

PAN Europe
Position on EU Pesticides Authorization
April 2004

The pesticides authorization process has been harmonised at the European level through the Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. During this time, it has sometimes served as a progressive example for the assessment of the impacts of chemicals on health and environment. But the risks connected with the use of pesticides prevail – including the contamination of groundwater, upon which 65% of the European drinking water production depends. The average use of pesticides per unit of land has risen, in spite of the increasing adoption of active ingredients with a higher activity per weight of active ingredient (source: EEA).

More advanced and progressive policy concepts and assessment tools for chemical substances have been introduced, such as the elimination of certain hazardous substances and the assessment based on intrinsic properties (OSPAR¹ 1998, introduced into the Water Framework Directive WFD; Swedish “New Guidelines on Chemical Policy” 2000) or the substitution principle leading to a comparative assessment of chemicals (Biocides Directive 98/8/EC). Moreover, many chemical policy processes have opened up for public interest groups (OSPAR, WFD Priority Setting, Risk Assessment of industrial chemicals) and gained from this increased transparency. The current pesticides authorization process is not only intransparent, but also suffers from a severe lack of democracy. Pesticides legislation in general should ensure full participation of the European Parliament in the same way as this is granted by legislation based on Art. 95 of the Treaty.

The “Commission Report to Parliament and Council on Progress in the evaluation of the active substances of plant production products, submitted in accordance with article 8(2) of Council Directive 91/414/EEC” now offers the opportunity to initiate the inclusion of these principles and tools -in line with the precautionary principle- also in the pesticides evaluation.

In this paper, PAN Europe and its partners call on the Commission to make use of the opportunity to propose a fundamental review of 91/414/EEC, which is aimed at modernising and harmonising the Directive in line with relevant EU legislation (e.g. WFD) and international agreements such as the OSPAR Convention.

Future pesticides regulation should be based on the *highest protection level available* in existing EU legislation or international agreements, in line with the Precautionary Principle. The overall objective of 91/414 should be that avoiding negative impacts on or dangers to “health, groundwater and the environment and human and animal health should take priority over the objective of improving plant production.” EU agricultural policy should aim at sustainable agriculture, and the pesticide authorization process should reconsider the degree of *need* for each individual pesticide.

PAN Europe does not believe that even carefully tested and assessed pesticides are safe. PAN Europe is committed to “fight for local, national and international agreements to restrict, reduce and eliminate pesticide dependence and to phase out and ban synthetic chemical pesticides, especially those that cause acute, chronic and endocrine disrupting effects” (PAN

¹ OSPAR Oslo and Paris Convention for the Protection of the Marine Environment of the North-East Atlantic

International Dakar Declaration). PAN Europe stresses that comments made here have to be understood in this context. For the pesticides authorization process we suggest a two-step procedure: I. Exclusion of non-acceptable active ingredients based on hazard-criteria (cut-offs). II. Careful evaluation and control of other active ingredients not meeting these cut-offs.

I. Hazard-based cut-offs as criteria for non-authorization

Several important national and international chemical policy processes have acknowledged the understanding that chemical substances with certain intrinsic properties cannot be controlled and concluded that releases of such substances (meeting certain defined cut-off criteria for P persistence, T toxicity, B bioaccumulation) must therefore come to an end (see OSPAR Convention, POP Convention, Dutch SOMS-Project, Swedish New Guidelines on Chemical Policy, a PTB policy was demanded by DG Environment, Commissioner Wallström for the EU Chemical Policy).

The European Commission and 12 of the 15 EU Member States as contracting parties to the OSPAR Convention have in fact already adopted this concept by signing the ministerial declaration of the 1998 OSPAR ministerial meeting in Sintra “to move towards the target of the cessation of discharges, emissions and losses of hazardous substances by the year 2020”. The EU has only just started to implement this objective by including parts of it into the Water Framework Directive. However, this approach is not yet included in the pesticides authorization process.

For pesticides stringent and consequent cut-offs need to be defined and used as a first step in the authorization process: Active ingredients that meet these cut-offs must not be considered for authorization. For such cut-off criteria for toxicity, persistence or bioaccumulation no exemptions shall be granted. Only pesticides which do *not* meet one or more of the above mentioned criteria can be further assessed for inclusion in Annex I.

