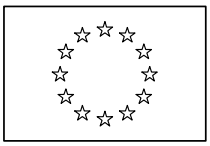

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17.10.2007
SEC(2007) 1411

PART I

COMMISSION STAFF WORKING DOCUMENT

Monitoring of Pesticide Residues in Products of Plant Origin in the European Union, Norway, Iceland and Liechtenstein

2005

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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 2005 in the 25 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 Estonia and Latvia are included in the report for the first time.

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 2005, 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 2005/178/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 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-

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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 061, 08/03/2005, p. 0031 – 0036

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 2005 report is the second 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 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/10216/2006. The Commission is required to compile and collate the information, annually.

Commission Regulation (EC) No 645/2000[12] 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.

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

[12] Official Journal No L 78, 29/03/2000, p. 0007 - 0009

reflects the acute (short-term) toxicity. At present, acute Reference Doses have been fixed for a number of pesticides.

4. NATIONAL MONITORING PROGRAMMES

4.1. Monitoring results for 2005

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*	52295	26728	51	22989	44	2578	4.9	1603	3.1
Fruit and veg., *enforcement*	2180	1050	48	871	40	259	11.9	171	7.8
Cereals, *surveillance*	2801	2203	79	569	20	29	1.0	23	0.8
Processed products (excl. babyfood), *surveillance*	3483	2323	67	1097	31	63	1.8	30	0.9
Babyfood, *surveillance*	1727	1625	94	92	5	10	0.6	10	0.6
Cereals, processed products incl. babyfood,	83	68	82	13	16	2	2	2	2
TOTAL (excl. processed)	57334	30025	52	24441	43	2868	5.0	1799	3.1
TOTAL (incl. processed)	**62569**	**33997**	**54.3**	**25631**	**41.0**	**2941**	**4.7**	**1839**	**2.9**

For the EU and EEA as a whole, the results of analysis of 62,569 samples of fruit and vegetables, cereals, and processed products including baby food are reported.

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.

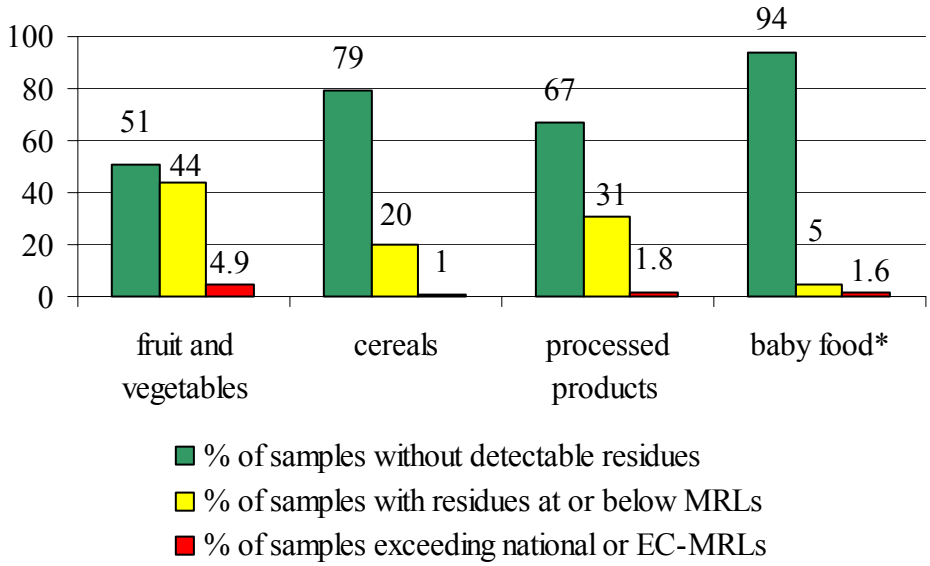
Follow-up enforcement samples are taken in case of suspicion, as a follow-up for violations found previously. Follow-up enforcement sampling is directed to a specific grower/producer or to a specific consignment.

In total, 706 different pesticide residues were sought in the surveillance samples of fruit and vegetables. The number of substances analysed in the individual States ranged from 44 to 631. 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 7,639,383 analyses for the 52,295 surveillance samples of fruit and vegetables, and on average 146 substances were sought in these samples. In total, 349 different pesticides and metabolites were detected.

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

In 54.3 % of all samples, no pesticide residues were detected. Residues at or below the MRL were detected in 41.0 % 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). 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)
- Differences in national MRLs, leading to differences in exceeded levels reported

4.1.2. Results for fresh fruit and vegetables

For fruit and vegetables 52,295 surveillance samples were analysed (see Table 1). No residues were detected in 51 % of the samples, the percentage of samples with residues at or below the MRL was 44 %, and the percentage of samples exceeding the MRL (national or EC) was 4.9 %. EC-MRLs were exceeded in 3.1 % 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, 2801 surveillance samples were analysed (see Table 1). No residues were detected in 79 % 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 20 % and 1.0 %, 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 2005, 96 % of the samples (60,306) were surveillance samples and 4 % (2,263) 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 (11.9 % of fruit and vegetable samples compared to 4.9 % in the surveillance sampling, see Table 1). A breakdown of the results of the different national programmes is provided in Annex 1, Table E.

4.1.5. Results for processed products

As in previous years, 8 % of the samples (5,235) taken in the EU and the EEA States were processed products. Sampling and analyses of processed products were reported by 22 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 31 % of the samples, and residues exceeding the MRL were found in 1.8 % of the samples. The percentage of samples with no residues detected was 67 %. 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[13] and Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children[14], 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 2005, 22 States reported data on analyses of baby food. Overall, 1727 samples were analysed (see Table 1). No residues were found in 1625 samples (94 %), residues at or below the MRLs were found in 92 samples (5 %), and exceedances of the MRLs specified in Directives 91/321/EEC and 96/5/EC, as amended, were found in 10 samples (0.6 %).

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, 6.5 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)[15].

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	42,275	1,012	2.4
Imported	11,491	751	6.5
Unknown	1,330	58	4.4
Total	55,069	1,821 *(in 1,626 samples[16])*	3.3 *(in 3.0 % of the samples)*

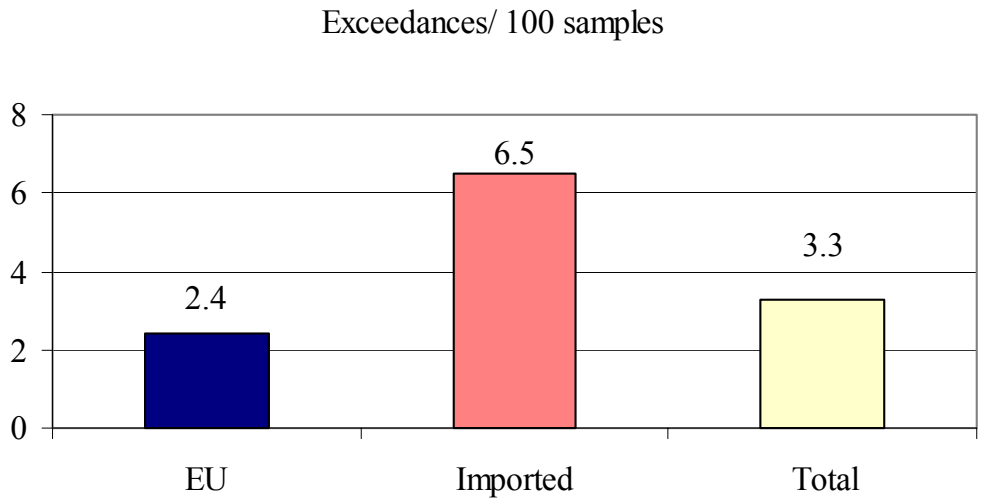
[13] Official Journal L 175, 04/07/1991, p. 0035 - 0049

[14] Official Journal L 49, 28/02/1996, p. 0017 – 0028. Repealed by Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children, Official Journal L 339, 6.12.2006, p. 16–35.

[15] LOD (limit of determination), also known as limit of quantification (LOQ). It means the validated lowest residue concentration which can be quantified and reported by routine monitoring with validated control methods. The term LOQ is more widely used than LOD because it avoids possible confusion with "limit of detection". However, in legislation MRLs that are set at the limit of quantification/determination are referred to as "LOD MRLs", not "LOQ MRLs".

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

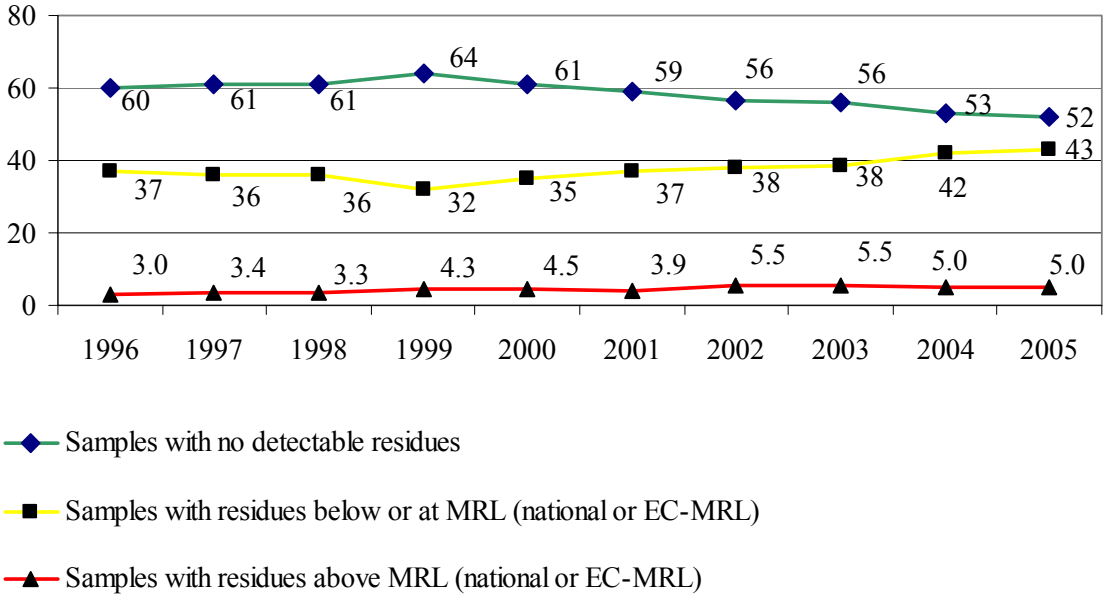
Figure 2: Exceedances of EC- MRLs in relation to the origin of samples (surveillance samples of fruit, vegetables and cereals)



4.2.Results of the 2005 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 52 % in 2005. Similarly, the percentage of samples with residues below or at the MRL (national or EC-MRL) has increased from 32 % in 1999 to 43 % in 2005. The percentage of samples with residues above the MRL varied from 3.0 % in 1996 up to 5.5 % in 2002/2003. In 2005 at 5.0 %, as in 2004, it is slightly lower than in the previous two years.

