculation. Furthermore, in order to

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[23] WHO/IPCS/2002.3 – JMPR Evaluation reports – EU Regulatory Decisions

[24] GEMS/FOOD Regional diets WHO/FSF/FOS 98.3 Revision September 2003

[25] Since these pesticides have the same residue definition, it can not be determined, from which of the pesticides the residues result, and a mixture of residues from the different pesticides of the group is likely. For this reason, the intake was calculated for the three different ADI values.

[26] acute_consumer_ver1_1.xls; PSD, York, UK; http://www.pesticides.gov.uk/approvals.asp?id=1687

consider worst case conditions default variability factors[27], taking into account unit-to-unit variability of single units, were used. For the medium sized commodities with a unit weight ≤ 250 g (i.e apples and tomatoes), a variability factor of seven was used. For rye/oats and strawberries, with a unit weight < 25 g, a variability factor of 1 was used. In case of lettuce and head cabbage, the evaluation was done with a variability factor of 3. The intake of the specific pesticide via a specific commodity was compared with the acute Reference Dose (ARfD).

For 8 of the 18 pesticides the intakes for the highest detected residue concentrations in a composite sample have been assessed above the ARfD: deltamethrin, dimethoate, lambda-cyhalothrin, the maneb group, methamidophos, methidathion, methomyl, and oxydemeton-methyl. For these 8 pesticides further intake assessments were performed on results below the maximum detected concentration to identify any further samples exceeding the ARfD[28].

Table 12: Indicative exposure assessment for **acute** risk for those 18 of the 47 pesticides, for which ARfDs have been set

Pesticide	**Food item**	**Max. Residue/ Range (mg / kg)[29]**	**ARfD (mg pesticide/ kg bw)[30]**	**Varia-bility factor**	**Intake in % of the ARfD**		**% samples excee-ding the ARfD[31]**
					Adult intake	**Highest intake**	
Acephate	lettuce	2.80	0.05	3	33	60 (4-6 yr child)	
Aldicarb	strawberries	0.089	0.003	1	8	21 (4-6 yr child)	
Chlorothalonil	lettuce	10.01-14.20	0.6	3	14	25 (4-6 yr child)	
Chlorpyriphos	tomatoes	0.51	0.1	7	5	25 (infant)	
Cypermethrin	lettuce	1.50	0.2	3	4	8 (4-6 yr child)	
Deltamethrin	lettuce	1.47	0.01	3	87	**157 (4-6 yr child)**	0.05 %

[27] The variability factors are currently under discussion in the EU. For this report, variability factors were taken from Document SANCO/3346/2001/ "Proposal on notification criteria for pesticide residue findings to the RASFF", and from WHO "Acute hazard exposure assessment for pesticide residues in food" (www.who.int/foodsafety/chem/acute_data/en/)

[28] The exact concentrations of the residues below the maximum concentration were not available, but the results had been grouped into categories, according to the concentration of the residues. The intake assessment was carried out with the lowest concentration in these groups and the maximum reported concentration. Example: There were 3 cases of residues of methamidophos in lettuce with concentrations between 0.51 and 7.7 mg/kg. The intake assessment was carried for the concentrations of 0.51 and 7.7 mg/kg.

[29] The highest value in this column represents the highest concentration found.

[30] JMPR and EU Regulatory Decisions

[31] Percentage of samples, which exceed the ARfD, of all samples analysed for the respective pesticide.