Such an approach also renders the authorization process more cost-effective and less time-consuming.

Consequent inclusion of hazard-based criteria

PAN Europe supports the OSPAR approach that the direct or indirect releases of all substances with PTB properties to the environment must cease. OSPAR defined the following cut-off criteria to protect the marine environment from chemical substances². PAN further acknowledges the Swedish chemical strategy to ban PB (P *and* B) substances³ ().

PAN however states that the cut-offs defined for chemicals in these approaches are not far-reaching enough to meet the requirements for pesticide evaluation. Pesticides are by definition toxic, are deliberately released into the environment, and come into direct contact with the users. Thus for pesticides more stringent cut-off criteria are needed. Also, a *combination* of the P T and B properties as cut-off criteria (P *and* B *and* T) is inappropriate for the evaluation of pesticides. Instead, pesticides must be judged based on *each* of these single aspects (P *or* B *or* T).

Toxicity: Hazard-based criteria for human toxicity

Users of pesticides have to comply with protective measures, such as wearing protective clothing. The authorization of pesticides has to acknowledge that these measures will not always be implemented in practice during the application of pesticide products. Furthermore,

² P DT50 = 40-50 days in freshwater (or a failed inherent test, if no DT50 data are available or a failed ready test, if no other test data are available), B log Kow > 4 and T (acute) LC50 < 1mg/l or NOEC ≤ 0.1 mg/l or T mammalian CMR (OSPAR definition of toxicity includes endocrine disruption).

³ with B = BCF 2000 and P < 20% degradation in inherent test

consumers, including vulnerable groups, are exposed to pesticides through drinking water and food.

A special provision for substances which cause irreversible effects has already been laid down in the Biocides Directive, where biocides that are carcinogenic, mutagenic, toxic to reproduction, or sensitizing cannot be approved under Annex Ia (low-risk products). Comparable cut-off criteria also have to be included in the pesticides authorization, and have to be made more stringent: A pesticide which causes irreversible effects must not gain approval – even for use by trained users.

PAN Europe calls for the following cut-off criteria for human toxicity:

Pesticides (including their metabolites) shall not be authorized if they are any of the following:

- Carcinogenic
- Mutagenic
- Toxic to reproduction
- Endocrine disrupting
- Sensitizing

The terms above must include ‘suspected carcinogens / mutagens / toxic to reproduction’ where scientific assessment acknowledges the possibility of such a potential but where absolute certainty is not known (precautionary principle must apply for these categories) (respective EU classes 1,2 or 3, or US EPA class A, B1, B2, C for carcinogens).

The production and use of pesticide active ingredients with these properties which are already authorized must be banned.

Persistence

The majority of the pesticide active ingredients are water-soluble and highly mobile. They can reach surface waters, groundwater, drinking water. The persistence criteria is thus the central criteria to assess environmental and (indirect) human health issues. In order to make sure that pesticides neither reach groundwater and drinking water nor persist in soil, they have to quickly degrade in the environment.

Pesticides currently have to be tested for their persistence in soil and in water (degradation of the active ingredient and relevant metabolites), and criteria for the non-inclusion of pesticides in Annex I have already been laid down in the uniform principles (DT 50 in soil > 3 months and DT 90 in soil > 1 year). PAN Europe generally welcomes the inclusion of cut-off criteria. Although, current authorization practice has shown that these criteria have not been applied. Instead, additional results from (non-standardized) field tests have been used to override these criteria.

The persistence in water courses (surface water or ground water) does not present a criterion for non-authorization at the moment. Further, there is no requirement to present data on the persistence under anaerobic conditions, and on the final degradation (mineralisation) of the active ingredient.

PAN Europe therefore calls for stringent cut-off criteria for persistence in the environment, based on standardized simulation tests:

A pesticide (including its metabolites) shall not be authorized if, under aerobic conditions,

- the degradation time (DT50 for mineralisation) in soil is > 30-40 days, and
- the degradation time (DT50) for mineralisation in surface water is > 20-30 days.
- the degradation time (DT50 for mineralisation) in sediment system is > 120 days (for substances with a log Kow > 5)

- Tests have also to prove degradation under anaerobic conditions (in soil and sediment/water systems).