Figure 3: National monitoring results 1996 – 2005 for fruit, vegetables and cereals: percentage of samples with no residues detected, with residues below and above MRLs (national or EC-MRL)



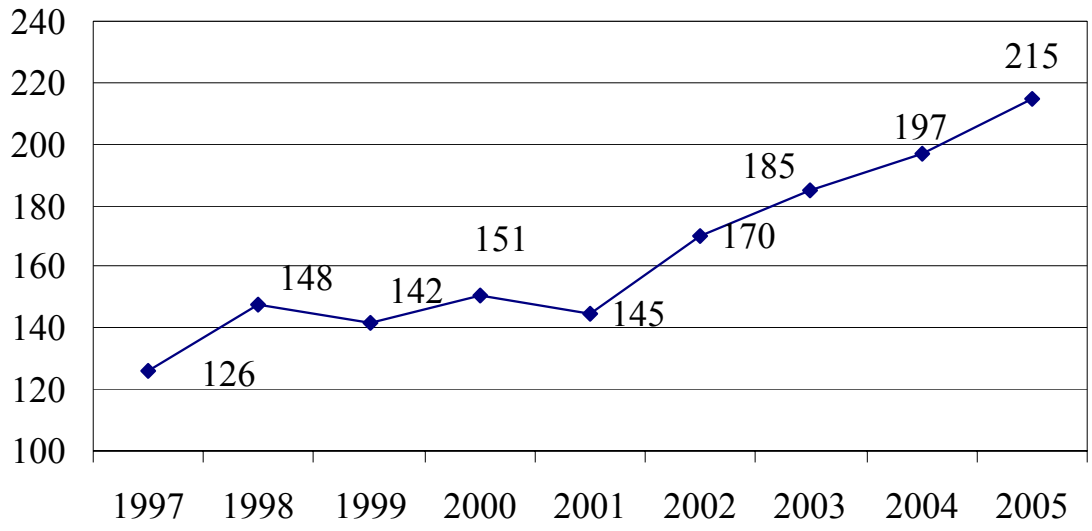
A number of factors may have contributed to the findings shown in Figure 3. Firstly, the analytical laboratories are constantly moving towards lower reporting levels, and towards enhanced capability to analyse more substances. The development is shown in Figure 4. In 1997, the analytical capabilities 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[17]. In 2005, the average was 184 (ranging from 44 to 631 detectable pesticides, see Table C of Annex 1). If only the EU 15 and EEA States are taken into account (which analysed 85 % of the samples), an average of 215 substances was analysed by the different States in 2005.

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.

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 28 in 2005.

Figure 4: Average number of pesticides analysed for in the participating States from 1997 to 2005 (EU 15 and EEA States), surveillance samples of fruit and vegetables



[17] Value is not identical to the average number of pesticides sought per sample, which was 146 in 2005.

4.3. Samples with multiple residues

Residues of two or more pesticides were found in 26.7 % of the analysed samples. In most of these cases (11.1 %, see Table 3), residues of two pesticides were found, while 6.6 % of samples contained residues of three pesticides. The percentage of samples with four or more residues (8.9 %) is higher than in previous years (2 % in 1998, 2.8 % in 2000, 5.4 % in 2002, and 7.3 % in 2003). 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.	57334	**15306**	6389	3804	2143	1146	637	420	767
%	100	**26.7**	11.1	6.6	3.7	2.00	1.11	0.73	1.34

Figure 5 a gives an overview of the percentage of samples with multiple residues in the years from 1997 to 2005 (fresh fruit, vegetables and cereals). The chart shows that the proportion of samples with multiple residues has increased since 1998. Similarly, the highest reported number of different pesticides detected in a sample has increased (Figure 5 b). While in 1998 up to 8 different pesticides were found in a sample, up to 23 different pesticides were detected in samples in 2005. More than 10 different pesticide residues were detected most frequently in sweet peppers and table grapes. While in 1998 only 0.009 % of the samples contained 8 pesticides, there were 1.34 % of the samples in 2005 found to contain 8 and more pesticides. When evaluating these data, the factors outlined in chapter 4.2, in particular the improvement of the analytical laboratories, are relevant.

Figure 5 a: Percentage of samples with multiple residues from 1997 to 2005, fruit, vegetables and cereals

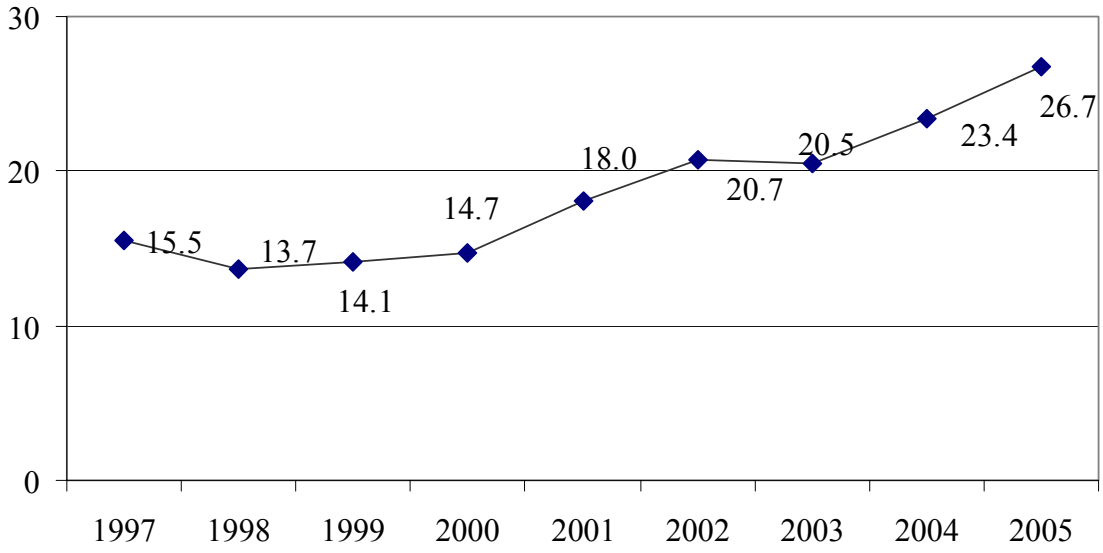
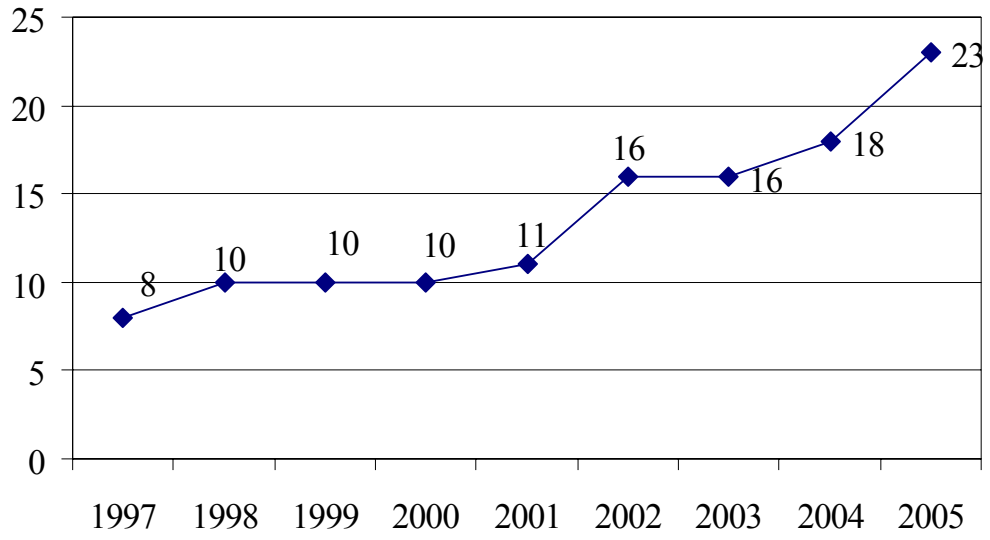


Figure 5 b: Highest reported number of different pesticides in a sample from 1997 to 2005, fruit, vegetables and cereals



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. There were 17 participating States, who provided a breakdown of the data for multi-residue and single-residue methods. The results from these 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**
Multi-residue method: Benomyl group, Imazalil, Thiabendazol, Chlorpyriphos, Iprodione, Procymidone, Tolylfluanid, Ortho-phenylphenol, Cyprodinil, Captan.	Multi-residue method: Pirimiphosmethyl, Malathion, Deltamethrin, Dichlorvos, Chlorpyriphos-methyl, Chlorpyriphos, Iprodione, Carbaryl, Bitertanol, Imazalil
Single-residue method: Maneb group, Chlormequat, Bromide, Maleic-hydrazide, Diquat, Ortho-phenylphenol, Propamocarb, 2,4-D, Benomyl group, Thiabendazol.	Single-residue method: Chlormequat, Glyphosate, Bromide, Hydrogen phosphide, Mepiquat, Phosphine.

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 is in line with the findings of previous years.