Pesticide	Food item	Max. Residue/ Range (mg / kg)[29]	ARfD (mg pesticide/ kg bw)[30]	Varia-bility factor	Intake in % of the ARfD		% samples excee-ding the ARfD[31]
					Adult intake	Highest intake	
Diazinon	head cabbage	0.34	0.03	3	8	29 (infant)	
Dimethoate	head cabbage	4.30	0.02	3	30	**106[32] (infant)**	0.1 %
Endosulfan	strawberries	1.40	0.02	1	18	49 (4-6 yr child)	
Lambda-cyhalothrin	lettuce	1.10	0.0075	3	87	**157 (4-6 yr child)**	0.05 %
Malathion	rye	2.40	2	1	0.2	0.8 (infant)	
Maneb group	lettuce	10.01-15.00	0.-0.6[33]	3	59 - 89	**107 - 160** ***propineb*** **(4-6 yr child)**	≤ 0.7 %
					30 - 44	54-80 *maneb* (4-6 yr child)	
					10 - 15	18-27 *mancozeb* (4-6 yr child)	
	apples	2.4		7	36	**235** ***propineb*** **(infant)**	≤0.07 %
					18	**118** ***maneb*** **(infant)**	
					6	39 *mancozeb* (infant)	
Methamido-phos	lettuce	0.51-7.70	0.01	3	60 - **456**	**108 - 823 (4-6 yr child)**	0.2 %
Methidathion	apples	0.22	0.01	7	33	**216 (infant)**	0.03 %
Methiocarb	strawberries	0.30	0.02	1	3.9	10 (4-6 yr child)	
Methomyl	lettuce	1.01-2.00	0.02	3	59	**107 (4-6 yr child)**	0.1 %
Oxydemeton-methyl	lettuce	0.21-2.20	0.002	3	62 - **651**	**112 - 1175 (4-6 yr child)**	0.5 %
	apples	0.03-0.96		7	22 - **718**	**147 - 4702 (infant)**	1.0 %
Parathion	lettuce	0.54	0.01	3	32	58 (4-6 yr child)	
Triazophos	rye	0.004	0.001	1	0.5	2.5 (infant)	

[32] A processing factor of 0.19 was applied to take account of the reduction of residues during cooking (based on data for cooked white cabbage. Data from the UK show that infants do not normally eat raw cabbage. For processing of cabbage into salad a similar factor of 0.21 would apply).

[33] propineb: 0.1 mg/kg; maneb: 0.2 mg/kg; mancozeb: 0.6 mg/kg; metiram: not applicable; zineb: not set

For 6 of the 18 pesticides (deltamethrin, dimethoate, lambda-cyhalothrin, the maneb group, methidathion, and methomyl), intakes above the ARfD were assessed for infants or 4-6 year old children, respectively, but not for adults. For 2 of the 18 pesticides (methamidophos and oxydemeton-methyl), intakes above the ARfD were assessed also for adults.

For deltamethrin, dimethoate, lambda-cyhalothrin, methomyl and methidathion the calculated exceedances of the ARfD were singular cases. The concentration of 0.22 mg methidation/kg apples complied with the EC-MRL of 0.3 mg/kg, although the calculated intake exceeded the ARfD. The concentration of 2 mg methomyl/kg lettuce was identical with the EC-MRL of 2 mg/kg, and the indicative intake assessment resulted in 107 % of the ARfD. Since 2004, the EC-MRLs for these pesticides have been revised and set at the LOD for apples and lettuce, respectively[34]. The other three cases represented exceedances of the EC-MRLs.

For methamidophos, 3 exceedances of the ARfD were found in lettuce, which is equivalent to 0.2 % of all lettuce samples analysed for this pesticide. The calculated intake for lettuce was up to 456 % of the ARfD for adults, and 823 % of the ARfD for 4 – 6 year old children. Each of these cases represented exceedance of the EC-MRLs.

The maneb-group includes metiram, with a relatively low acute toxicity (for this reason no ARfD was established), as well as maneb, mancozeb and propineb, each with different values for acute toxicity. It is not possible to determine, whether the detected residues relate to metiram (with no ARfD), to mancozeb (for which the ARfD was not exceeded), or to maneb and propineb (for which an intake of up to 235 % of the ARfD were calculated for infants).

