

PAN Europe

Pesticides Action Network Europe

Position Paper on MRL Harmonisation March 2004

PAN Europe position on the European Commission Proposal for a Regulation of the European Parliament and of the Council on maximum residue levels of pesticides in products of plant and animal origin COM(2003) 117 final, 2003/0052 (COD)

The Pesticide Action Network Europe welcomes the EU Commission's initiative to harmonise maximum residue limits (MRLs). PAN Europe welcomes a limit of 0.01 mg/kg being set for pesticides which are non-authorized or not allowed in the European Union.

The proposal, however, contains significant deficiencies and ought to be revised and improved accordingly: Our main comments are:

1. Good Agriculture Practice (GAP) should be defined as ICM (Integrated Crop Management) as a minimum standard to prevent environmentally less desirable methods of farming;
2. Temporary MRLs could be harmful to consumers and are not necessary;
3. Consumers should be protected against additive and synergistic effects of combined residues in total food and exposure from other environmental sources.
4. Transparency and participation in evaluation and decision-making processes in MRL-setting should be secured.

In addition, PAN Europe believes that another objective must be to protect environment and human health – especially vulnerable groups such as foetuses, infants and children – according to the precautionary principle. MRL-setting at the lowest level possible can contribute to the protection of consumers and the environment at the same time. In this respect, there must be a co-ordination and coherence between the proposed regulation and the upcoming EC Thematic Strategy on the sustainable use of pesticides¹.

PAN Europe has the following comments:

¹ Commission Communication "Towards a thematic strategy on the sustainable use of pesticides" (COM (2002) 349)

1. *Reduce the contamination of food by pesticides generally below 0.01 mg/kg.*

MRLs should be set at the lowest possible level with the aim of setting products on the markets without any measurable residues. As outlined already in the EASAC-briefing², there is no guarantee on complete safety in setting MRL levels since there will always be uncertainty given the limited toxicological information on each chemical. As a general leading principle in the Residue Regulation, residues have to be set as close to zero as possible with the aim of no residues (limit of determination).

Contamination of foodstuffs with pesticides always means a risk to the consumer. Foetuses, infants and children, a particularly sensitive group, are currently protected by a limit of 0.01 mg/kg in baby food. But this protection is not given for infants that eat food, such as fresh fruit or vegetables, which meet only the EU's standard requirements.

Other population groups of persons besides infants are also in need of protection, especially women of reproductive age and pregnant women. The "benomyl" case in the USA³ proves that even at low ("safe") levels, pregnant women can be exposed in certain "windows of vulnerability of the foetus" with very harmful effects on the foetus (babies without eyes). For the group of pyrethroids the same is proven by Sweden's Professor Eriksson and colleagues, demonstrating windows of vulnerability in the pregnancy phase and effects on development of offspring. For organophosphates like diazinon and others it is known already for a long time that development of the nervous system can be harmed at low doses of exposure, even by (combined doses of organophosphates) eating everyday food⁴.

According to the precautionary principle, contamination of foodstuffs with pesticides should be kept as low as possible in future in order to fully protect sensitive groups such as foetuses, infants and children, and to protect the normal general population as a precautionary measure. Therefore, the toxicological risk assessment should reflect vulnerable groups as standard on principle when used to set Acceptable Daily Intake (ADI) and Acute Reference Doses (ArfD) values⁵.

The general success to date in adherence to the MRL of 0.01 mg/kg in the production of baby food shows that producing food on a large scale with these limits applied is possible. Organic agriculture and 40-60% of all conventional agriculture can already keep to these limits. According to the objective of the Thematic Strategy, contamination of all food in the EU ought to be brought down to below 0.01 mg/kg for individual pesticides. The regulation must set a goal to this end and a fixed timetable to meet this goal, i.e. within five to ten years.

² Briefing on the European Commission proposal for a regulation on maximum residue levels of pesticides in plant and animal products. European Academies Science Advisory Council (EASAC), November 2003
<http://www.europarl.eu.int/comparl/envi/pdf/externalexpertise/easac/mrl.pdf>

³ Court finds du Pont product responsible for birth defects. *Pesticides News* 62 16-17, 2003

⁴ Have we lost our heads. *Consumentenbond* (SNM), 2001:

⁵ WHO/EEA, 2002: Children's Health and Environment: a review of evidence, Env'tal issue report n°29

2. *Define Good Agriculture Practice (GAP) as Integrated Crop Management (ICM)*

In the current MRL Directives and the proposal, *Good Agriculture Practice (GAP)* is the starting point to set the MRLs. There is a big difference between GAP and ICM. The Regulation draft explains that “**the GAP giving rise to the highest levels** (the so-called 'critical' GAP) **is used to set the MRL** as all other authorised uses should be covered by it. If the residues arising from the critical GAP are not safe for the consumer, then that use is not authorised and the next critical GAP below is examined” (see MRLs Regulation proposal Explanatory Memorandum, page 5). Authors of the EASAC-briefing criticised this usage of the critical GAP level because it would give way to less environmentally desirable methods of crop protection.

