REPORT FROM THE COMMISSION TO THE COUNCIL

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Introduction


In particular, Article 7(5) of Council Directive 86/362/EEC and Article 4(5) of Council Directive 90/642/EEC (as last amended by Directive 1999/71/EC³) stipulate that the Commission shall forward to the Council, before the end of 1999, a report on the application of these Articles concerning the monitoring of pesticide residues. This Report is submitted to the Council in accordance with those provisions. It contains the following elements:

1. Objectives of the monitoring,
2. The authorities carrying out the monitoring,
3. Planning the monitoring,
4. Organisation of the monitoring,
5. Reporting the results,
6. Actions by the Commission,
7. Missions by the Food and Veterinary Office
8. Points of concern,

(1) Objectives of the monitoring

The general objective of the monitoring is to enable the Commission to work towards a system that could permit the estimation of actual dietary exposure. Other objectives include the estimation of the extent of infringements of maximum residue levels and the actual levels of residues with respect to the maximum residue levels established.

³ OJ L 194, 27.7.1999, p. 36.
(2) **The authorities carrying out the monitoring**


Member States have designated the appropriate authorities to carry out the monitoring.

The Articles also stipulate that monitoring is to be carried out in accordance with Council Directives 89/397/EEC\(^4\) and 93/99/EEC\(^5\) on the official control of foodstuffs. The latter directive requires that laboratories are accredited by 1 November 1998.

(3) **Planning the monitoring**

It was originally provided for that Member States submit their national plans for the following year to the Commission by 30 June each year. This caused difficulties for many Member States because their forward planning is, to various extents, contingent on the analysis of the monitoring results from the previous year. The problem was foreseen in the original Council Directives that delegated the power to change the dates to the Commission. The problem was solved by Commission Directive 1999/65/EC\(^6\) that changed the deadline from 30 June to 30 September. This should enable Member States to submit their national plans in the future in time to the Commission.

The Commission has since 1996 submitted annually draft Monitoring Recommendations to the Standing Committee on Plant Health for opinions. Following positive opinions, these were then adopted by the Commission and were published in the Official Journal as Monitoring Recommendations 96/199/EC\(^7\) (for 1996), 96/738/EC\(^8\) (for 1997), 97/822/EC\(^9\) (for 1998), 1999/333/EC\(^10\) (for 1999, including, for the first time, guidance on quality control procedures), and for 2000\(^11\).

These Monitoring Recommendations define the product/pesticide combinations to be monitored in the year in question. These combinations are chosen to be in line with a larger overall strategy to monitor over a 5-year period a sufficient variety of products for groups of pesticides to enable the Commission and the Member States to get a view on the actual dietary intake of these pesticides. In 2001, the first 5-year cycle will be complete and it should then be possible to make a first Community-wide estimation of the actual intake of the first group of 5 pesticides during this period, for the main fruit and vegetable components of the diet that contain these pesticides. This will be followed by similar activities in the succeeding years.

In the Monitoring Recommendation for 1999, another new element - the variability exercise was introduced. This should allow the Commission and the Member States to address acute intake concerns for certain acutely toxic pesticides. In practice the exercise involves, for pesticide/product combinations two samples are taken, one is analysed as a composite sample

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\(7\) OJ L 64 of 14.3.1996, p. 18.


and the second is divided into individual items, which are individually analysed in order to be able to evaluate the variability within the sample.

(4) Organisation of the Monitoring

There is a wide variation among the Member States in the amount of samples analysed each year. In 1997, it varied from 220 samples in Luxembourg to 9,540 samples in The Netherlands. Since the Directives only stipulate the obligation to sample and do not mention a minimum number of samples to be taken, it is up to each Member State to define for itself the number of samples necessary to ensure compliance. Most of the annual national monitoring reports received by the Commission described the criteria used for the products to be analysed. The number of samples and pesticide residues monitored is mainly based on analytical capabilities. The resources and the state of the art of the laboratories in the Member States have not always been satisfactory in the countries visited to date. These issues were also discussed during various missions to the Member States’ authorities (see 7 below). Criteria are also given for the choice of crops. In general the authorities try to monitor according to what products are on the market and in addition, they try to respect the imported/domestic production ratio in their planning. The Commission does not, however, have information from all Member States on these aspects. Even where criteria are provided, that does not always mean that the situation is satisfactory, as often, the main criterion driving the sampling is the availability of resources and this tends to be limited.