Of the 706 pesticides analysed for (see Table A in Annex 1), a total of 349 substances (49 %) were detected. 118 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 2005 via Commission Recommendation 2005/178/EC that nine commodities should be tested (pears, beans (fresh or frozen), potatoes, carrots, oranges or mandarines, spinach (fresh or frozen), rice and cucumber. The list of pesticides analysed for in 2005 includes 55 substances, 41 of which were analysed for in 2004, with fourteen additions – bifenthrin, bupirimate, carbaryl, chlormequat, chlorpropham, fludioxonil, imidacloprid, phosalone, pirimicarb, propargite, pyrethrins, pyrimethanil, tolclofos-methyl and triadimefon. For diphenylamine, only results for pears, and for chlormequat only results for rice and pears 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.

All 25 Member States and the three EEA States participated in the EU co-ordinated programme. Overall, 12,495 samples were analysed. A total of 173 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

Pears	Beans	Potatoes	Carrots	Oranges	Mandarins	Spinach	Rice	Cucumber
2001	1122	1909	1759	1598*	694	1010	847	1555

*: one participating State could not differentiate the data between oranges and mandarins.

5.1. Sampling design applied in the 2005 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[18]. 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

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

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 2005/118/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 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 55 pesticides.

The values for 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 the attached figures. 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 captan in the food items. In total for all food items 10359 samples have been analysed and 275 of them showed residues below or at the MRL. The number of 10359 samples represents only a part of the whole European market, therefore the calculated fraction of samples with residues below or at the MRL (275 /10359 = 2.65 %) 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 captan this means that the true value of the number of samples with residues at or below the MRL would vary between 243 and 310 samples which corresponds to a range of 2.4 % to 3 %, estimated at a 95 % confidence level.

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 aldicarb was found in the co-ordinated monitoring exercise, but the upper limit of the error range (95 % confidence level) is 0.06 %. This upper limit of the error range for the other pesticides, for which no residues exceeding the MRL have been found (aldicarb, bifenthrin, bromopropylate, bupirimate, carbaryl, chlormequat, chlorpyriphos-methyl, dichlofluanid, diphenylamine, kresoxim-methyl, malathion, myclobutanil, phosalone, pirimiphos-methyl, propargite, spiroxamine, vinclozolin) varied from 0.03 % to 0.47 %. The exact value depended on the number of samples included. For instance the upper limit of the

error range of 0.47 % corresponded to chlormequat, where less samples (i.e. 832) compared to the other pesticides were measured. Nevertheless, the indicated error range of all pesticides was considered as very low. This ensures sufficient precision of the results and allows for subsequent risk analysis calculations to be carried out.

In the following figures 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 are shown.

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

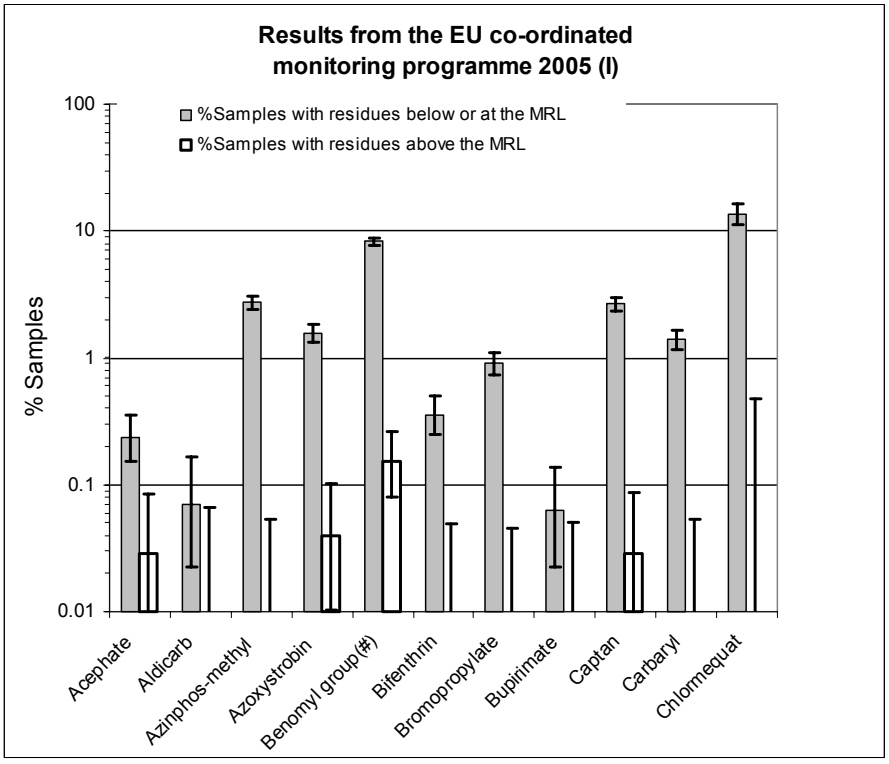


Figure 6b: Statistical evaluation of results from the EU co-ordinated programme (II)

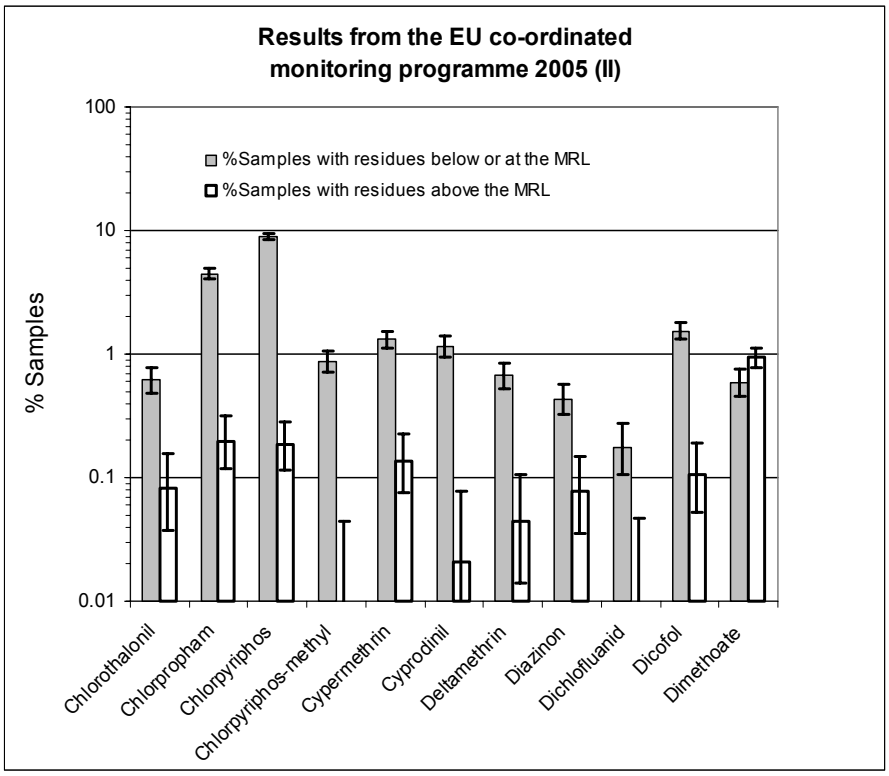


Figure 6c: Statistical evaluation of results from the EU co-ordinated programme (III)

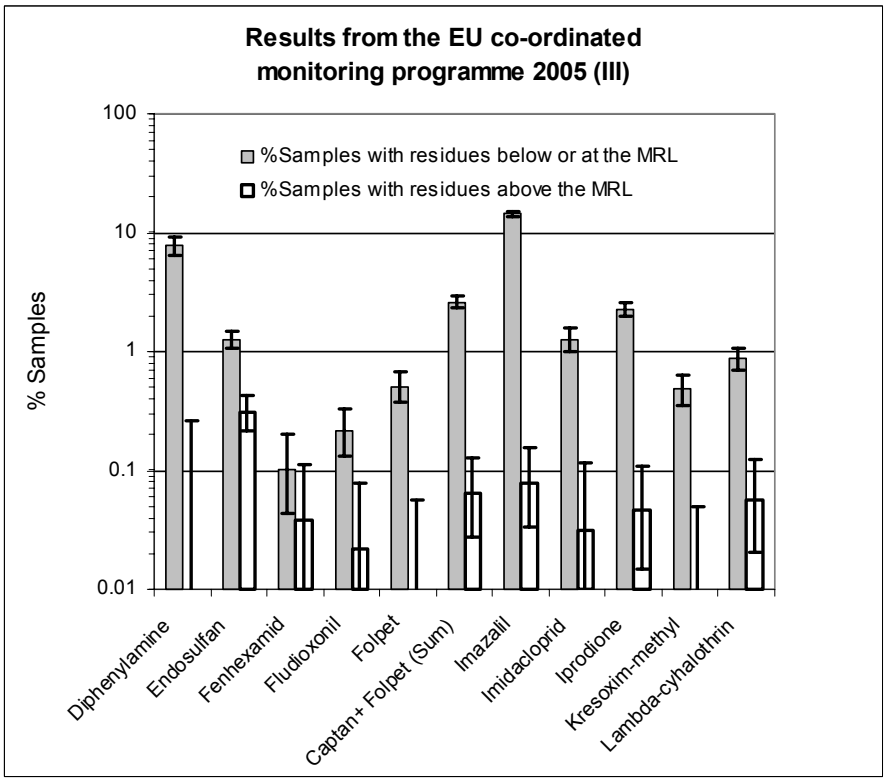


Figure 6d: Statistical evaluation of results from the EU co-ordinated programme (IV)