Furthermore, Recital 13 in the proposal sets out: “Directive 91/414/EEC provides that Member States, when issuing authorisations, are to prescribe that plant protection products be used properly. Proper use includes the application of the **principles of good plant protection practice** as well as the **principles of integrated control** so that whenever possible and practicable, the use and the choice of pesticides does not interfere with the use of biological control methods. **The MRLs should be set as low as is consistent with such biological control methods.**“

There is a lack of common understanding in Community legislation concerning the terms good agricultural practice and integrated (pest and crop) control. Since none of these terms have been adequately defined, it is not at all clear what exactly is meant here, as well as the evaluation strategies of “whenever possible and practicable”.

In consequence, the starting point to set MRLs is vague, can lead to less environmentally desirable methods and does not protect consumers adequately. The MRLs Regulation Proposal reflects this issue in Recital 13 but without detailed explanation: “It is necessary to define at Community level certain terms used for the setting, monitoring and control of MRLs in and on products of plant and animal origin.”

PAN Europe has criticized the lack of any public and occupational health and environmental safety aspects in the definition of GAP (Article 3(4)), which must be taken into account (e.g. see the official FAO definition of GAP ⁶).

Furthermore, PAN Europe proposes that the Commission definition of GAP is based on Integrated Crop Management as a mandatory minimum standard.

ICM gives priority to non-chemical methods of crop protection and uses chemicals only as a last resort. We think integrated farming system is current state-of-the-art in conventional agriculture so the EC definition of GAP has to be abandoned as an outdated way of thinking. The Commission should use ICM defined by Member States (per crop or crop rotation system) as a minimal standard for MRL setting to prevent environmentally desirable methods of farming and to ensure maximum consumer protection by setting the lowest MRL possible.

⁶FAO definition in the Rules of Procedure of the Codex Alimentarius Commission: "Good Agricultural Practice in the use of Pesticides (GAP) includes the nationally authorized safe uses of pesticides under actual conditions necessary for effective and reliable pest control. It encompasses a range of levels of pesticide applications up to the highest authorised use, applied in a manner which leaves a residue which is the smallest amount practicable **Authorised safe uses** are determined at the national level and include nationally registered or recommended uses, which **take into account public and occupational health and environmental safety considerations**. Actual conditions include any stage in the production, storage, transport, distribution and processing of food commodities and animal feed."

Formally, the critical-GAP would mean the worst spraying method in a Member State, but now the Commission proposes that this critical-GAP level is to be used for the whole of Europe. This means the worst methods of chemical spraying somewhere in Europe would be made the standard for Europe as a whole! This is an unbelievable move of the Commission, legalising the worst spraying methods and exposing consumers to the highest possible residues of pesticides.

To address these problems PAN Europe proposes:

- i) The inclusion of the definition “Integrated Crop Management” as mandatory and minimum standard of GAP in the Residue Regulation (Article 3).
- ii) The inclusion of an Annex in the Residue Regulation, which defines more concretely the GAP/ICM hierarchy and standards for every crop and crop rotation system. The GAP/ICM-hierarchy should include:
 - system requirements (like rotation),
 - agricultural techniques (like resistant varieties);
 - non-chemical methods (like mechanical weeding);
 - biological control (use of predators and natural habitats);
 - decision prediction systems (counting, weather stations);
 - choosing the least harmful pesticide, not harming the biological control;
 - spraying with the lowest dose possible and not in the weeks before harvest.

All field trials of industry should be based on this ICM-hierarchy and set at the lowest possible level. Every 5 years the MRL should be renewed to get it to a lower level by applying new techniques and system improvements (GAP/ICM) with the aim of zero residues.

3. No temporary MRLs

The proposal emphasizes to co-ordinate the timing of decisions on MRLs for active substances with decisions taken for those substances under Directive 91/414/EEC. In the MRL Regulation proposal, it is stated : “For many substances for which Community MRLs have not yet been set, decisions are not due to be taken under that Directive before the date of entry into force of this Regulation”. “It is therefore necessary to adopt separate rules providing for temporary but mandatory MRLs, with a view to setting MRLs progressively as decisions are taken on individual active substances in the framework of the evaluations under Directive 91/414/EEC.” (Recital 27 and 28).