For oxydemeton-methyl, a total of 5 lettuce samples and 15 apple samples were found to exceed the ARfD, which is equivalent to 0.5 % and 1.0 %, respectively, of all lettuce and apple samples analysed for this pesticide. The calculated intake for apples was up to 718 % of the ARfD for adults, and 4702 % of the ARfD for infants. All of these cases represented exceedances of the EC-MRLs. It should be noted that a significantly higher percentage of samples were analysed for this pesticide in 2004 compared to 2001, when lettuce and apples were last analysed in the EU co-ordinated programme: In 2001, only 16 % of the lettuce samples and 13 % of the apples samples had been analysed for oxydemeton-methyl, compared to 50 % and 43 % of the samples, respectively, in 2004. The main reason for the increased number of analyses is the improvement of the analytical capabilities in the laboratories.

The above results emerge from an indicative assessment of worst-case scenarios, based on the maximum levels of residues detected, combined with high food consumption data and low body weight.

In conclusion, exceedances of the ARfD were estimated for residues of eight pesticides. For five of these pesticides, the exceedances were isolated cases. Particular attention is drawn to oxydemeton-methyl, where considerable exceedances of the ARfD were estimated in a number of apple and lettuce samples.

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[34] Commission Directive 2006/59/EC of 28 June 2006 ; OJ L 175 of 29.06.2006, p. 61-76; Commission Directive 2006/61/EC of 7 July 2006; OJ L 206 of 27.07.2006, p. 12-26.

6. SAMPLING

Commission Directive 2002/63/EC established sampling methods for the official control of pesticide residues in and on products of plant and animal origin. Annex 2 contains the information on sampling given in the summaries of the national monitoring reports of the Member States and EEA States. In most cases, sampling followed annual national plans that were usually established taking into consideration consumption, production, share of imported and exported products as well as risks (e.g. results from previous years).

Samples were taken at different points, such as wholesalers and retailers, local and central markets, points of entry (for imported products), and processing industries.

The share of domestic and imported samples should reflect the situation in the respective national market. In total, about 79 % of samples were taken from EU produce, and approximately 18 % of samples were taken from imported produce. For 3.4 % of samples the origin was unknown.

On average, 13 samples were taken per 100,000 inhabitants of the EU and EEA States. The value varies significantly between the States. Within the EU it ranges from 2 samples/100,000 inhabitants to up to 48 samples/100.000 inhabitants. The three EEA States (with a relatively small population size) took up to 110 samples/100,000 inhabitants.

More information about the numbers and origin of the samples taken by the participating States is given in Table O of Annex 1.

7. QUALITY ASSURANCE

Council Directive 90/642/EEC, as amended by Council Directive 97/41/EC, requires Member States to control maximum residue levels according to Council Directives 89/397/EEC and 93/99/EEC. This also means that laboratories have to comply with the European Standard EN 45001, which has been replaced by ISO 17025, and that Member States are requested to assess the laboratories by applying the criteria as laid down in European Standard EN 45002. Member States shall also apply proficiency testing schemes where appropriate.

Commission Recommendation 2004/74/EC lays down that Member States should provide information about the details of accreditation of the laboratories which carry out the analyses for the monitoring programme, about the application of the EU Quality Control Procedures and about their participation in proficiency and ring tests. It also requires the States contributing to the monitoring to provide the accreditation certificates. Workshops on Analytical Quality Control are regularly held in order to review the Quality Control Procedures. Proficiency tests, supported by the European Commission, are also regularly organised (until 2004, six proficiency tests have been organised).

The European Commission's Monitoring Regulation No. 645/2000 (cf. chapter 2) ensures the financial contribution of the European Commission to the organisation of proficiency tests and Analytical Quality Control workshops. It also confirms and further specifies the requirements for accreditation of monitoring laboratories and their participation in proficiency tests.

Figure 17 gives an overview of the development since 1998 regarding accreditation of monitoring laboratories. The overall situation of the laboratories has continuously improved

since 1998. In 2004, all participating States use at least partly accredited laboratories, while 18 out of 26 States use only accredited laboratories (69 %).