(5) Reporting the results

The Directives stipulated that the Member States had to report the results of the previous year to the Commission by 31 August. The Commission, in turn, then had to forward this information to the Standing Committee on Plant Health by 30 September. As with the deadline for the planning (see 3 above) there were difficulties meeting the latter deadline each year. The problem was also solved by Commission Directive 1999/65/EC that changed the deadline from 30 September to 31 December.

At an early stage in the annual monitoring activity there was consensus among the Member States and the Commission about making the information available to the general public. To date, reports on monitoring for pesticides residues in the European Union are available for the first two annual exercises (1996 and 1997) and these have been published on the public Internet site of DG SANCO (http://europa.eu.int/comm/dg24/health/fnaoi/reports/pesticides/mon_rep/index_en.html). At the time of publication, the Commission issued Press Releases with statements from the competent Commissioners.

The actual levels of pesticides residues detected in the 1996 and 1997 exercises were examined in relation to the Community MRL’s that were set for them. The results were consistent from one year to the next. In about 60% of the analysed samples in national programmes, no detectable residues were found. Less than 4% of samples contained pesticides residues in excedence of an MRL. In the Community co-ordinated programme, 0.3-0.5% of samples contained pesticides residues exceeding MRLs. In one case, a product contained such a high level of residue that the ADI was temporarily exceeded but this has to be interpreted in conjunction with the WHO conclusion that short-term temporary exceedences of the ADI are not a cause for concern. Realistic intake calculations using the available actual data showed that there is no chronic or acute health concern for any of the limited number of pesticide-product combinations analysed. Therefore it was considered

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12 Guidelines for predicting dietary intake of pesticide residues, WHO/FSF/FOS/97.7.
unnecessary for any action to be taken at Community level on public health grounds with respect to reported infringements of the maximum levels. In 2001, when we will have a more complete overview on the dietary intake for the first group of pesticides, this aspect will be reconsidered. For serious exceedences of MRLs and for cases where there are high risks of acute toxicity the Community Rapid Alert System for foods can be and is used. Discussions are currently underway between the Commission and the Member States on how to improve its functioning in the area of pesticides residues in foods.

In reporting infringements of MRL’s the issue was raised when, technically and statistically speaking, is an MRL exceeded in a way that one can speak of an infringement. In the Directives this was not specified, and Member States have different views and responses for such cases. Until now this has not led to trade problems, but potentially problems could arise and it should be useful to solve this problem.

(6) Actions by the Commission

As described in sections 3 and 5 above, the Commission has already, in Directive 1999/65/EC, introduced amendments to the dates of notification and reporting.

The Commission has also introduced detailed implementing rules in the form of guidance notes concerning formats and about quality assurance, which were published along with the Monitoring Recommendation for 1999. These documents are under constant revision and funding for these activities is foreseen in a draft monitoring Regulation submitted to the Standing Committee on Plant Health for an opinion on 2 December 1999.

The Member States also participate in the regular proficiency tests that are co-organised and funded by the Commission. In view of the future enlargement of the Community, the Services of the Commission have agreed to allow participation of laboratories from Central and Eastern European countries in these activities.

The draft Regulation also provides for regular proficiency tests, updating of the quality assurance guidance document and the calculation of the actual consumer intake at the end of the 5-year monitoring cycle. Accreditation is a matter for national accreditation bodies to do. Their tasks are facilitated by the Commission through the organisation and sponsoring of biennial proficiency tests and through the development of quality assurance guidelines.

(7) Missions by the Food and Veterinary Office

Missions are carried out by the Food and Veterinary Office of the Commission to Member States to check the conditions under which the monitoring is performed and to verify whether the specifications of Articles 4(4) and 3(4) of Council Directives 86/362/EEC and 90/642/EEC, respectively, are being met. These missions sometimes also include checks to monitor the controls of member states according to Council Directive 91/414/EEC (Article 17) on marketing and uses of plant protection products.