PAN Europe proposes instead, that temporary MRLs should NOT be set, because:

- i) It is a waste of time because the temporary MRLs will be used for only a short time until 2007/2008 when the harmonisation process is completed. We think EFSA can use its time more efficiently by setting final MRLs for the substances included in Annex I under Directive 91/414.

ii) The draft Regulation proposes a simplified procedure for setting temporary MRLs in certain circumstances (Article 27), e.g. where pesticide residues may arise as a result of environmental or other contamination, or where the product concerned constitutes a very minor component of the diet of European consumers. The continued validity of those temporary MRLs shall be re-assessed at least once every 10 years. This long timeframe of “temporary” MRLs is not acceptable. Furthermore, the source of contamination and the relevance of consumption should not to be used as an argument to reduce protection standards. The Commission should recognize varying eating habits of different consumers and cultural groups in Europe, for instance, the preference of a special or uncommon foodstuff.

iii) Even more important is that setting provisional MRLs will lead to higher MRLs in several Member States according to the proposed “critical GAP”-concept. The EASAC-briefing points to the less environmentally desirable methods of farming which will be made possible by these higher MRLs. Furthermore, consumers will be exposed to higher levels of residues, being in contradiction with the general principle of lowering MRLs to zero.

iv) The monitoring of temporary MRLs is not ensured (see item 6). If temporary MRLs will be set above 0.01 mg/kg an extensive monitoring programme and other scientific assessment activities must be established at the same time in order to guarantee conditions for re-evaluation of the MRL-setting within a dynamic decision-making process.

Concerning the criteria and requirements given in the EC proposal, the idea of setting temporary MRLs is not useful, it is harmful for consumers and should be abandoned.

4. Accounting for additive and synergistic effects in MRL-setting

Between 1998 and 2001, the proportion of food in the EU contaminated with several pesticides rose from 13 to 18 per cent. In three to four per cent of the food analysed as many as four or more pesticides were detected. Each individual substance could have possibly additive or synergistic effects on the human organism. The present proposal as well as the current MRL-Directives provides only limits on individual substances. The Explanatory Memorandum (page 5) acknowledges that “Acceptable methodologies are not yet available to systematically look at aggregate exposure (from other sources such as home and workplace) or **cumulative exposure** (intake from all dietary sources of similarly-acting substances). These are being developed.”

The reality that the daily food basket contains a number of similar-acting substances (e.g. certain organophosphates acting as nerve toxins) is not reflected in the proposal. The single limit approach provided in the Regulation does not adequately protect health. Cumulative risk assessment is perfectly feasible, as shown by the work of the U.S. Environmental Protection Agency, which developed guidance on cumulative risk assessment of pesticides that have a common mechanism of toxicity⁷.

⁷ U.S. Environmental Protection Agency, Office of Pesticides Programs (2002): Guidance on cumulative risk assessment of pesticide chemicals that have a common mechanism of toxicity. Washington, D.C.

Cumulative limits must be provided in the regulation as a matter of urgency. Here the EPA approach of potencies could be chosen or a temporary additional uncertainty factor for ADI/ArfD determination, for every pesticide member of a group of similar effects and for every pesticide for which synergetic effects have been published.

5. *Setting MRL limits for processed foods as well*

In the MRL Directives and in the current proposal, the MRLs apply to the raw commodity (fresh foodstuffs or part thereof). In contrast, according to the 'babyfood'-Directives (Directives 91/321/EEC and 96/5/EC), MRLs are set and are applicable for the processed food to be eaten and calculated as the whole diet. Equally, however, limits must be laid down for processed foodstuffs for young and adult consumers as well. This means there must be regulations for all processed foodstuffs in the MRL-Regulation together with appropriate monitoring requirements.

6. *Ensuring effective monitoring of all substances with set limits for MRL.*

Globally, there are approximately 1000 active ingredients in use. In 2001, EU countries analysed an average of only 161 substances, in Germany, for example, only 90. This means that limits on most of the substances permitted are not at present monitored in Germany or the EU. Considering the analytical potential, the number of substances actually monitored is well below what could be analysed. At present, residue monitoring in the EU is thus blind to a significant number of pesticides which can be present as residues in food.

The regulation must, as a matter of urgency, ensure bindingly that limits on all substances for which MRLs have been laid down are effectively monitored. There can be no use of substances which are not monitored. Licences on substances which cannot at present be guaranteed to be monitored EU-wide because of the lack of measurement procedures or monitoring authority equipment must be suspended until adequate MRL monitoring is ensured.