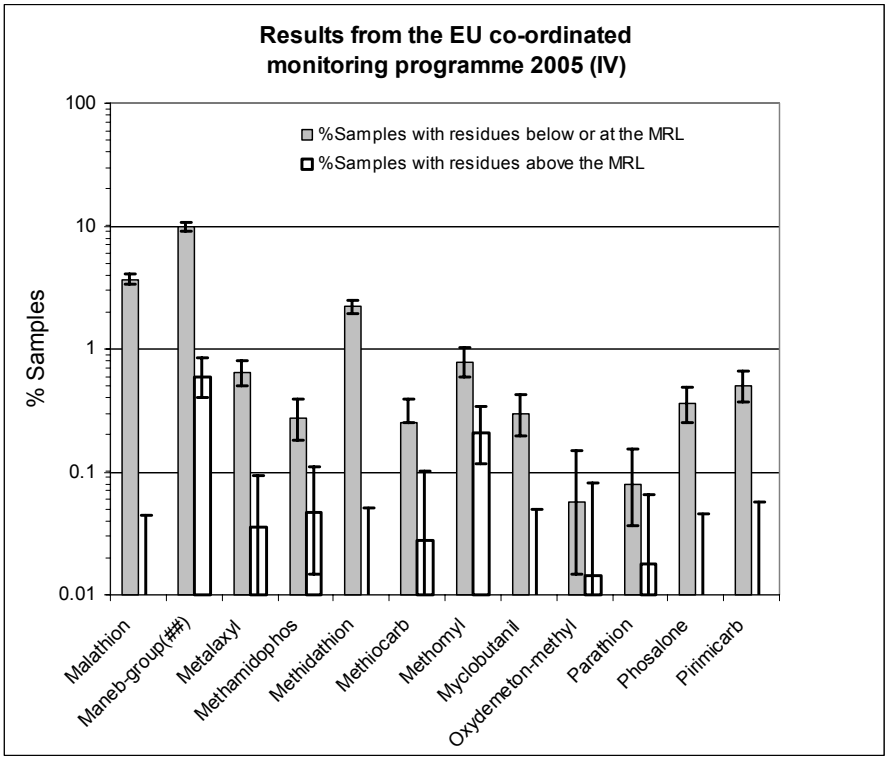
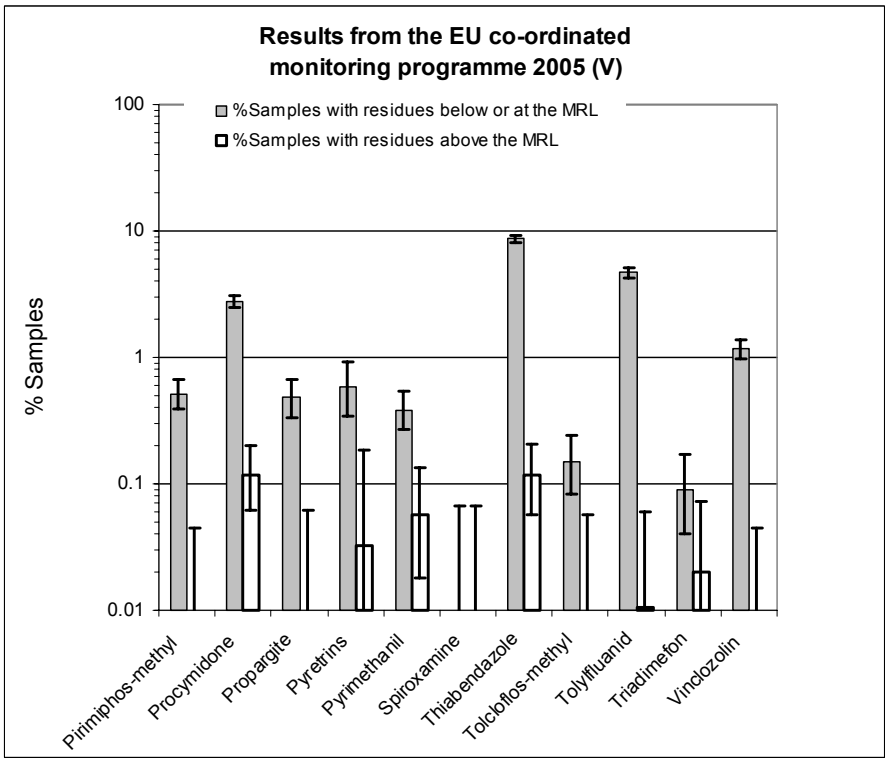


Figure 6e: Statistical evaluation of results from the EU co-ordinated programme (V)



5.2. Evaluation by pesticide

Figures 7 and 8 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 imazalil (14.4 % of the samples analysed for the substance), followed by chlormequat (13.6 %, analysed in pears and rice only), the maneb group (9.9 %), chlorpyriphos (9.0 %), thiabendazole (8.7 %), the benomyl group (8.2 %), diphenylamine (7.8 %, analysed in pears only), tolylfluanid (4.7 %), chlorpropham (4.5 %) and malathion (3.7 %). For 31 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 dimethoate, where 0.94 % of all samples exceeded MRLs. The main other exceedances, in decreasing order, are the maneb group (0.59 %), endosulfan (0.31 %) methomyl (0.21 %) , chlorpropham (0.20 %), chlorpyriphos (0.18 %) and the benomyl group (0.15 %). For 17 substances no exceedance has been reported.

Figure 7: Percentage of samples with residues at or below MRL (national or EC-MRL); results by pesticide (31 pesticides where less than 1 % of samples had residues at or below the MRL are not included in the chart.)

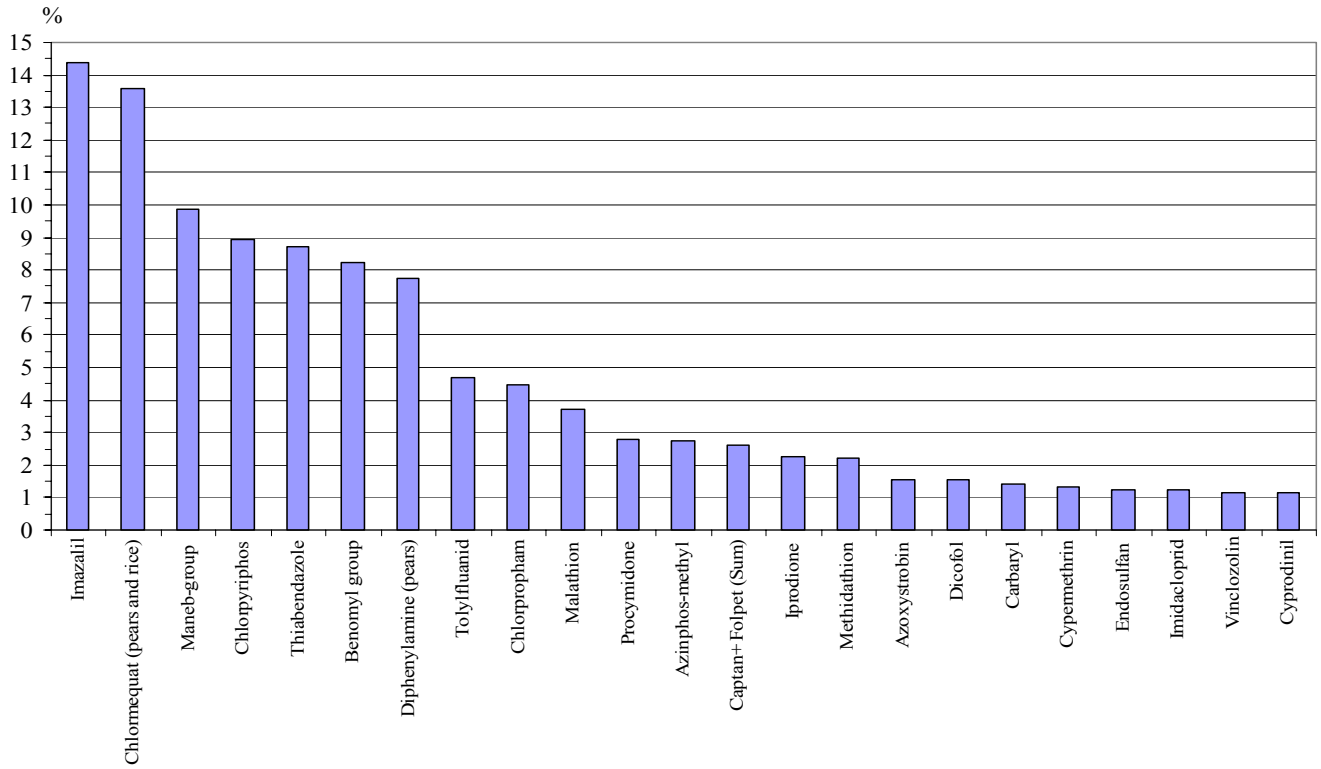
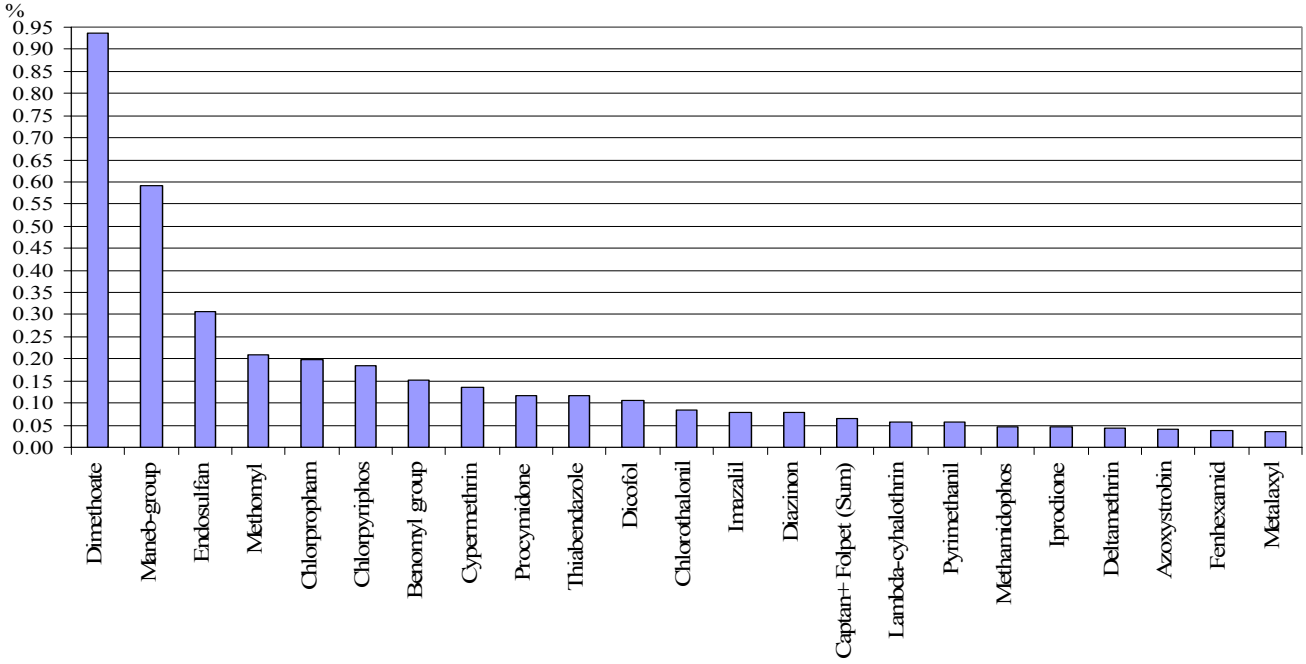


Figure 8: Percentage of samples with residues exceeding the MRL (national or EC-MRL); results by pesticide (14 pesticides where less than 0.04 % of samples had residues above the MRL are not included in the chart.)



