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Briefing on the European Commission Proposal for a Regulation on maximum residue levels of pesticides in plant and animal products [COM (2003) 117]

Prepared for the European Parliament Committee on Environment, Public Health and Consumer Policy

INTRODUCTION

The Committee on Environment, Public Health and Consumer Policy of the European Parliament has made a contract with the European Academies' Science Advisory Council (EASAC) for the provision of technical-scientific advice in the area of Environment Public Health and Food Safety (project EP/IV/A/2003/09/02). As part of the contract, the Committee has commissioned a review of the European Commission's proposal for a Regulation on maximum residue levels of pesticides in products of plant and animal origin, contained in the Commission document COM (2003) 117.

Four independent EASAC experts have reviewed the draft Directive, and their comments are summarised in this paper. The experts come from Denmark, Italy and The Netherlands. Their expertise covers the fields of environmental chemistry, environmental health and pesticides.

This review focuses on the scientific merits of the proposal and touches briefly on some implementation and trade issues that are likely to arise from it. It does not deal with broad economic issues, which are not within the competence of the reviewers.

SUMMARY

In this document, the Commission proposes a simplification of the current arrangements for securing pesticide safety within the EU. It proposes unified arrangements for setting safety levels and transfers responsibility for them from Member States to the European Food Safety Authority (EFSA).

The opinion of reviewers was that the harmonisation and simplification proposed is useful in principle. There are, however, a number of reservations about how it would work in practice and these are detailed below.

BACKGROUND

This proposal is for a simplification and harmonisation of the arrangements for protecting public health against toxic effects of pesticide residues. The current position is that member states have responsible for setting temporary (provisional) Maximum Residue Levels (MRLs) for new chemicals. Member states have then to notify their conclusions to Brussels and other member states, which may then respond - for example, by adopting them themselves.

The member states also play an important role in the production of the monographs necessary to substantiate their action.

Under the Commissions proposal, as our reviewers understand them, these tasks would be taken over by the EFSA. Risk assessment, under the proposal, will become a responsibility of EFSA, which will use its network and institutes in member states to provide an opinion on the safety of the MRL for a particular pesticide.

THE COMMISSION'S APPROACH

The proposed method to establish MRLs is in accordance with the approach already used in most member states. The MRL is first fixed at the lowest residue level measured in the various crops under conditions of Good Agricultural Practice (GAP). However, as is noted in the Commission's proposal (p. 5), GAP with authorised use of pesticides varies between member states (e.g. due to climate) and may give rise to different residue levels. The EC proposal is to use the highest levels ('critical' GAP) to set MRLs, unless this level is not considered safe for the consumers. This proposal means that member states using GAP developed to minimize the use of pesticides will then use the higher MRLs applied in countries using less environmentally desirable methods.

An alternative approach would be to accept the higher (less stringent) MRLs from countries using the 'critical' GAP only provisionally and to guide these member states towards improving their agricultural methods. Our reviewers believe that a provision for this would strengthen the Commission's proposal and ensure that public protection in member states remains at the current levels. Member States may find it presentationally unacceptable to raise the MRLs in use in their jurisdictions.

The next step in setting the MRLs is to make an assessment of the value based on GAP to ensure that it is safe for the consumers. This assessment will depend on the total exposure level and hence on dietary habits, which vary considerably between member states. According to the Commission's proposal, all member states will provide EFSA with data on national diets, authorised

pesticide use, and agricultural practices. Then EFSA will combine these data with available toxicity data to determine the safety of each MRL.

This evaluation could be complicated, since a high MRL for a food item (such as chilli) consumed only in small amounts may be less problematic than a lower MRL for an item (such as carrots) sometimes consumed in substantial amounts.

It is not apparent how differences in diets – and occurrence of ‘extreme’ diets – will be taken into account. Most previous evaluations have been based on average intakes, but in some instances marginal distributions, including the 95th percentile, have been considered. To protect (virtually) all consumers, the population within the EU with the highest intake of a particular product should be used to evaluate the MRL, since this population would be considered ‘vulnerable’ because of the higher exposure.