7. *Import tolerances*

The proposal provides 'import tolerances' for three cases, described in the Explanatory Memorandum. 'Import tolerance' means "a MRL based on a Codex Alimentarius Commission MRL or on a GAP implemented in a third country for the legal use of an active substance in that third country where: (a) the use of the active substance in a plant protection product on a commodity is not authorised in the Community; or b) an existing MRL is not sufficient to meet the needs of international trade" (Article 3(5)).

The Commission should ensure, that

- i) import tolerances are clearly time limited and exceptional cases,
- ii) import tolerances cannot undermine the standard limit of 0.01 mg/kg for pesticides which are non-authorized or not allowed in the European Union (case a).

- iii) the application of import tolerances include the responsibility to support the producer in exporting countries to develop and use pesticide reduction measures (e.g. IPM/ICM), if the current GAP applied in an exporting country leads to a higher level of pesticide residues as compared with the equivalent commodity produced in the EU.

8. *Transparency and participation*

The MRL Regulation proposal states “An application to set, modify or delete an MRL may be made by Member States as well as other non-governmental parties, meaning interested parties (e.g. producers) and any party identifying an appropriate and scientifically substantiated possible concern for human or animal health due to the intake of pesticide residues (Article 4). PAN Europe welcomes this opportunity, which recognizes the participation of public interest groups in political processes. In addition, NGOs should be involved in stakeholder dialogue and consultations which contribute to government decisions, e.g. the development of evaluation-guidelines in MRL-setting. Transparency is one fundamental precondition of an effective public participation. PAN Europe propose timeliness and full publication of all documents regarding evaluation and decision-making processes in MRL-setting.

Regarding monitoring of pesticide residues in foodstuffs, PAN Europe proposes the publication by Member States of monitoring results on the internet, every three months, with name of trader, retailer and source of collection. If MRLs are exceeded, the competent administration body should publish as soon as possible:

- i) their activities, e.g. pesticide use reduction strategies, if MRLs are exceeded repeatedly for a particular crop or country,
- ii) the steps taken against the responsible party and action to protect consumers (e.g. market prohibition, complaint) and
- iii) the consequences for the responsible party (e.g. penalties, which should be clearly defined, at a level to act as a deterrent).

9. *Integrated European actions to reduce pesticide residue levels*

On the one hand, European consumers do not want pesticide residues in foodstuffs and should be protected according to the precautionary principle. This demand is recognised by many supermarkets and food companies, for instance EURO COOP, which criticized weak governmental regulations and has already established its own stricter residue limits⁸. Also, some Member State governmental agencies, e.g. UK’s Food Standard Agency, Norway or Denmark, are looking at residue reduction actions and zero residues approaches. On the other hand, European agriculture and the European market should be strengthened and harmonized. In addition, the European Union has a responsibility for enabling developing countries in particular to take part in international trade. In this case, to enable farmers and exporters from those countries to comply with strict European protection standards.

To fulfil these different objectives integrated European actions are necessary, including:

⁸ EURO COOP Comments to the European Commission draft Regulation to harmonise maximum residue levels of pesticides allowed in products of plant and animal origin COM (2003) 117 (26-09-2003)
Download under: <http://www.eurocoop.org/publications/en/position/archive2003.asp>

- The Decision⁹ laying down the Community Environmental Action Programme 2001 - 2010 which calls for action to “reduce the impacts of pesticides on human health and the environment and more generally to achieve a more sustainable use of pesticides as well as a significant overall reduction in risks and of the use of pesticides consistent with the necessary crop protection”.¹⁰
- The objective of the new CAP reform (Common Agriculture Policy) to achieving sustainable agriculture. This would mean addressing not only economic and social challenges but also ecological challenges, by promoting good environmental practices as well as the provision of services linked to the maintenance of habitats, biodiversity and landscape. Sustainable agricultural production must also reflect the concerns of consumers, particularly as regards quality, safety and traditional/organic production methods.
- Close collaboration with Member States, farmer organisations, retailers and other stakeholders to prepare and establish mandatory IPM/ICM standards (see 2; ii),
- Support activities in close collaboration with retailers which enable farmers to change agricultural practices to low input farming. This also includes financial and expert support for farmers in developing countries (see 7).

⁹ Decision n° 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the Sixth Community Environment Action Programme, O.J. L242 10-09-02, p: 1-15

¹⁰ PAN Europe has published a “Suggested text for a directive on pesticides use reduction in Europe” (PURE, May 2002), Comments on the European Commission’s Communication “Towards a Thematic Strategy on the Sustainable Use of Pesticides” (September 2002), and a Joint Stakeholders Declaration on the Commission Communication (November 4, 2002). Download under: <http://www.pan-europe.net>