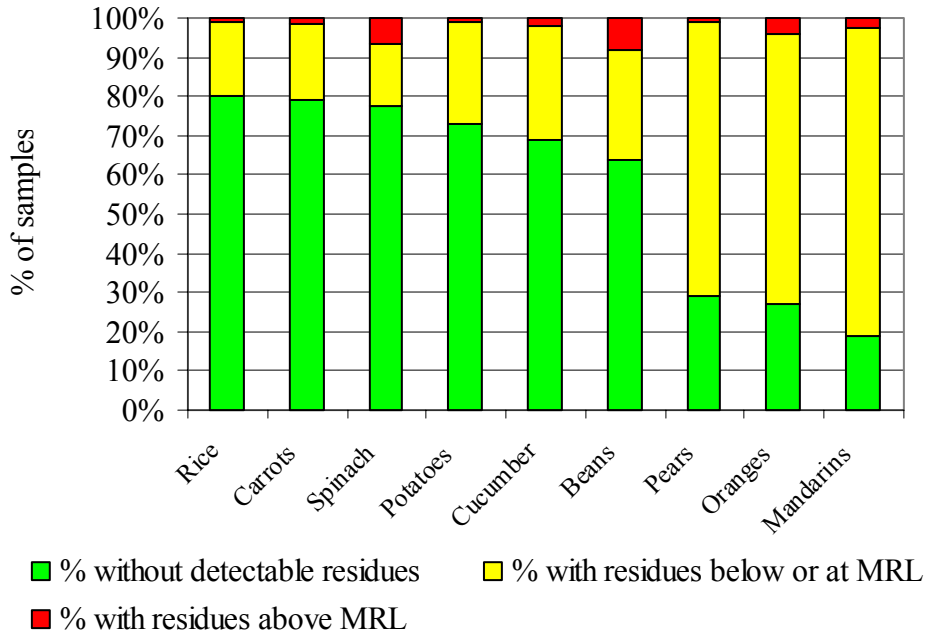
5.3. Evaluation by commodity

Table 6 gives an overview of the findings in the different commodities. With regard to all nine commodities investigated, no residues were detected in 58 % of the samples, 40 % of the samples contained residues of pesticides at or below the MRL (national or EC-MRL), and 2.8 % above the MRL. However, these percentages vary significantly between the analysed commodities, as the illustrated data in Figure 9 show.

Table 6: Residues found in the nine 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)**	**%**
Rice	847	680	80	157	19	10	1.2
Carrots	1759	1393	79	342	19	24	1.4
Spinach	1010	784	78	159	16	67	6.6
Potatoes	1909	1404	74	483	25	22	1.2
Cucumber	1555	1072	69	454	29	29	1.9
Beans	1122	717	64	311	28	94	8.4
Pears	2001	587	29	1398	70	16	0.8
Oranges	1598	430	27	1100	69	68	4.3
Mandarins	694	130	19	545	79	19	2.7
SUM	12495	7197	58	4949	40	349	2.8

Figure 9: Residues found in the nine commodities analysed in the EU co-ordinated monitoring programme



Mandarins had the highest percentage of samples with pesticide residues (79 %) below or at MRLs, 70 % of the pear samples and 69 % of the orange samples contained residues at or below the MRL. Samples of cucumber, beans and potato contained residues at or below the MRL less frequently (29%, 28 % and 26 %, respectively). Rice, carrots and spinach had the lowest percentage of samples containing residues (< 20 %).

Most of the samples did not exceed the MRLs. The highest percentage of MRL exceedances was found in beans (8.4 %), followed by spinach (6.6 %), oranges (4.3 %) and mandarins (2.7 %).

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 mandarins, followed by oranges and pears. These are the same commodities as in Table 6. Regarding MRL exceedance, the highest frequency was found in beans, followed by spinach and oranges. This is also consistent with the results in Table 6.

It can be concluded that mandarins, oranges and pears were the commodities on which pesticide residues were most often detected, whereas MRLs (national or EC-MRLs) were most often exceeded in beans, spinach and oranges.

Table 7: Residues found in individual determinations (ind. det.) in the nine 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)	%
Carrots	76,250	75,823	400	0.5	27	0.04
Spinach	42,590	42,316	195	0.5	79	0.19
Rice	30,949	30,793	146	0.5	10	0.03
Potatoes	79,155	78,600	533	0.7	22	0.03
Beans	50,249	49,607	525	1.0	117	0.23
Cucumber	66,058	65,296	733	1.1	29	0.04
Pears	88,603	85,226	3361	3.8	16	0.02
Oranges	67,532	64,848	2616	3.9	68	0.10
Mandarins	29,128	27,562	1546	5.3	20	0.07
TOTAL	530,514	520,071	10055	1.9	388	0.07

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 imazalil/mandarins, and residues of imazalil were detected in 74.83 % of mandarin samples (Table 8). This is followed by imazalil/oranges (67.73 %), chlorpyriphos/mandarins (49.76 %), thiabendazole/oranges (32.80 %), and the maneb group/pears (32.53 %).

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

Pesticide	**Commodity**	**% samples with detectable residues**
Imazalil	Mandarins	74.83
Imazalil	Oranges	67.73
Chlorpyriphos	Mandarins	49.76
Thiabendazole	Mandarins	38.99
Thiabendazole	Oranges	32.80
Maneb-group	Pears	32.53
Malathion	Mandarins	31.36
Tolylfluanid	Pears	28.24
Chlorpyriphos	Oranges	28.22
Chlorpropham	Potatoes	24.60
Benomyl group	Pears	21.37
Chlormequat	Pears	19.79
Benomyl	Mandarins	18.78
Azinphos-methyl	Pears	16.47
Captan	Pears	14.68
Methidathion	Mandarins	14.37
Benomyl	Oranges	13.94
Dicofol	Mandarins	13.25
Captan+ Folpet (Sum)	Pears	12.57
Malathion	Oranges	11.69
Chlorpyriphos	Pears	11.40
Methidathion	Oranges	10.61
Procymidone	Pears	10.47

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.

There were six combinations with MRL exceedances above 1 % (see Table 9). The highest percentages were found for the maneb group, which exceeded MRLs most often in spinach (5.12 % of all samples), followed by dimethoate in beans and oranges (3.9 and 3.02 % of all samples, respectively), cypermethrin in spinach (1.42 % of all samples), the benomyl group in beans (1.27 %), endosulfan in cucumber (1.07 %), chlorpropham in potatoes (0.95 %), endosulfan in beans (0.95 %), dimethoate in mandarins (0.92 %) and imazalil in mandarins (0.86 %). Notably the two pesticides dimethoate and endosulfan were part of six of these combinations.

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

Pesticide	**Commodity**	**% MRL exceedances**
Maneb-group	Spinach	5.12
Dimethoate	Beans	3.90
Dimethoate	Oranges	3.02
Cypermethrin	Spinach	1.42
Benomyl group	Beans	1.27
Endosulfan	Cucumber	1.07
Chlorpropham	Potatoes	0.95
Endosulfan	Beans	0.95
Dimethoate	Mandarins	0.92
Imazalil	Mandarins	0.86
Endosulfan	Spinach	0.86
Chlorpyriphos	Beans	0.85
Methomyl	Beans	0.84
Dicofol	Beans	0.81
Methomyl	Cucumber	0.79
Chlorothalonil	Beans	0.78
Diazinon	Mandarins	0.64
Maneb-group	Beans	0.63
Lambda-cyhalothrin	Spinach	0.61
Thiabendazole	Oranges	0.61
Iprodione	Spinach	0.57
Procymidone	Carrots	0.50

5.5. Indicative Exposure Assessment

5.5.1. Chronic risk

To estimate the chronic risk to the consumer for the commodities investigated in the EU co-ordinated programme, an indicative chronic risk assessment was carried out with the EFSA model[19], which is based on data on consumption of individual commodities submitted by different EU Member States. It should be noted that this model was not developed for the risk assessment of monitoring data, but for the risk assessment of proposed temporary MRLs according to Article 24 of Regulation (EC) 396/2005. The model is a first screening tool based on conservative assumptions[20]. The model was used for this EU monitoring report, because it is the only available model which contains data on food consumption from different EU Member States. 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. 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[21].

For 47 of the 55 pesticides of the co-ordinated programme the 90th percentile was below 0.01 mg/kg. For these pesticides, only insignificant intakes are expected. For eight pesticides (azinphos-methyl, captan, chlormequat, tolylfluanid, chlorpropham, thiabendazole, malathion, methidathion) the 90th percentile was above 0.01 mg/kg. The intake of the pesticide was calculated with the EFSA model for those commodities, in which the highest residues were found, and compared with the acceptable daily intake (ADI). The contribution from residues in other commodities was not calculated.