Bioaccumulation

Generally, bioaccumulation of (bioaccumulative) substances can take place if these substances persist long enough in the environment to be taken up by organisms. The persistence criteria described above might not be sufficient to avoid bioaccumulation of pesticides with a high potential to bioaccumulate. The production and use of bioaccumulating pesticides is therefore unacceptable, even if these pesticides degrade quickly.

PAN calls for a ban of the use and production of pesticides which are (or whose metabolites are) bioaccumulating with a BCF ≥ 500 or log Kow ≥ 4 (in line with the OSPAR B criteria).

II. Evaluation and control of other pesticide active ingredients

Even those pesticides that do not meet the cut-off criteria, and which are carefully assessed before authorization along the lines described in the paper, may pose a considerable risk to human health and environment. The environmental and human health effects of pesticides cannot be fully predicted and occurrence of these pesticides in human tissues, food and the environment should be thoroughly monitored. These monitoring programmes must be financed by industry.

PAN Europe calls for

- a 10 year authorisation period, using this time to prioritise reviewing the most problematic pesticides
- monitoring of pesticides active ingredients to be financed by industry

Inclusion of the comparative assessment, with special attention to non-chemical alternatives

A comparative assessment offers the chance to identify the least harmful alternative for a certain pesticide use category. It also has the advantage of comparing the hazardous properties of a group of substances with the same mode of action.

The substitution principle has already been introduced to the Biocides Directive, although it only relates to a comparison of active ingredients. It has also been proposed and used by Northern European countries. The substitution principle must also be transferred to the pesticides approval process.

PAN Europe therefore asks for

The comparative assessment to be introduced into 91/414 and its daughter directives:

- An active ingredient must not be authorised if it can be substituted by non-chemical methods or active ingredients that are less harmful to human health or the environment.
- Economical or practical disadvantages are secondary to a higher protection of human health and the environment.
- A prerequisite for the comparative assessment is that the assessment of all active ingredients with the same use pattern be performed at the same time and that information on their properties, use patterns and market volumes is made available.
- A database containing non-chemical alternatives has to be set up at the European level, to assist this process
- An assessment of the alternatives has to be carried out by independent experts.

Transparency of the pesticides regulation

Transparency of the authorization process

PAN Europe welcomes the access to some of the Commission documents via the DG Sanco website. However, the actual authorization process is still not transparent and input from public interest groups is very restricted, while industry may meet with regulators in tripartite meetings.

PAN Europe calls for

- the dossiers for the active ingredients to be made available when produced by Member States.
- the term 'commercial confidentiality' needs to be clearly defined. It should not be used as an excuse for over-excessive restriction of dossiers and other information held by regulators.
- the schedule, agendas, full minutes of meetings, and reports of relevant bodies (SCPH, working group legislation, working group evaluation) to be published (on the DG Sanco website).
- access to the regulatory committees as observers and clear procedures for the inclusion of comments given by public interest NGOs.

Publication of and public access to pesticide properties

The analysis of the effects of pesticides on human health and the environment is severely hampered by the restricted access of the public to data on pesticide usage and also pesticide properties. For example, epidemiological analysis of hazardous effects is impossible without detailed information on pesticide usage. Equally the wider overall impact of pesticides on the European environment cannot be assessed if inputs are not adequately recorded. As pesticides are openly introduced into the environment, and consumers are exposed to pesticides via usage, drinking water and food, information on the properties of pesticides have to be made available to the public according to the right to get access to environmental information. Data confidentiality claims have to be lifted. Confidentiality must only be granted in exemptions, based on a case-by-case decision and strict criteria.

PAN Europe therefore calls for a pesticides database, including the following information:

- Production volumes (per active ingredient and product)
- Sales volumes (per active ingredient and product)
- Usage volumes (by active ingredient, product, application rate/frequency pest, area, crop and time) and use patterns
- Properties of pesticides (results of all study reports)
- Pesticide poisoning and pollution incidence reporting
- Non-chemical alternatives to pesticides use and alternative crop-growing systems.

This database must be available to the public without any costs (internet access).

Responsibility for delivery and updating lies with industry and trade (usage volumes must be reported by farmers, and data on poisonings and non-chemical alternatives by member states). The information at Member State level can be the starting point for such a database. To this end, a clear and strict criteria for exceptional confidentiality must be developed.