Figure 17: **Status of laboratory accreditation**. Number of States with accreditation of all, of some or of none of the monitoring laboratories in 2004 compared to previous years

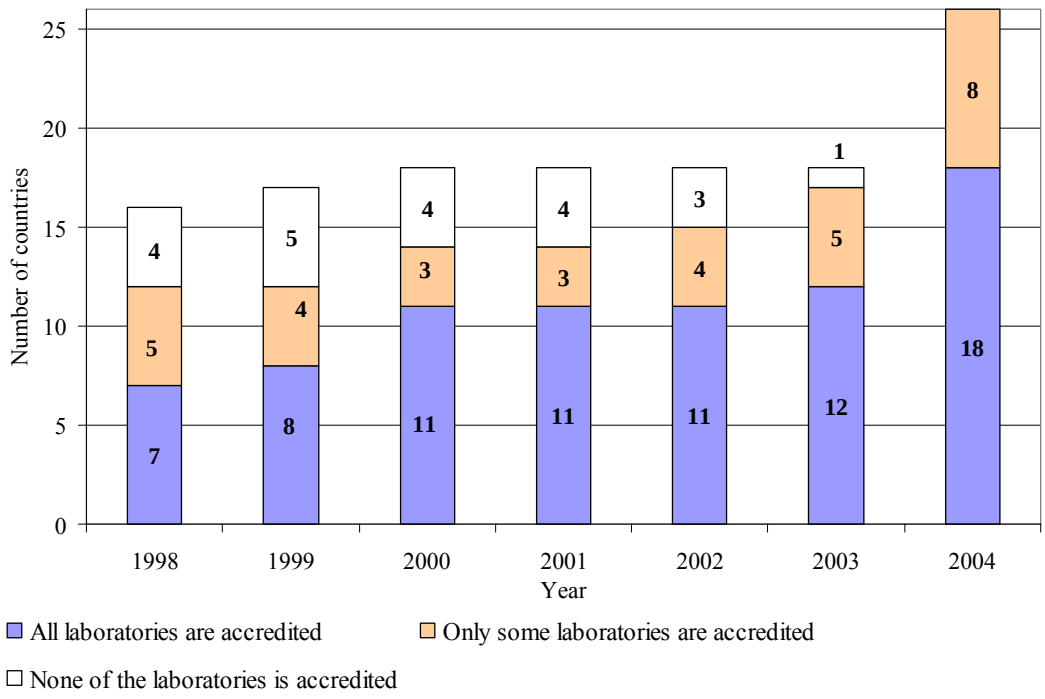
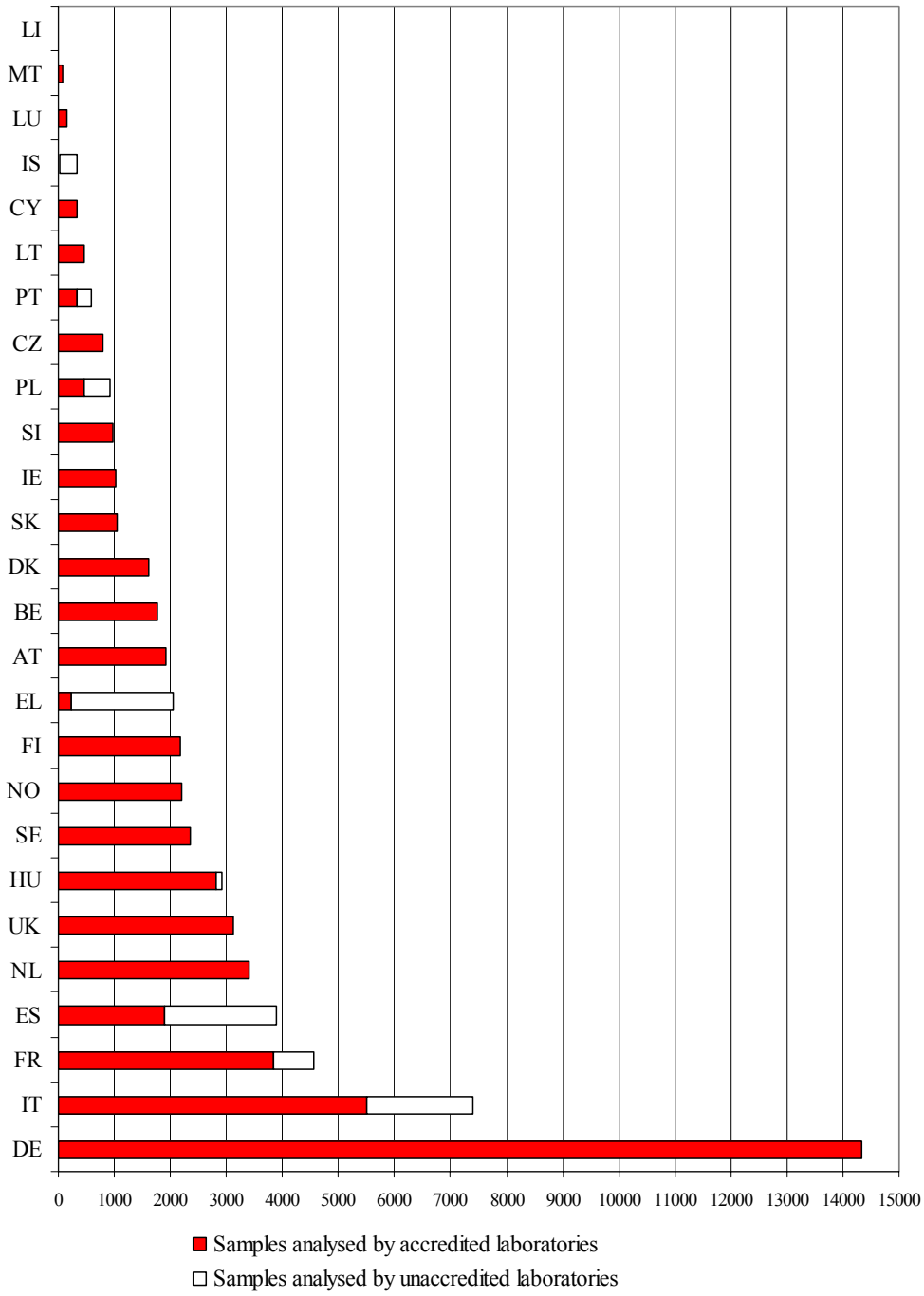


