PAN Europe

Pesticides Action Network Europe

Position Paper on
Transparency & Participation in Pesticides Authorisation

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This position paper deals with the role of public interest groups in the process of the evaluating and authorizing pesticides and with PAN Europe's demands on the pesticide registration process in the framework of EU legislation and the forthcoming review of Directive 91/414.

On a national and international level it is increasingly recognised that public interest groups can and should play an important role in the formation of opinions and decision-making processes relevant to health and environmental protection. Authorities in a modern democracy should encourage and welcome public interest groups and set up structures that make effective participation possible. There is considerable public concern in Europe on how pesticides are assessed since many are commonly found as residues in food and water or are banned in some EU Member States because of their dangerous properties. Nevertheless, compared to other policy areas (e.g. chemicals or protection of the marine environment), transparency and participation in the way pesticides are authorised at EU and national levels is still very limited. Steps towards improving transparency and public participation will soon be undertaken in certain Member States, such as Germany and UK, as well as at European level. This paper presents PAN Europe's point of view on these issues.

General Considerations

Effective public participation can only take place if a number of basic preconditions are met. Transparency is one such fundamental precondition. This concerns decision-making processes, the implementation of decisions made, their underlying assumptions, assessment criteria and the reasons for the choices made. Although transparency and participation are strongly linked to each other, they also should be viewed separately.

Transparency means that the interested public has easy access to all information concerning the considerations which governmental decisions are based on.
The demand for transparency includes the following key issues:

- Access to information should be possible with a minimum of effort and time.
- Timeliness and the form of access need to ensure that it is possible to comment on up-coming decisions- publishing information after decisions are taken does not constitute transparency even if full documentation of the decision-making is available.
- Information should be presented in a way that is understandable to public interest groups.

Participation means the involvement of the public in political processes. By the term 'public' we mean non-profit NGOs and civil society organisations acting as public

interest groups. The role of NGOs and government regulators should not be confused. It is the responsibility of governments to make the decisions on which pesticides are to be authorised or not. In the context of risk assessment during the pesticide registration process, PAN Europe believes that NGO participation in governmental decision-making committees is not appropriate, but that they should be involved in stakeholder dialogue and consultations which contribute to government decisions. However, we insist on full public involvement in creating the legal framework for pesticide policies.

A second precondition is balance. In all cases where participation is offered in the framework of the pesticide policy, a balanced representation of stakeholder groups should be ensured. Long-term dominance of particular interest groups has to be avoided. A more balanced participation can be realized by providing financial support for competent non-profit NGOs when commercial interest groups are over-represented because of their financial strength. In some cases, it might be necessary to restrict or even rule out the participation of commercial interests if public interest groups are not able to participate in an equivalent way. PAN Europe demands public participation in all decisions on the composition of bodies responsible for risk assessments and evaluation and transparency in declaring the interests of all those on such bodies.

Participation opportunities must be offered by the authorities regardless of whether specific public interest groups have the capacity to take part. This participation is voluntary - whether a particular NGO chooses to participate or not is its own decision. Therefore, non-participation or lack of a response should not be interpreted as agreement with the subsequent decisions.

Decision-making in the pesticides authorisation process

The pesticides evaluation process is highly complex and hard for non-experts to follow. The technical framework for assessing the risks of specific pesticides covers test requirements, models for predicting the fate of pesticides in the environment and criteria for evaluation. It has been set up in close cooperation with industry and under working groups of various EU and national governmental institutions and research bodies. What is missing is a clear decision-making step from the work done in the different groups to how this work is used to evaluate pesticides. Public interest groups are not involved in any of the evaluation procedures, while industry is present in all bodies that determine the technical framework.

Table 1 summarises the evaluation process for active ingredients at EU level. Until now the Commission Coordination (ECCO) peer review has been handled by Germany and UK. The ECCO team will hand over this task to the new European Food Safety Authority (EFSA) once this becomes operational during 2003-04. EFSA could provide new opportunities for public participation and representation of their interests yet its current 15 member board contains only one person from a consumer organisation and none of the members have environmental expertise. A public voice in the setting up of EFSA has been limited so far.

Table 1. EU evaluation process for active ingredients (adapted from the BBA German Federal Biological Research Centre for Agriculture and Forestry website www.bba.de)

Procedure	**Documents produced**
Step 1	
Applicant (company) submits required data (“Dossier”) to a Rapporteur Member State.	Dossier
Step 2	
The Rapporteur Member State (RMS) checks the completeness of the	

dossier.	
Step 3	
If data are complete, the RMS prepares the draft assessment report (DAR or monograph).	Draft assessment report (DAR)
The DAR is circulated to the EU Member States which have 90 days for comments.	Comments on DAR
Step 4	
The DAR and the comments are examined in normally 5 small expert group meetings with experts from up to 7 MS plus Commission (ECCO –peer review meetings). Detailed technical discussions.	Evaluation tables List of end points Concise outline report
Step 5	
ECCO overview meeting: 15 MS plus Commission plus applicant company observers. Based on this meeting, the ECCO team produces the full report.	Full report **European Crop Protection Association representative participates**
Step 6	
Working Group "Plant Protection Products" (Evaluation) of the Standing Committee on the Food Chain and Animal Health (SCFA) examines full report.	Draft review report
Step 7	
Consultation and opinion of the SCP (Scientific Committee on Plants) and the WG 'Plant Protection Products' (Legislation) with participation of 15 MS and Commission	**Opinion published**
Step 8	
SCFA gives vote	
Step 9	
Adoption by the European Commission	
Step 10	
Publication of Directive or Decision on inclusion / non-inclusion of active substances in Annex I of Council Directive 91/414/EEC and preparation of Background Documents A, B, C to the Review Report by COM, RMS and ECCO-Team	**Decision published** Doc A= draft monograph Doc B = Peer review report Doc C= Comments after peer review **Review report publicly available**

The information available on the DGSANCO website does not provide either an overall introduction to pesticide policies (as compared to the website of DG Environment) or an overview over the evaluation and authorisation of pesticides. The regularly updated report on the state of works is not very helpful for groups that are not involved in the technical processes and discussions held therein. Information in the form of minutes obviously addresses Member State officials rather than the interested public. Based on the ECCO timetable, published on the BBA website, public interest groups could plan on written submissions, but as the Draft Assessment Reports are not published nor any other document that gives an insight into the state of the discussion, targeted submissions cannot be made.

