

INTRODUCTION TO EC PESTICIDES RESIDUES LEGISLATION

This document provides summary information on Commission and Member State activities in the area of legislation for pesticide residues and on the setting of maximum residue limits (MRLs) for pesticides residues in food commodities.

1. INTRODUCTORY REMARKS

The Community has in place a regime permitting the setting, on a scientific basis, of MRLs protecting adequately the whole consumer population, including infants, and being based on a shared responsibility between the Community and the Member States. The work is under constant review.

Legislation for pesticide residues, including the setting of maximum residues limits (MRLs) in food commodities is a shared responsibility of the Commission and the Member States. To date, more than 17,000 Community MRLs have been set for various commodities for 133 pesticide active substances. These are listed in the files accompanying this text on this site.

It is important to note that these MRLs are not maximum toxicological limits. They are based on good agricultural practice and they represent the maximum amount of residue that might be expected on a commodity if good agricultural practice was adhered to during the use of a pesticide. Nonetheless, when MRLs are set (see section 4 below), care is taken to ensure that the maximum levels do not give rise to toxicological concerns.

For those pesticide/commodity combinations where no Community MRL exists, the situation is not harmonized and the Member States may (subject to satisfying their obligations under the Treaty) set MRLs at national level to protect the health of consumers.

The work of the Commission in this area, acting in concert with the Member States, is aimed at gradually fixing Community MRLs for all pesticide/commodity combinations. Until that work is complete, and where unharmonised national MRLs exist, there is always a possibility of trade disputes within the Community. To cover this eventuality, a conciliation procedure exists to resolve cases where differing national MRLs lead to barriers of trade within the Community.

Legislation at Community level dates back to November 1976 when Council Directive 76/895/EEC fixed MRLs for 43 active substances in selected fruits and vegetables. The MRLs that were set in the Directive were based the best data available at that time. These older MRLs are gradually being reviewed and, where appropriate, being replaced with newer MRLs based on the newer information and the higher standards of today.

Current pesticide MRL legislation is derived from/based on four Council Directives:

- (a) Council Directive 76/895/EEC establishing MRLs for selected fruits and vegetables

- (b) Council Directive 86/362/EEC establishing MRLs for cereals and cereal products;
- (c) Council Directive 86/363/EEC establishing MRLs in products of animal origin; and
- (d) Council Directive 90/642/EEC establishing MRLs in products of plant origin, including fruits and vegetables.

A list of these and all relevant amending legislation in this area is given in the programme of work which accompanies this file on this site.

2. WORK ALREADY DONE

Lists of all substances for which Community MRLs have been set for one or more commodities is given in the accompanying files on this site.

The procedures used for setting these MRLs are described in Section 4 (below). The existing MRLs have been set on the basis of the best available information so that, in general, they should be considered as representing an adequate level of protection for all consumers. The Commission has responded to recent concerns about the adequacy of the level of protection that the MRLs might afford to young infants by adopting new legislation (Directive 99/39/EC) which places severe restrictions on the use of pesticides in the production of food for infants and young children.

Until 1997, MRLs were fixed for active substances in Council Directives only for raw commodities. Directive 97/41/EC changed three important aspects of the work:

- (a) it provided for a system to set MRLs in processed products and composite foodstuffs, based on the MRL's fixed for the raw agricultural products,
- (b) it established a conciliation procedure through which cases where national MRLs leading to barriers of trade within the Community could be resolved, and
- (c) it transferred the competence for setting MRLs from the Council to the Commission.

3. WORK PLANNED AND/OR IN PROGRESS

3.1 Programme of work

A programme of work on pesticides residues was agreed on 30 July 1999 in the Standing Committee on Plant Health. This document (reference doc. 9205/VI/97 rev.-8) is posted on this site and is also available on request.

The document gives complete details of current and planned work and it includes details of procedures, timetables, substances, and legislation.

3.2 Work in the framework of Directive 91/414/EEC

In 1991, the Council adopted Directive 91/414/EEC concerning the placing of plant protection products on the market. This Directive provides for the Commission to examine pesticide active substances under *all* their safety aspects (consumer protection

(~ residues), worker protection, fate and behavior in the environment, ecotoxicology). It distinguishes between “existing” and “new” substances. The programme of work on pesticides residues in food is gradually being aligned with that on the evaluation of pesticides.

3.3 Coordination activities

Work on the setting of MRLs is very closely coordinated with parallel activities on the evaluation of pesticides active ingredients as well as similar Commission activities where Community legislation covers pesticides e.g. Directive 67/548 on the classification and labelling of dangerous substances. At the global level, a continuing liaison is maintained with the Codex Alimentarius (responsible for setting MRLs at global level) and with the Pesticides Programme of the OECD. The EU Member States are actively involved in all aspects of the MRL setting process, from the evaluation of dossiers through to voting (in the Standing Committee on Plant Health) on necessary regulatory measures. Regular contact and consultation is also maintained with the Scientific Committee for Plants which can be consulted for independent advice on questions of a scientific nature e.g. adequacy of evaluation methodologies, consumer exposure assessments etc.

4. HOW MRLs ARE SET

In principle, MRLs are set on the basis of the following:

- (a) Supervised agricultural residue trials establish the residue level in or on an agricultural crop treated with a pesticide under specified use conditions (Good Agricultural Practice = GAP),
- (b) Using appropriate consumer intake models, the daily residue intake under normal and worst case conditions can be estimated for the European population and for national populations and sub-populations (e.g. infants),
- (c) Data from toxicological tests on the pesticide allow for the fixing of an “acceptable daily intake” (ADI). Usually this involves finding the highest dose that would produce *no* adverse effects over a lifetime (chronic) exposure period and then applying appropriate safety factors. Recently, concerns have been raised that some residues may be toxic after short-term (acute) exposure and that chronic exposure scenarios may not be appropriate for setting the MRL. This topic is being heavily discussed within the Commission and in the Member States and methodologies to set Acute Reference Doses (ARfD) and consumer intake models are being reviewed to cover for this possibility.
- (d) If the estimated daily consumer intake for all commodities calculated under (b) is lower than the ADI calculated under (c) then the residue level under (a) is set as the MRL. In cases where the calculated intake is higher, the use conditions described in (a) need to be modified to reduce the residue level in the commodity. If this is not possible the use of that pesticide on that crop cannot be tolerated and the MRL is set at the limit of determination (effectively zero).

MRLs for processed products and composite foodstuffs are normally calculated on the basis of the MRL set for the agricultural commodity by application of an appropriate dilution or concentration factor. For composite foodstuffs MRLs are calculated taking into account the relative concentrations of the ingredients in the composite foodstuff. Only exceptionally may specific MRLs be determined for certain processed products or certain composite foodstuffs.

5. MONITORING OF PESTICIDES IN FOOD

Since 1996 the Commission has made annual recommendations concerning Coordinated Community Monitoring Programmes for pesticides residues in food. These annual Community Programmes complement the national monitoring programmes of the Member States. The report of the results of the 1996 programme was published late in 1998 and the report for 1997 will be posted on this site in the coming weeks. The objectives of the programmes are (i) to ensure compliance with residues legislation and (ii) to better estimate the actual exposure of consumers to pesticides residues in food.