Figure 18 gives information about the number of samples analysed by accredited laboratories or by non accredited laboratories for the different participating States. It is noted that in France, Greece, Hungary, Iceland, Italy, Poland, Portugal and Spain, some laboratories have not yet been accredited. The majority of the new Member States, which participated in the EU co-ordinated programme for the first time in 2004, used only accredited laboratories.

Out of the total of 60,450 analysed samples (sum of fresh and processed products), 87.5% were analysed by accredited laboratories. This percentage is significantly higher than in 2003, when 75.5 % of the samples had been analysed by accredited laboratories.

Figure 18: Numbers of samples analysed by accredited laboratories or by non accredited laboratories by State in the year 2004[35]



In addition to the information on accreditation of laboratories, Figure 19 gives an overview on the implementation of the EU Guidelines on Quality control procedures for pesticide residues analysis[36]. According to Article 4, second indent, of Regulation (EC) 645/2000, Member

[35] no information submitted by Estonia and Latvia

[36] Quality control procedures for pesticide residues analysis (Document N° SANCO/10476/2003 of 5 February 2004), http://europa.eu.int/comm/food/plant/protection/resources/qualcontrol_en.pdf

States "shall make every effort to implement the quality control procedures for pesticide residue analysis provided for […]." The EU Guidelines contain requirements for laboratories in the following ten chapters:

1 Accreditation
2 Sampling, transport, processing and storage of samples
3 Pesticide standards, calibration, solutions, etc.
4 Extraction and concentration
5 Contamination and interference
6 Analytical calibration, representative analytes, matrix effects and chromatographic integration
7 Analytical methods and analytical performance
8 Proficiency testing and analysis of reference materials
9 Confirmation of results
10 Reporting of results