Oranges and mandarins are normally peeled, and potatoes cooked, before consumption. The German Federal Institute for Risk Assessment (BfR) published a collection of processing factors to take account of the reduction of pesticide residues by peeling, cooking or other reasons[22]. When these processing factors are taken into account for chlorpropham in potatoes (cooking), thiabendazole in oranges (peeling) and methidathion in oranges (peeling, assuming a similar distribution for mandarins), the calculated exposure is significantly lower.

As shown by the results in Table 11, the intake of pesticide residues remains clearly below the ADI in every case. The estimated exposure ranges from 0.03 % of the ADI for captan on pears, to 19 % of the ADI for thiabendazole on oranges. If processing factors are taken into account, the estimated exposure reaches not more than 4 % of the ADI (chlorpropham in potatoes).

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[19] http://www.efsa.europa.eu/etc/medialib/efsa/science/praper/mrl.Par.0009.File.dat/EFSA_acutechronic_model.xls

[20] For a full description of the model and the underlying assumptions please consult the following document: reasoned opinion on the potential chronic and acute risks to consumers' health arising from proposed temporary EU MRLs, 15 March 2007, http://www.efsa.europa.eu/de/science/praper/maximum_residue_levels/mrl_opinion.html

[21] Example: the 90th percentile for the content of residues of azinphos-methyl in pears is to be determined: 1,791 samples were analysed in total, out of which 1,496 samples contained no detectable residues. 295 samples showed different residue contents, categorised in 8 categories (from “up to 0.01 mg/kg” to “1.1-2 mg/kg”). 90 % of all values would comprise 1,791*0.9= 1,611.9 samples. The 1,611/1,612th sample falls within the samples of the category “0.021-0.05 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 ≤ 0.05 mg/kg

[22] http://www.bfr.bund.de/cm/218/bfr_programm_zu_verarbeitungsfaktoren_von_pflanzenschutzmittel_rueckstaenden.zip

Table 11: Indicative exposure assessment for **chronic** risk for those 8 of the 55 pesticides, where the 90th percentile was above 0.01 mg/kg

Compound	Commodity	90th percentile (mg pesticide / kg commodity)	ADI (mg pesticide / kg body weight/day) [23]	Highest intake[24]	Highest calculated TMDI in % of the ADI
Azinphos-methyl	Pears	≤ 0.05	0.005	Danish child	0.7
Captan	Pears	≤ 0.05	0.1	Danish child	0.03
Chlormequat	Pears	≤ 0.05	0.05	Danish child	0.07
Chlorpropham	Potatoes	≤ 1	0.05	Dutch child	12 (4 if a processing factor of 0.33 is considered)
Malathion	Mandarins	≤ 0.2	0.03	Dutch child	0.07
Methidathion	Mandarins	≤ 0.05	0.001	Dutch child	4 (0.1 if a processing factor of 0.03 is considered)
Thiabendazole	Oranges	≤ 5	0.1	German child	19 (2 if a processing factor of 0.1 is considered)
Tolylfluanid	Pears	≤ 0.2	0.1	Danish child	0.1

5.5.2. Acute risk

There is no generally accepted model for evaluating risks from acute exposure for monitoring data in the EU. As an example, the acute risk can be evaluated by using the EFSA model, which is based on IESTI (international estimated short term intake) equations. The joint FAO/WHO meeting on pesticide residues stated in their report of 2006[25] that the adequacy of applying the IESTI equations to assess the safety of food containing residues at levels found in monitoring and/or enforcement programs needs to be discussed further. As stated in chapter 5.5.1, the EFSA model was developed as a first screening tool, based on conservative assumptions. The calculation with this model implied that a person from a vulnerable group consumes, with an extraordinary appetite (the maximum food intake reported in the EU), food from the lot with the highest identified residue in the EU. The likelihood of this possibility is

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

[24] For children, the highest available average consumption figures for mandarins and potatoes relate to Dutch children, for oranges they relate to German children, and for pears to Danish children.

[25] http://www.fao.org/ag/AGP/AGPP/Pesticid/JMPR/DOWNLOAD/2006_rep/report2006jmpr.pdf

not evaluated. However, the EFSA model is the only available model which includes data on food consumption from different EU Member States. For children, the highest available consumption figures for large portions of beans and cucumbers relate to Dutch children, for carrots, potatoes and oranges they relate to UK infants, for mandarins and rice to UK toddlers, for pears to German children, and for spinach to Belgian children.

The evaluation of the acute risk was carried out for each of those 29 of the 55 pesticides of the EU co-ordinated programme, for which acute Reference Doses (ARfDs) have been set[26]. The highest residue found for each pesticide was used in this calculation. To consider worst case conditions default variability factors, taking into account unit-to-unit variability of single units, were used. A variability factor of 5 was used for cucumber, and 7 was used for oranges, mandarins, pears, carrots and potatoes[27]. Where appropriate and available[28], processing factors were used to take account of the reduction of pesticide residues by peeling or cooking. The estimated intake of the specific pesticide via a specific commodity was compared with the ARfD, as established by EU Regulatory Decisions, the EFSA or the JMPR.

Table 12: Indicative exposure assessment for **acute** risk for those 29 of the 55 pesticides, for which ARfDs have been set

Pesticide	Food item	ARfD	Max. Residue/ Range[29]	Pro-cessing factor	Intake in % of the ARfD		No. of samples > ARfD
					Adult	Child	
Acephate	beans	0.1	0.22	0.5	0.6	1	
Aldicarb	potatoes	0.003	0.06	-	**220**	**308**	1
Carbaryl	pears	0.01	1.09	-	**993**	**234**	32
Chlormequat	rice	0.05	0.7	-	11	18	
Chlorothalonil	cucumber	0.6	0.94	-	3	9	
Chlorpropham	potatoes	0.5	10.01-14.66	0.33	20-29	**102-149**	3
Chlorpyriphos	beans	0.1	1.3	-	7	15	
Cypermethrin	spinach	0.2	3.4	-	9	19	
Deltamethrin	rice	0.01	2.1	0.15	24	40	
Diazinon	pears	0.025	0.52	-	45	**189**	1
Dimethoate	beans	0.01	1.01 - 1.9	-	54 - **101**	**115-216**	3
Dimethoate	oranges	0.01	0.42	0.14	15	78	
Dimethoate	spinach	0.01	1.1	-	98	**249**	1

[26] JMPR, EFSA and EU Regulatory Decisions

[27] A variability factor of 3 was used for folpet in/on pears based on experimental data on variability, evaluated when setting the EU MRL.

[28] Database of BfR, see chapter 5.5.1 and footnote 22

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

Pesticide	Food item	ARfD	Max. Residue/ Range[29]	Pro-cessing factor	Intake in % of the ARfD		No. of samples > ARfD
					Adult	Child	
Dimethoate	pears	0.01	0.75	-	**161**	**683**	1
Dimethoate	mandarins	0.01	0.44	0.14	8	34	
Dimethoate	cucumber	0.01	0.21-0.23	-	41-45	**123-135**	2
Endosulfan	potatoes	0.02	3.0	-	**448**	**2308**	1
Endosulfan	pears	0.02	0.27	-	29	**129**	1
Endosulfan	cucumber	0.02	0.4	-	39	**117**	1
Endosulfan	oranges	0.02	0.21-0.23	-	27-29	**139-153**	2
Endosulfan	mandarins	0.02	0.69	-	46	**192**	1
Endosulfan	spinach	0.02	0.91	-	41	**103**	1
Folpet	pears	0.1	2.72	-	31	**109**	1
Imazalil	pears	0.05	1.01 - 2.9	-	43 - 90	**184-383**	2
Imazalil	oranges	0.05	6.6	0.05	17	88	1
Imazalil	mandarins	0.05	45.5	0.05	62	**253**	1
Imidacloprid	oranges	0.4	0.37	-	2	12	-
Lambda-cyhalothrin	spinach	0.0075	0.5	-	60	151	1
Malathion	mandarins	0.3	0.97	-	4	18	-
Maneb-group (propineb)	spinach	0.1	6.4	-	97	**583**	?
Methamidophos	beans	0.01	1.8	-	95	**204**	1
Methamidophos	spinach	0.01	0.63	-	56	**142**	1
Methidathion	oranges	0.01	1.4	0.03	11	56	-
Methidathion	mandarins	0.01	2.4	0.03	10	40	-
Methiocarb	beans	0.013	0.84	-	34	73	-
Methomyl	pears	0.0025	0.39	-	**335**	**1421**	16
Methomyl	beans	0.0025	0.3		64	**136**	1
Oxydemeton-methyl	spinach	0.0015	0.049	-	29	74	-
Parathion	oranges	0.01	0.14	-	36	**186**	1
Phosalone	pears	0.1	0.92	-	20	84	-
Pirimicarb	mandarins	0.1	0.15	-	2	8	-

Pesticide	Food item	ARfD	Max. Residue/ Range[29]	Pro-cessing factor	Intake in % of the ARfD		No. of samples > ARfD
					Adult	Child	
Pyrethrins	carrots	0.2	8.1	-	48	**257**	1
Tolylfluanid	pears	0.25	1.1	-	9	40	-
Triadimefon	beans	0.08	0.14	-	0.9	2	-

For 13 of the 29 pesticides the intakes for the highest detected residue concentrations in a composite sample have been assessed above the ARfD: aldicarb, carbaryl, chlorpropham, diazinon, dimethoate, endosulfan, folpet, imazalil, lambda-cyhalothrin, methamidophos, methomyl, parathion, pyrethrins. For these 13 pesticides further intake assessments were performed on results below the maximum detected concentration to identify any further samples exceeding the ARfD[30].

For the majority of ARfD exceedances, intakes above the ARfD were found for children, but not for adults. For 5 of the 29 pesticides (aldicarb, carbaryl, dimethoate, endosulfan and methomyl), intakes above the ARfD were found also for adults.

For six of the thirteen substances where the estimated exposure exceeded the ARfD (aldicarb, diazinon, folpet, lambda-cyhalothrin, parathion and pyrethrins), the calculated exceedances of the ARfD were singular cases.