The reports of these missions are published on the public Internet site of DG SANCO (see (5)). Missions to five member states have been undertaken so far. Accreditation of the laboratories has been and still is a problem and in many countries. In two countries (Portugal and Ireland) there was no accreditation at all.
Points of concern

1) Pesticide residues in foods of animal origin are not monitored in the Community co-ordinated monitoring programme under the above articles in the Directives. They are monitored in the Member States under the provisions of Directive 96/23/EC (Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC). This directive also provides that reports are sent to the Commission by 31 March each year. However, there are no provisions for the compilation of the results at Community level and for their inclusion in the Annual Commission Reports provided in the articles of Directive 96/23/EC. Furthermore, the objective of the monitoring undertaken within Directive 96/23/EC is to ensure compliance with Community legislation and neither the scale of the monitoring nor its design lends it to an easy complementarity with the coordinated community monitoring programme foreseen under the articles.

2) MRLs for pesticides in products of animal origin are set by the Commission (Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin13). Some pesticides may have a dual use. When used in veterinary medicines, these substances are evaluated according to Council Regulation 2377/90/EEC14, laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. The evaluation of the data is made within the EMEA by the Committee for Veterinary Medicinal Products (CVMP). The MRLs following this evaluation are set up by the Commission.

Some discrepancies in residue definitions and the products to which they apply reflect differences in the methodology of calculation resulting on different residue levels for the same substance in the same foodstuff. It was noted that the values proposed by the scientific Committee for Veterinary Medicinal Products are stricter than those adopted for pesticides.

These discrepancies were also found at global level of the Codex Alimentarius work. The Services of the Commission are therefore working to resolve these differences both within the Community and in the work of the Codex Alimentarius.

However, any further adjustment will require the modification of the current legislation. Therefore a parallel review of the Annexes of the Residue Directives and the Annexes of Regulation 2377/90 would be desirable to improve the transparency and applicability of Community legislation.

3) Council Directive 97/41/EC (of 25 June 1997 amending Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC relating to the fixing of maximum levels for pesticide residues in and on, respectively, fruit and vegetables, cereals, foodstuffs of animal origin, and certain products of plant origin, including fruit and vegetables)15 extended the scope of Community MRL’s to include animal feedingstuffs. However, residues in animal feedingstuffs are not monitored to the extent that primary agricultural products are. It is only when feedingstuffs also happen to be primary agricultural products (e.g. cereals) that there is sampling compliance with the Directives although potentially, feedingstuffs can be monitored under Directive 96/23/EC.

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4) Member States have an obligation to monitor the levels of pesticides residues in food and agricultural commodities but there are no “minimum” requirements and the monitoring activity varies considerably among them. Because of the limited number of commodities to be analysed in the co-ordinated programme, it takes five years before intake estimates can be carried out and then even only for a limited number of pesticides. There are also a limited number of accredited laboratories capable of monitoring in the Member States.

5) The rate of excedence of Community MRLs, although limited, is a matter for concern and for further investigation. It may be linked to the way that Community MRL’s are set (whereby there is a finite statistical probability of excedence) but it may also be linked to unauthorised uses of the pesticides. There has been a concern about excedences in tropical fruits, but this may have been caused by the few non-zero import tolerances granted and the lack of guidance about submission of data for these. This situation may improve following the issuance of guidelines by the Commission in October 1999.

6) The competence of the Commission to make inspections in the Member States is limited.

7) In working towards a system permitting estimation of the actual exposure to pesticides residues, complementary data is required whose collection is not provided for in the Directives. This data mainly concerns actual diets of the population and of population subgroups and exposure to pesticides from other sources that are not monitored under the articles (e.g. water, occupational, domestic, products of animal origin).

The Commission addresses many of these points in its White Paper on Food Safety and is addressing the others already in legislation in preparation.

(9) Conclusions and Recommendations.

The application of Article 7 of Council Directive 86/362/EEC and Article 4 of Council Directive 90/642/EEC, concerning the monitoring of pesticide residues generally works well throughout the Community and has enabled, for the first time, an appreciation of the actual situation in the Community regarding the exposure of consumers to pesticide residues in fruit and vegetables. It is encouraging to note that the levels of pesticides residues detected to date do not pose a health risk to the consumer. Nonetheless, there is no room for complacency and the Commission should, with the Member States, continue to monitor closely the levels of pesticides residues in food and to address the points of concern listed in section 8, above. In particular, the Commission favours an integrated approach, as proposed in the White Paper on Food Safety. This approach by which the Commission should eventually be able to evaluate the presence of all kinds of substances such as residues of contaminants, pesticides, additives, veterinary medicines etc. in food, can only be achieved if there are integrated community monitoring programmes for all of these types of substances, and a set of standard diets for several types of European consumers by which the presence of these substances can be evaluated.