Combination toxicity evaluation

The use of only one pesticide per crop is very rare, and pesticides run-off and leaching lead to the contamination of surface and ground waters with multiple mixtures of pesticides. According to state-of-the-art research, concentration additive effects of mixtures have been proven, and tools have been developed to predict toxicity of mixtures.

Taking into account that methodologies for the inclusion of mixture toxicity effects have already been developed in the USA (cite US EPA). PAN Europe recommends the Commission also introduces these approaches to the European pesticides authorization.

PAN Europe calls for

- the inclusion of an assessment of the combination toxicity of pesticides in the environment (A safety factor should be added to the toxicity/exposure ratio, proportional to the number of pesticides to be expected in an environmental compartment in a realistic worst-case scenario).
- The inclusion of combination toxicity approaches in the setting of ADI values for human uptake (ADI values for pesticides with the same mode of action should be lowered, based on the approach taken by the US EPA).

The evaluation of combination toxicity and relating risk management measures should also be covered through the Water Framework Directive: If the toxicity/exposure ratio of a mixture of pesticides found in a water body exceeds the limit value for single substances, then production and use of the pesticide with the highest share of total toxicity should be restricted or banned.

Faster inclusion of newly recognised effects

The case of endocrine disrupting pesticides has shown that, although scientifically sound knowledge of newly discovered detrimental effects of substances might exist, this information will not be used in the approval process until internationally agreed testing protocols are available. PAN Europe is of the opinion that, in order to protect human health and the environment, risk reduction measures must in such cases be based on the precautionary principle.

PAN Europe calls for

- a biannual evaluation of the annexes II and III, in order to identify new endpoints to be required in the authorization process based on scientifically agreed testing protocols (these protocols do not have to be established at the international level),
- A mandatory inclusion of the two-generation study,
- the identification and inclusion of tests to identify toxicities (such as neurotoxicity, immunotoxicity, induced carcinogenicity) to developing organisms /foetus.
- An extensive survey of the open literature to be part of the data requirements, including effects on human health and the environment as well as monitoring results and environmental quality criteria

As the interaction between pesticide active ingredients and the so-called inert ingredients might also lead to unexpected toxic effects (e.g. short term toxicity, genotoxicity, carcinogenicity, reproduction toxicity, neurotoxicity, immunotoxicity, endocrine disrupting potential), tests for the evaluation of such effects must be developed.

Special protection of vulnerable groups

The setting of ADI values is designed for healthy adults and does not sufficiently take into account vulnerable groups such as foetus, infants or children, with special metabolic pathways and a lower body weight. The special sensitivity of babies has been addressed in the baby food directive, and the US EPA has set additional safety factors for their protection.

PAN Europe therefore calls for

- An additional safety factor of 10 for the protection of vulnerable groups in the setting of ADI values.

Mutual recognition

The authorization of pesticides follows a two-step approach: after the evaluation and inclusion of an active ingredient in Annex I of the directive at European level, products containing this active ingredient have to be approved at Member State level, and these authorizations have to be accepted by other Member States unless the agricultural, environmental and climatic conditions are not comparable. (see also Zonal Registration below)

It is now possible that a pesticide is included in Annex I for a “safe” application under very limited agricultural conditions and usage (e.g. glasshouse use). The inclusion in Annex I can give a wrong signal to third countries and also to the Member States for which mutual recognition is claimed.

PAN Europe therefore calls for

- A clear indication for which uses a pesticide active ingredient in Annex I has been approved,
- The need (instead of the possibility) for a second Member State to assess the product and usage in question with special regard to comparability of the agricultural, plant health, environmental and climatic conditions. The burden of proof that conditions are comparable lies with industry /notifier.
- Allow for non-authorized usages only with prior consent of the Commission

Zonal registration of products

At the 31 January 2004 Stakeholder meeting organised by DG 24, the proposal of registering pesticide products at three zonal levels (Scandinavia, Northern Europe and Southern Europe). This has come about because the European Commission has recognised that mutual recognition at the member state level for the registration of pesticide products has not work as originally designed under 91/414. From the meeting it was clear that many of the member state regulators were generally in favour of zonal registration.