Figure 19: Percentage of laboratories, which have fully, partially, or not, implemented the different chapters of the EU Quality Control Guidelines

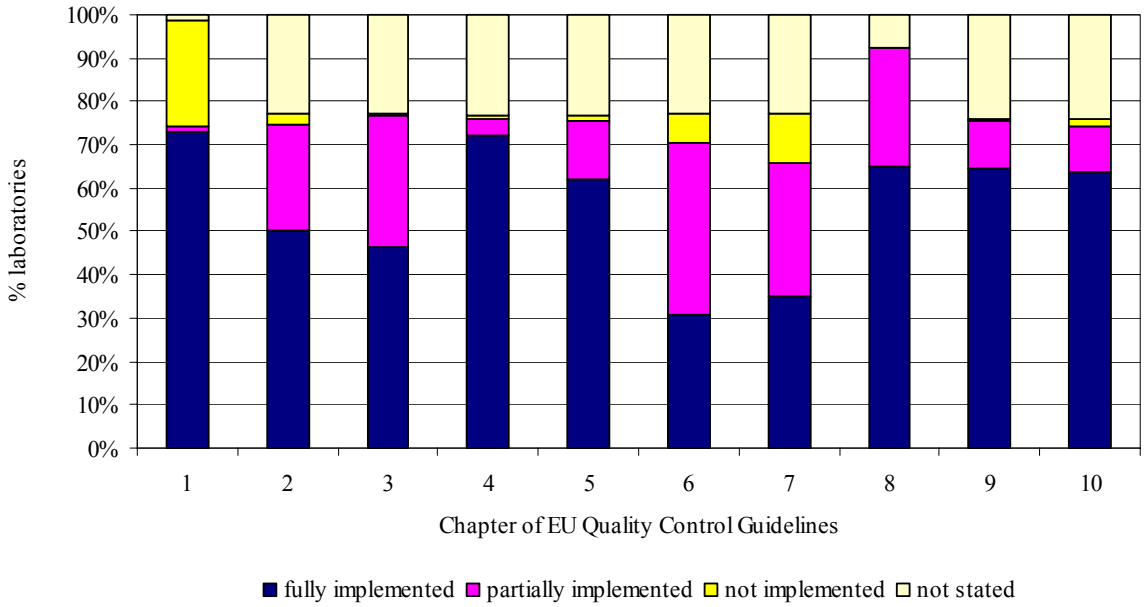


Figure 19 shows the percentage of laboratories, which have fully, partially, or not, implemented the different chapters of the EU Quality Control Guidelines (the information was not available for all 155 laboratories). The level of implementation varies between the different chapters: Chapters 1, 4, 5, 8, 9 and 10 have been fully implemented by the majority of laboratories (64 - 74 %). Chapters 2 and 3 are less frequently implemented (50 % and 46 % of the laboratories, respectively). Chapters 6 and 7 are the least frequently implemented chapters, and have been fully implemented by only 31 % and 35 % of the laboratories, respectively. Notably, 7 % and 12 % of the laboratories, respectively, stated that they did not implement chapters 6 and 7 in their laboratories, raising questions about reliability of results.

Member States reported the participation of 124 of the 155 laboratories (80 %) in proficiency tests. Laboratories from 25 participating States reported participation in proficiency tests. Laboratories from 23 of the States participated in the EU proficiency test (EU PT 6) and

another often-used proficiency test scheme was FAPAS[37]. Some laboratories also took part in other nationally or internationally organised proficiency tests.

A summary of the information provided by all participating States about accreditation, participation in proficiency tests and implementation of the EU Quality Control Procedures is provided in Table P of Annex 1.

8. RAPID ALERT SYSTEM

The Rapid Alert System for Food and Feed (RASFF) was established by Council Directive 92/59/EEC[38] on General Product Safety. In February 2002, new provisions entered into force as laid down in Regulation (EC) 178/2002[39] of the European Parliament and of the Council.