For carbaryl, 32 exceedances of the ARfD were calculated in pears. The calculated intake in pears was up to 234 % of the ARfD for adults, and up to 993 % for children. Since 2005, the MRL for carbaryl in pears was reduced to 0.05 mg/kg (LOD) by Commission Directive 2006/59/EC[31]. Furthermore, Commission Directive 2007/355/EC[32] stipulates that in the EU all authorisations of plant protection products containing carbaryl must be withdrawn by 21 November 2007.

For methomyl, 16 exceedances of the ARfD were calculated in pears, and one in beans. The calculated intake in pears was up to 335 % of the ARfD for adults, and up to 1421 % for children.

For endosulfan, two exceedances of the ARfD were calculated for oranges, and one each for potatoes, pears, cucumber, mandarins and spinach. The calculated intake in potatoes was up to 448 % of the ARfD for adults, and up to 2,308 % for children (there were no processing factors available for this combination to take into account the reduction of endosulfan residues by cooking potatoes).

[30] 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 chlorpropham in potatoes with concentrations between 10.01 and 14.66 mg/kg. The intake assessment was carried for the concentrations of 10.01 and 14.66 mg/kg.

[31] Official Journal L 175, 29.6.2006, p. 61–76

[32] Official Journal L 133, 25.5.2007, p. 40–41

For dimethoate, three exceedances of the ARfD were found in beans, two in cucumber, and one each in spinach and pears. The calculated intake in pears was up to 161 % of the ARfD for adults, and up to 683 % for children.

For chlorpropham, three exceedances of the ARfD were found in potatoes. For methamidophos, one exceedance of the ARfD was found each for spinach and beans.

For imazalil, two exceedances of the ARfD were calculated for pears, and one for mandarins. The calculated intake in pears was up to 90 % of the ARfD for adults, and up to 383 % for children.

The maneb-group includes metiram and zineb, 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 or zineb (with no ARfD), to mancozeb, maneb or to propineb (for which an intake of up to 583 % of the ARfD was calculated for children).

In conclusion, the indicative assessment of acute exposure, based on worst-case scenarios, show exceedances of the ARfD for residues of thirteen pesticides. For six of these pesticides, the exceedances were isolated cases. However, a number of exceedances of the ARfD were estimated for residues of carbaryl and methomyl in pears. Dimethoate and endosulfan exceeded the ARfD in samples of several commodities.

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 76 % of samples were taken from EU produce, and approximately 21 % of samples were taken from imported produce. For 2.7 % of samples the origin was unknown.

On average, 13.47 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 3 samples/100,000 inhabitants to up to 61 samples/100.000 inhabitants. The three EEA States (with a relatively small population size) took up to 107 samples/100,000 inhabitants.

More information about the numbers and origin of the samples taken by the participating States is given in Table N 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[33]. This also means that laboratories have to comply with the European Standard EN 45001, which has been replaced by ISO/EN 17025.

Commission Recommendation 2005/178/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 2005, seven 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

[33] Repealed by Regulation (EC) No. 882/2004. See footnote 9.

requirements for accreditation of monitoring laboratories and their participation in proficiency tests.

Figure 10 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 2005, all participating States use at least partly accredited laboratories, while 20 out of 28 States use only accredited laboratories (71 %).

Figure 10: **Status of laboratory accreditation**. Number of States with accreditation of all, of some or of none of the monitoring laboratories in 2005 compared to previous years

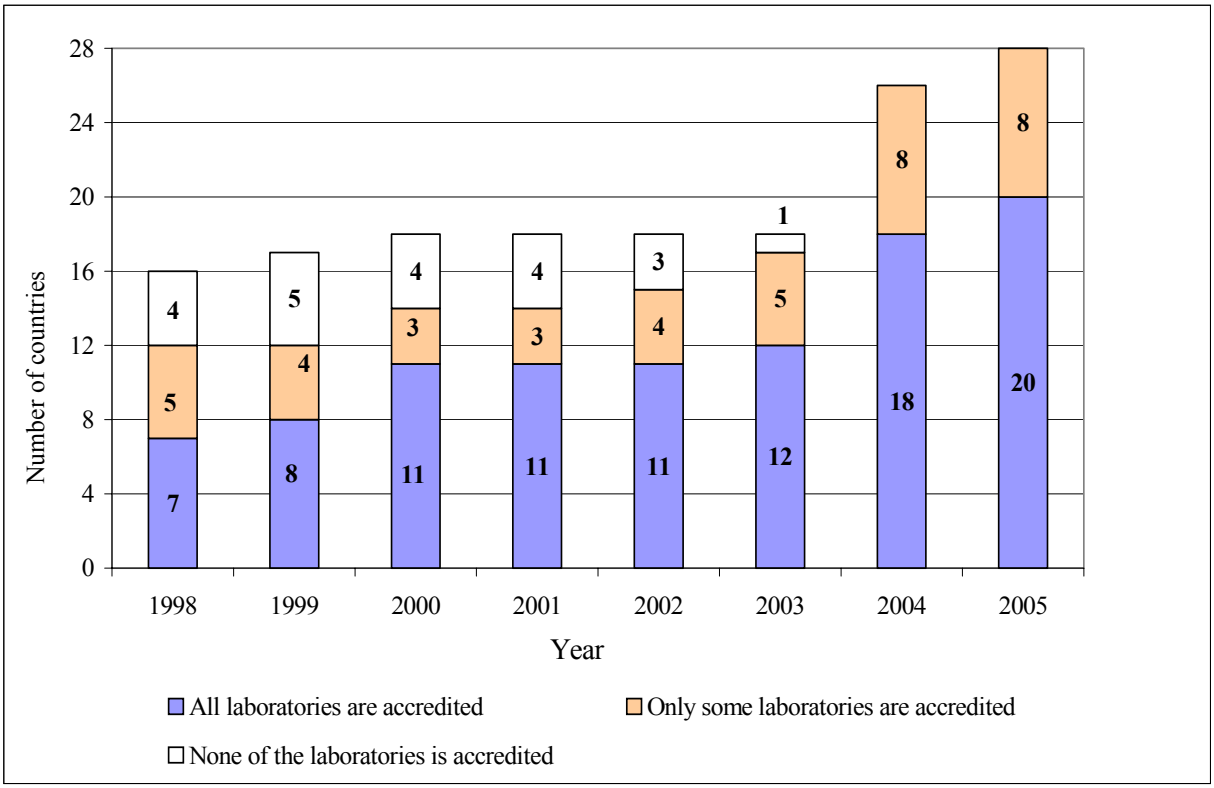
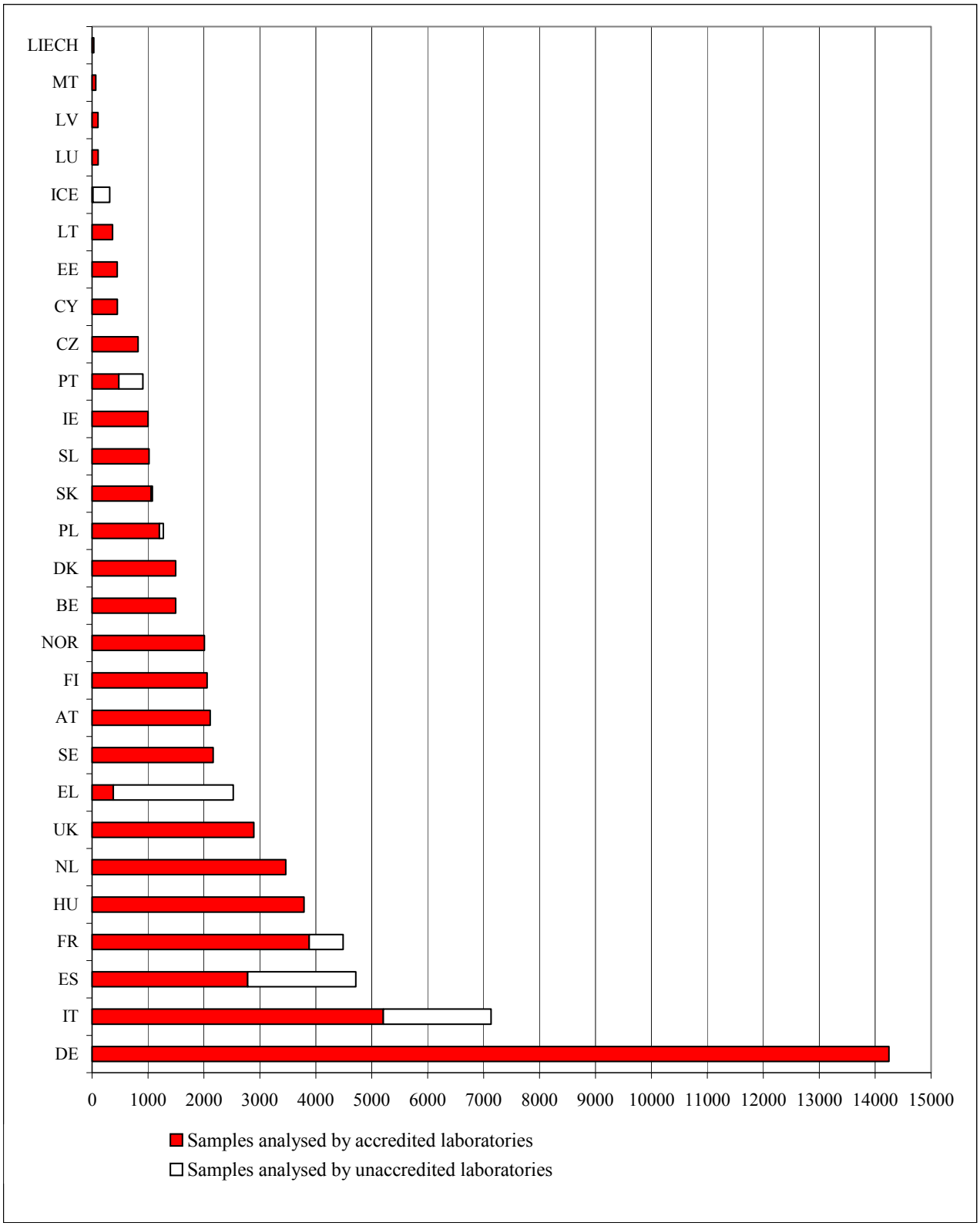


Figure 11 gives information about the number of samples analysed by accredited laboratories or by non accredited laboratories as submitted by the different participating States. There was a small number of samples from non-accredited laboratories in the new Member States Poland and Slovakia (5.6 % and 2 %, respectively). However, in the Mediterranean countries Greece, France, Italy, Spain and Portugal, the number of samples from non-accredited laboratories was significant (between 13 % and 85 %), and there was no considerable change since 2004.