In practice, the pesticides evaluation procedure gives hardly any opportunity for public participation because the state of work, the discussions held and the documents and arguments used in the process with regard to single active substances are completely unknown to the public. It is almost impossible to add any targeted information or concerns to the process.

Commercial confidentiality
This remains a serious restriction on transparency and participation. The current approach in which access to information is the exemption and confidentiality the rule is inappropriate and in contrast to the EU legislation on *Right to Know*, freedom of access to information on the environment and the Aarhus Convention (1998) on participation in decision-making and public access to information and justice. At a stakeholder workshop in 2002 on the revision of the authorisation directive 91/414, there was general agreement that there that there is a need for a clear definition of a 'positive' list of items that can be considered as confidential. Also that there should be early access to the Draft Assessment Report on the EFSA website, following a quality check. Confidential information should be submitted by industry in separate documents, to enable open access to the majority of data used in the evaluation process. The Swedish authorities, for example, already circulate draft assessments reports and other official documents from the evaluation process among interested parties for comment. From the Swedish point of view, the distribution of official documents prepared by the authorities does not affect property rights of the notifiers.

Opening up the evaluation process
Many Member States support an opening up of the evaluation and authorisation process at European and national levels. The Netherlands officially involve the public in their national decision-making process: the Dutch Board for Pesticides Authorisation has to publish the assessment report for a 6 week period, and consider the comments submitted by the public. The publication of the report offers the opportunity for public interest groups to challenge the decision by initiating a review and using court cases in case of data gaps etc. The decisions of the Board can be challenged by formal objections, which requires appointing an objection committee.

The Commission itself has strong reservations on public participation and has argued that the authorities are capable of serving consumer needs themselves. Yet much more open and democratic forms of evaluation already take place in other policy areas. In the EU's chemicals risk assessment, public interest groups are fully involved and invited to submit information on the substances under assessment, in meetings with an open and constructive atmosphere. The key lesson from these processes is the willingness of all parties to cooperate and communicate.

In workshops where the setting of the framework for evaluation takes place, public interest groups should be invited and informed and the guidelines developed must be made transparent. DGSANCO website should communicate clearly how guidelines and criteria are developed by the various committees and working groups. Additionally, there are several bodies or groups establishing the scientific and technical framework for the assessment of pesticides (e.g., the OECD Working Group on Pesticides; Forum for the Co-ordination of pesticide fate models and their use, FOCUS ; The Society of Environmental Toxicology and Chemistry ,SETAC). Their work also influences the authorisation process and should be made transparent. We demand that the European and national authorization bodies provide the information upon which their decisions are based to the public. Whenever possible, this should be done in a suitable, easy-to-understand format.

In the long term, we need a fund to be set up, financed by Member States, to enable full participation by public interest groups. In the meantime, we demand travel costs and a daily allowance as the minimum.

PAN Europe demands:

1. The Commission and Member States actively welcome and facilitate public participation as a valuable contribution and necessary feedback channel.
2. Clear communication about risk assessment procedures and a clear link between scientific discussions and the implementation of their outcomes in the evaluation process.
3. Dates for evaluating specific active ingredients must be published early on and regularly updated, to allow strategic planning of public involvement.
4. The evaluation process of single active ingredients must be fully transparent, with clear website design and well-structured information, and confidentiality limited to specific cases on an agreed 'positive' list.
5. A 3 months comment period must be allowed on the ECCO/EFSA full report. Comments must be treated via predetermined and agreed procedures and consultation meetings organised for specific critical cases.
6. Public participation should be made possible in the meetings of the Standing Committee on the Food Chain and Animal Health.
7. Decision-making on the composition of scientific committees should be transparent and balanced, with public participation in proposing members.
8. In line with the Aarhus Convention, easy and cheap access to justice must be ensured for public interest groups at EU level.
9. Travel costs must be covered for participation of public interest groups in working group meetings as a minimum.

Taking its limited resources into account, PAN Europe demands the following for the different levels of the pesticide process:

Setting the legal framework for the authorisation and use of pesticides		
European legislation	Transparency	Participation
National legislation	Transparency	Participation
European registration of active ingredients		
ECCO peer review process- Step 4 (COM, MS, 2 AC)	Transparency	
ECCO overview meetings- Step 5 (COM, MS, 12 AC)	Transparency	
Scientific Committee: decisions on composition	Transparency	Participation
Standing Committee: decisions / voting Step 8	Transparency	

Participation opportunities at national level differ between member states and have to be treated separately, according to what is appropriate for public interest groups in each country.

This Position Paper was prepared with reference to the PAN Europe report *How to Organise Public Participation in the Pesticides Evaluation Process ?* by Dr Ute Meyer, March 2003. The report can be obtained from the PAN Europe Coordinator at the PAN UK office, <stephanie-paneurope@pan-uk.org>.