Member States shall immediately notify the European Commission under the RASFF whenever they have any information relating to the existence of a serious direct or indirect risk to human health deriving from food and feed. Such notifications are classified as Alert notifications. Subsequently, the Commission forwards the Alert to the contact points in all Member States. Member States are required to take appropriate action and inform the Commission Services of any measure adopted. Notifications which do not fulfil the above requirements but which are nevertheless regarded as important information, are forwarded by the Commission to the contact points in the Member States as information notifications (Non-Alerts).

The dissemination of information via the RASFF can play an important role in the Member States' planning of monitoring programmes. It allows the identification of specific problems at an early stage and possible adaptation of the sampling programmes accordingly, if considered necessary.

In 2004, a total of 45 notifications regarding pesticide residues in food of plant origin were distributed within the RASFF. Five of the notifications were sent as Alerts. The majority of notifications (35) related to fruit and vegetables, in particular to grapes, peppers, lettuce and apples of different origins, 8 related to herbs and spices, and 2 related to tea.

Of the 28 samples from the EU co-ordinated programme, for which an exceedance of the ARfD was estimated (chapter 5.6.2), only 4 cases were notified in the RASFF. Two of these related to oxydemeton-methyl in apples, and two related to methamidophos in lettuce. The reason for the non-notification of the remaining 24 samples cannot be explained, but the use of an alternative assessment model for short-term intake could be a contributing factor.

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[37] Food analysis performance assessment scheme, a proficiency testing scheme organised by the UK

[38] Official Journal No. L 228, 11/08/1992 p. 0024 – 0032; repealed by Directive 2001/95/EC of the European Parliament and of the Council, Official Journal L 011 , 15/01/2002 p. 0004 – 0017.

[39] Official Journal No. L 31, 01/02/2002 p. 0001 - 0024

9. SUMMARY

9.1. National Monitoring programmes

This report covers the situation with regard to pesticide residues monitoring for the 2004 calendar year in the participating Member States of the EU and the three EEA States Norway, Iceland and Liechtenstein. This year, data from the eight new Member States Cyprus, Czech Republic, Hungary, Lithuania, Malta, Poland, Slovakia and Slovenia were included in the report for the first time.

A total of 60,450 samples were analysed. About 92 % of the samples analysed were fresh (incl. frozen) fruit, vegetables and cereals, while about 8 % were processed products. In total, 677 different pesticides were sought. The analytical capabilities of laboratories in the participating States ranged from 41 to 595. A total of 6,783,859 analyses were reported for the 50,428 surveillance samples of fruit and vegetables and on average 135 substances were sought in these samples. Of all pesticides analysed for, 324 substances (48 %) were detected.

Overall, no residues were detected in 55.6 % of the samples, while a further 39.7 % of the samples contained residues that were below or equal to the maximum residue limits (MRL) laid down at EU or national level. In 4.7 % of all samples, residues above the MRL (national or EC-MRL) were found. When only fresh products are considered, the percentage of samples with no residues detected is 53 %, the percentage of samples with residues at or below the MRLs is 42 % and the percentage of MRL exceedances is 5.0 %. For processed food, no residues were found in 75 % of the samples, residues at or below the MRLs were detected in 24 %, and exceedances of the MRLs in 1.2 % of the samples. For baby food, no residues were found in 92 % of the samples, residues at or below the MRLs were found in 6 %, and exceedances of the MRLs in 2.7 % of the samples (specific, lower, MRLs apply for baby food).

The number of exceedances of EC-MRLs is higher in produce imported from Third Countries (6.8 exceedances/100 samples) than in produce from the EU (2.4 exceedances/ 100 samples).

Compared to previous years, the percentage of samples with residues at or below the MRL shows an increase in recent years to a current level of 42 % (in fresh products). The frequency of samples exceeding MRLs is slightly lower than in the previous two years. The frequency of samples with multiple residues in fresh fruit, vegetables and cereals shows an increasing tendency, rising to 23.4 % in 2004.