PAN Europe is concerned about these developments and therefore call for greater clarity:

- It is widely acknowledged that mutual recognition is not working under the current regime – what justification is there that it would work under the proposed system?
- With so little details given, it is not clear what the implications are comparative assessment/substitution, GAP, integrated crop management.
- What are the implications for a member state that wanted to restrict the use of a pesticide product?
- There may be different environmental impacts with the large zonal areas. For example there may be water catchments that are particularly sensitive to water soluble pesticides, which can vary across the zone.
- What are the implications for Southern and possibly Northern countries to adopt less intensive strategies?

Improper pesticide applications

The authorization of pesticides is based on the assumption that pesticides are “properly used”, which includes compliance with Good Agricultural Practice (GAP). Only a very broad definition of GAP is given in the directive, and the misuse of pesticides cannot be ruled out.

PAN Europe therefore calls for:

- The evaluation of pesticides for authorisation shall take into consideration possible impacts on health and environment of known types of inappropriate use.
- Proper use should not only include GAP, but IPM / ICM as a minimum (see PAN Europe Position on Good Agricultural Practice).

- “Essential uses” have to be regarded as improper use, if the criteria of 91/414/EEC are not met when classifying pesticides as essential

Non-Compliance: Control and Sanctions

Regulations on control of production and usage in line with the authorization of pesticides are missing or patchy and there are no sanctions on non-compliance.

PAN Europe calls for

consequent enforcement of the requirements laid down in 91/414/EEC.

- Responsibilities (on national levels) should be clarified in 91/414/EEC. Basic procedures for control measures and general items that lead to sanctions for non-compliance should already be laid down in the directive. Sanctions should e.g. cover data gaps (failing to deliver or update information on pesticides), unauthorized usage (illegal imports) or marketing of pesticides to unattested traders or users.

Responsibility and liability of users, producers and traders

Downstream usage of pesticides including actual use volumes, use patterns and misuse can barely be tracked nor controlled by regulators. Trade in and application of pesticides is not restricted at the European level, Yet some member states have already successfully established training programmes for farmers (e.g. Swedish pesticides use reduction programme).

PAN Europe calls for

- Regular mandatory training for pesticides users
- Regular mandatory testing of pesticide application equipment
- A ban on the amateur pesticides used in gardens and allotments (covered by 91/414)
- Industry and traders must only market pesticides to authorized traders and users and document these sales accordingly (standardised OECD attestation).
- Authorized users have to report on usage patterns back to the relevant databases.

International implications of 91/414/EEC

The European Community will be ratifying the Rotterdam Convention on Prior Informed Consent Procedure (PIC) for Certain Hazardous Chemicals and Pesticides in International Trade. Article 5 of the Convention requires that Parties notify any final regulatory action to ban or severely restrict a chemical no later than 90 days after the date on which this action has taken effect.

When pesticides or other active substances are not approved under Directive 91/414/EEC, it is important that clear and transparent information is made available to distinguish chemicals not listed for commercial reasons from those not listed because of a risk to health or the environment. Failure to notify these as a ban or severe restriction would severely undermine the PIC procedure.

To avoid this potential loophole PAN Europe calls for

- the reasons for the final regulatory action to be unambiguously stated
- a system must be established to ensure automatic consideration for notification under Article 5 of the Convention of all active substances refused listing under 91/414.

Signatories to the PAN Europe Position on EU Pesticides Authorization

- MAMMA TERRA, Romania
- Bond Beter Leefmilieu, Belgium
- Comisiones Obreras, Spain
- Coordination gegen BAYER-Gefahren (BAYERwatch), Germany
- Danish Ecological Council
- Ekorol, Poland
- European Public Health Alliance, EPHA, Belgium
- For Mother Earth, Romania
- General Workers Union (SID), Denmark
- Green Doctors Ukraine
- Inter-Environnement Wallonie, Belgium
- Leefmilieu, the Netherlands
- MDRGF, France
- Monitoring Network Health and Environment, the Netherlands
- Österreichische Bergbauernvereinigung, Austria
- PAN Belgium
- PAN UK
- Polish Ecological Club City of Gliwice Chapter
- Stichting Natuur en Milieu, the Netherlands
- SLF, Svenska Lantarbetareförbundet, Sweden



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