Other vulnerable populations may exist due to their particular susceptibility to toxic effects. For certain pesticides, such as those causing neurotoxicity (e.g. organophosphates or carbamates) or endocrine disruption (e.g. estrogenic or anti-androgenic effects), pregnant women should be considered the subset of the general population that is most vulnerable. The MRLs should therefore protect such groups, especially if their diets include increased amounts of products with pesticide residues.

Toxicity evaluations are usually based on available information, and certain “safety factors” are applied when calculating ‘safe’ intake levels. Such safety factors are in fact not strictly to do with safety but with uncertainty, because they are applied when reliable information is lacking. (‘Safety’ is therefore a misnomer and the Commission may wish to reconsider using it.) Although the use of such factors has in general been supported by the experience from past decades, complete safety can never be guaranteed. Accordingly, in the interest of protecting public health, the residues of toxic chemicals should be kept as close to zero as possible.

If MRLs are fixed - in effect this means decreased - on the basis of toxicity considerations, then that will likely lead to an increase in the number of reported MRL violations, since the MRLs in that case will be below what can be attained by standard GAP.

Our reviewers are unanimous that use of an LOD (Limit Of Detection) at 0.01 mg/kg as MRL for pesticides banned or not used in EU would appear acceptable from a health point of view, since the LOD is the lowest limit that would be possible to enforce. However, banned substances would tend to be more toxic and more bioaccumulative than those currently approved, and for them, a similar MRL applies. Thus, an MRL at the LOD would provide less protection against banned pesticides.

MRLs that are based on climatic conditions in Europe may not be applicable elsewhere, particularly in the tropics. In addition, such countries may still use pesticides that have now been banned in the EU. The current proposal may therefore lead to trade barriers against import of products from tropical countries, even though in some cases the pesticides may have been produced and exported by EU member states.

There are concerns, expressed by our reviewers, that this Commission proposal as it stands might lead to a considerable delay in the process of setting MRLs compared to the present situation. Member States are now responsible for the setting MRLs for new chemicals on a provisional basis and for informing other Member States and the Commission about them. There is a broad consensus that agreement among the Member States is generally achieved without major problem. The member states role in producing monographs is to be taken over by EFSA, but there is a view amongst our reviewers that member states should remain responsible for the monographs in order that the process can continue efficiently. The Commissions document as it stands is not clear on how this would be done under the proposed new arrangements. For example, the Explanatory memorandum suggests that Risk assessment will become a responsibility of EFSA acting with its network of experts and institutes in the member states. EFSA will have the responsibility for giving an opinion on the safety of each MRL. It is not clear what responsibility these institutes in the member states will have apart from delivering data on, for example, national diets.

POINTS OF DETAIL

Explanatory memorandum

1.1.3 For the MRL to be set at the LOD, the LOD must be below the theoretical MRL based on toxicity data for consumer safety.

1.1.4 Although the 0.01 mg/kg level for the LOD has wide scientific credibility, there should be reference to the need to ensure that this is achievable with all combinations of substance and matrix. There should therefore be a provision for filling gaps in the analytical methods to ensure that in future there will be sufficiently sensitive methods available for all combinations.

Proposed text

Chapter III Should Article 14 Contain a reference to Annex V? The specific concentrations or dilution factors should be filled in.
Chapter IV Section 3 In article 27, the provision c for exemption in the case of a minor component of international trade, is considered insecure by one of our reviewers as such products, despite being a small component in trade, may nevertheless be a significant dietary component in some European populations.
Chapter V There should be further measures to ensure that laboratories conform to the highest standards of proficiency and for accrediting them.

CONCLUSIONS

The proposal has been broadly welcomed by our reviewers as a desirable simplification of the arrangements for consumer protection against pesticide residues in foods. However, there are reservations on two general counts.

Firstly the arrangements for setting harmonised maximum residue levels (MRLs) may lead to MRLs increasing in countries with advanced agricultural practice. This is scientifically indefensible and would be difficult to “sell” to the publics in those member states. There should therefore be provision for “provisional” MRLs and for programmes to upgrade agricultural practice where necessary.

Secondly, there is concern that the system proposed under the general responsibility of the European Food Standards Agency will be slow compared to the current arrangements and would be cumbersome. This could be addressed by making more specific (or clearer) arrangements for the participation of the institutions within member states that have this responsibility at present in the new arrangements.

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