The increased rates of pesticide detections can be partly explained by the enhanced analytical capabilities of the laboratories. This development is reflected by the continuously increasing numbers of pesticides sought in the analytical screens since 1997.

9.2. EU co-ordinated monitoring programme

In the EU co-ordinated programme, eight commodities (apples, tomatoes, lettuce, strawberries, leek, orange juice, head cabbage and rye/oats) were analysed for 47 pesticides. The list of pesticides analysed in 2004 includes all 42 substances analysed in 2003, with five additions. Overall, 13953 samples were analysed in this programme.

The most frequently detected pesticides were diphenylamine, the maneb group, cyprodinil, tolylfluanid, the benomyl group, iprodione, procymidone and fenhexamid. The highest

frequency of MRL exceedances were found for the maneb group, oxydemeton-methyl, benomyl group, endosulfan, bromopropylate, dicofol and procymidone.

Strawberries, apples, and lettuce had the highest percentage of samples with residues, and 63 % of the strawberry samples contained residues at or below the MRL. Samples of head cabbage and tomatoes contained pesticide residues less frequently (23 % and 36 %, respectively). Orange juice, leek and rye/oats had the lowest percentage of samples containing residues at or below the MRL (< 20 %). In all eight commodities, the vast majority of detected residues did not exceed the MRLs. The highest percentage of MRL exceedances was found in lettuce (3.3 %), followed by strawberries (2.8 %), head cabbage (2.3 %) and apples (1.8 %).

The pesticide-commodity combination where residues were detected most frequently was cyprodinil/strawberries, and cyprodinil was detected in 34 % of strawberry samples. This is followed by iprodione/lettuce (23 %), fenhexamid/strawberries (22 %), and the maneb group/lettuce (22 %). There were eight pesticide-commodity combinations with more than 0.5 % of samples exceeding MRLs. The highest percentages were found for the maneb group, which exceeded MRLs most often in head cabbage (3.7 % of all samples), followed by oxydemeton-methyl in lettuce (1.5 % of all samples), and the benomyl group in strawberries (1.5 % of all samples), the maneb group in lettuce (1.4 %), and oxdemeton-methyl in apples (0.9 %).

A special exercise was carried out to determine the distribution of pesticide residues between the individual units of samples taken from commercial trade. Due to the low numbers of individual units in the samples, the data do not allow conclusions on the homogeneity of the sampled lots. The data show that where the sampled lots do not clearly originate from single producers, there is a higher variability of results for individual units.

Chronic (long-term) exposure assessments demonstrate that the intake of pesticides remains clearly below the ADI[40] and there is no concern of chronic toxicity. The data from an indicative assessment of acute (short-term) exposure, based on worst-case scenarios using the highest levels of residues detected, combined with high food consumption data and low body weight, show exceedances of the ARfD[41] in some of the samples, in particular for oxydemeton-methyl in apple and lettuce.

9.3. Quality assurance and sampling

Samples for the national and the EU co-ordinated programmes were taken at different points such as retailers, wholesalers, markets, points of entry and processing industries. National sampling plans exist in most States, taking into consideration e.g. consumption data; production figures import/export relation and risks (e.g. results from previous years).

There has been continuous progress with accreditation since 1998. In 2004, all participating States use at least some accredited laboratories, while 18 out of 26 States (69 %) use only accredited laboratories. It is noted that the majority of the new Member States, which participated in the EU monitoring programme for the first time in 2004, used only accredited

[40] Acceptable Daily Intake
[41] Acute Reference Dose

laboratories. Overall, 87.5% of the monitoring samples were analysed by accredited laboratories in 2004.

The participating States reported the participation of 124 of the 155 laboratories (80%) in proficiency tests. The majority of laboratories have, at least partly, implemented the EU Guidelines on Quality control procedures for pesticide residues analysis, although the level of implementation varies for the different chapters of the Guidelines.