Out of the total of 62,569 analysed samples (sum of fresh and processed products), 88% were analysed by accredited laboratories. This percentage is similar to 2004, when 87.5 % of the samples had been analysed by accredited laboratories.

Figure 11: Numbers of samples analysed by accredited laboratories or by non accredited laboratories by State in the year 2005



In addition to the information on accreditation of laboratories, Figure 12 gives an overview on the implementation of the EU Guidelines on Quality control procedures for pesticide residues analysis[34]. According to Article 4, second indent, of Regulation (EC) 645/2000, Member 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 12: Percentage of laboratories, which have fully, partially, or not, implemented the different chapters of the EU Quality Control Guidelines

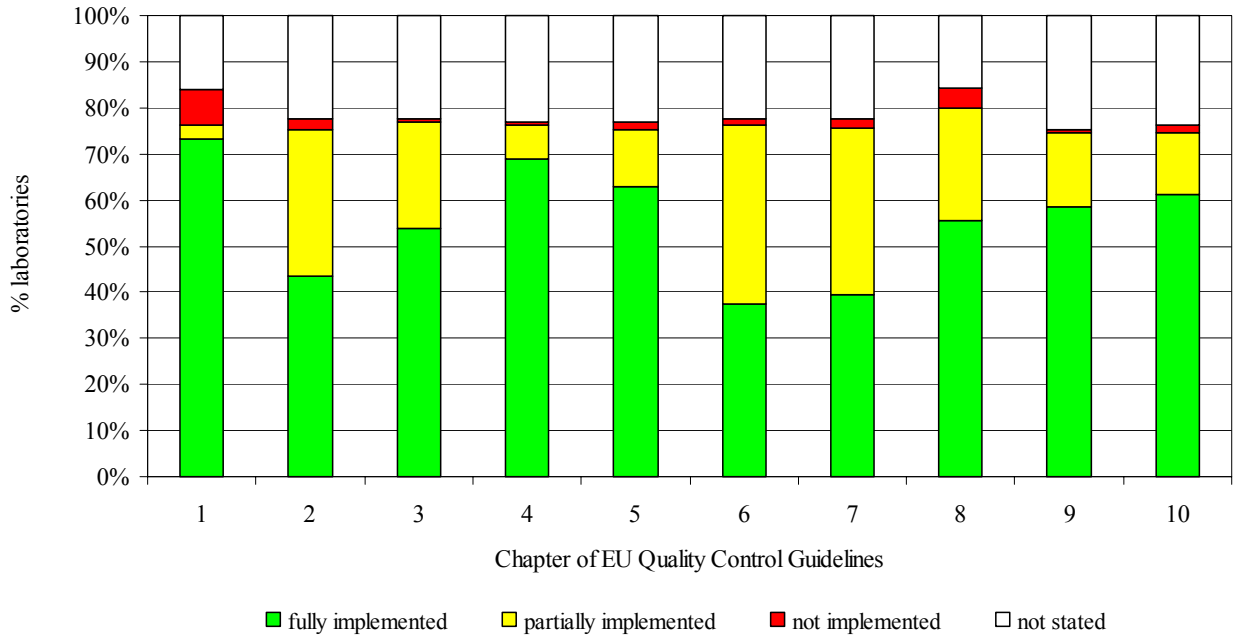


Figure 12 shows the percentage of laboratories, which have fully, partially, or not, implemented the different chapters of the EU Quality Control Guidelines (the information was not available for all 173 laboratories). The level of implementation varies between the different chapters: Chapters 1, 3, 4, 5, 8, 9 and 10 have been fully implemented by the majority of laboratories (54 - 73 %). Chapters 2, 6 and 7 are the least frequently implemented

[34] Quality control procedures for pesticide residues analysis (last amended by Document N° SANCO/10232/2006 of 24 March 2006, http://ec.europa.eu/food/plant/protection/resources/qualcontrol_en.pdf

chapters, and have been fully implemented by only 38 % to 43 % of the laboratories. However, only 1 % - 2 % of the laboratories stated that they did not implement chapters 2, 6 and 7 in their laboratories. This is a lower percentage than in 2004, when 7 % and 12 % of the laboratories, respectively, stated, that they did not implement chapters 6 and 7.

Member States reported the participation of 135 of the 173 laboratories (78 %) in proficiency tests. Laboratories from 26 of the 28 States participated in the EU proficiency test (EU PT 7)[35]. Another often-used proficiency test scheme was FAPAS[36]. 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 O of Annex 1.

8. RAPID ALERT SYSTEM

The Rapid Alert System for Food and Feed (RASFF) was established by Council Directive 92/59/EEC[37] on General Product Safety. In February 2002, new provisions entered into force as laid down in Regulation (EC) 178/2002[38] 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 2005, a total of 67 notifications regarding pesticide residues in food of plant origin were distributed within the RASFF. Six of the notifications were sent as Alerts. The majority of notifications (63) related to fruit and vegetables, in particular to lettuce (10), grapes (6), peppers (8), beans (8), citrus (7) and pears (3) of different origins. Four notifications related to herbs and spices.

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[35] Malta uses an Italian laboratory, and there was no information about participation in proficiency tests of the laboratory in Liechtenstein.

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

[37] 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.

[38] 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 2005 calendar year in the 25 participating Member States of the EU and the three EEA States Norway, Iceland and Liechtenstein. This year, data from the two new Member States Estonia and Latvia were included in the report for the first time.

A total of 62,569 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, 706 different pesticides were sought. The analytical capabilities of laboratories in the participating States ranged from 44 to 631. On average 146 substances were sought in the surveillance samples of fruit and vegetables samples. Of all pesticides analysed for, 349 substances (49 %) were detected.

Overall, no residues were detected in 54.3 % of the samples, while a further 41.0 % 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 51 %, the percentage of samples with residues at or below the MRLs is 44 % and the percentage of MRL exceedances is 4.9 %. For processed food, no residues were found in 67 % of the samples, residues at or below the MRLs were detected in 31 %, and exceedances of the MRLs in 1.8 % of the samples. For baby food, no residues were found in 94 % of the samples, residues at or below the MRLs were found in 5 %, and exceedances of the MRLs in 0.6 % 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 (6.5 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 to a current level of 43 % (in fresh products and cereals). The frequency of samples exceeding MRLs is the same as in 2004 and slightly lower than in the previous two years 2003 and 2002. The frequency of samples with multiple residues in fresh fruit, vegetables and cereals shows an increasing tendency, rising to 26.7 % in 2005.

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, nine commodities (pears, beans, potatoes, carrots, oranges or mandarines, spinach, rice and cucumber) were analysed for 55 pesticides. The list of pesticides analysed in 2005 includes 41 substances analysed in 2004, with 14 additions. Overall, 12495 samples were analysed in this programme.

The most frequently detected pesticides were imazalil, chlormequat (analysed in pears and rice only), the maneb group, chlorpyriphos, thiabendazole, the benomyl group ,

diphenylamine (analysed in pears only), tolylfluanid, chlorpropham and malathion. The highest frequency of MRL exceedances were found for dimethoate, the maneb group, endosulfan, methomyl, chlorpropham, chlorpyriphos and the benomyl group.

Mandarins, pears and oranges had the highest percentage of samples with residues, and 79 % of the mandarin samples contained residues at or below the MRL. Samples of cucumber, beans and potato contained residues at or below the MRL less frequently (26 % to 29). Rice, carrots and spinach had the lowest percentage of samples containing residues (< 20 %). Most of the detected residues did not exceed the MRLs. The highest percentage of MRL exceedances was found in beans (8.4 %), followed by spinach (6.6 %), oranges (4.3 %) and mandarins (2.7 %).

The pesticide-commodity combination where residues were detected most frequently was imazalil/mandarins, and residues of imazalil were detected in 74.8 % of mandarin samples. This is followed by imazalil/oranges (67.7 %), chlorpyriphos/mandarins (49.8 %), thiabendazole/oranges (32.8 %), and the maneb group/pears (32.5 %). The highest percentages of MRL exceedances in a particular commodity were found for the maneb group, which exceeded MRLs most often in spinach (5.12 % of all samples), followed by dimethoate in beans and oranges (3.9 and 3.0 % of all samples, respectively), cypermethrin in spinach (1.4 %), the benomyl group in beans (1.3 %), endosulfan in cucumber (1.1 %), chlorpropham in potatoes (0.95 %), endosulfan in beans (0.95 %), dimethoate in mandarins (0.92 %) and imazalil in mandarins (0.86 %). Notably the two pesticides dimethoate and endosulfan were part of six of these combinations.

Indicative chronic (long-term) exposure assessments demonstrate that the intake of pesticides remains clearly below the ADI[39] 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, show exceedances of the ARfD[40] in some of the samples. In particular, exceedances of the ARfD were estimated for residues of carbaryl and methomyl in pears. Dimethoate and endosulfan exceeded the ARfD in samples of several commodities.

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 2005, all participating States used at least some accredited laboratories, while 20 out of 28 States (71 %) use only accredited laboratories. Overall, 88 % of the monitoring samples were analysed by accredited laboratories in 2005.

The participating States reported the participation of 135 of the 173 laboratories (78 %) 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.

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[39] Acceptable Daily Intake

[40] Acute Reference Dose