Relating precaution to proportionality: how to proceed with Directive 90/220 concerning the deliberate release of genetically modified organisms into the environment

Rene von Schomberg

Tilburg University, Postbox 90153, 5000 Le Tilburg, The Netherlands.
Tel/Fax +31-13-5360751
E-mail: R.vonSchomberg@kub.nl
Home page: http://kub.nl/~FSW_2/fww/home/schomberg/index.htm

Date received: 22 June 1998
Date accepted: 30 June 1998
Date published: 8 July 1998

Code Number:BY98003
Sizes of Files:
   Text: 24.1K
   Graphics: No associated graphics files

ABSTRACT

The European Commission has proposed the amendment of the current Directive 90/220, concerning the deliberate release of genetically modified organisms into the environment. During 1998, the European Parliament and the European Council will respond to the Commission's proposal. In the context of the Directive, public pressure from bioindustry, environmental and consumer organisations have called for a continuation of the precautionary approach as well an approach which would be proportional to the risks involved. This paper seeks a way forward towards consensual decision making on this controversial subject and evaluates the new proposal of the European Commission in the light of basic notions required for a Directive that would meet the necessary standards for both precaution and proportionality.

Keywords: Precautionary principle, genetic modification, Biotechnology regulation,
Defining precaution

An international agreement on the precautionary principle was reached during the United Nations Conference on Environment and (UNCED) in Rio de Janeiro 1992 and became part of Agenda 21. Since then the precautionary principle has been mainly discussed in two areas of international environmental policy, e.g. global climate change and biodiversity conservation/biotechnology regulation. National governments have also discussed and implemented the precautionary principle in other areas such as the emission of chemical waste or areas for (nuclear) waste disposal. The precautionary principle is also written into the Treaty establishing the European Community (article 130R).

In the framework of Agenda 21, the precautionary principle has two basic characteristics. This note is based on the following interpretation of such a precautionary principle.

1. The principle is to be applied in cases of potentially irreversible impacts on the environment with relatively high consequences (implying that these consequences are unacceptable).

2. Governmental action should be taken without the availability of complete scientific evidence. These circumstances are referred to as instances of scientific uncertainty. Scientific uncertainties arise because of controversies over the possibility or the scope of environmental effects caused by human (technological) interventions.

It is important to note that the precautionary principle is a formal principle which implies that, depending on the area to which it would be applied, it could result in quite different types of environmental policies or regulation.

3. Implementing the precautionary principle in European Biotechnology regulation

The European Directive 90/220/EC concerning the deliberate release of genetically modified organisms (GMOs) into the environment is the first piece of international legislation in which the precautionary principle is translated into precautionary regulation. There is no experimental scientific evidence for harm to humans or the environment caused by GMOs but ecologists consider it plausible that single releases of GMOs could cause, for instance, irreversible effects on the natural vegetation (decrease of biodiversity) or the development of resistant weeds. There is scientific uncertainty whether GMOs pose an additional risk in comparison to conventional cultivation methods. In the framework of this Directive the precautionary principle is formalised by a so-called case by case and a step by step procedure. The case by case procedure facilitates (in most cases) a mandatory
scientific evaluation by Member States of every single release of a GMO. The step by step procedure facilitates a progressive line of development of GMO's by evaluating the environmental impacts of releases in decreasing steps of physical/biological containment (from greenhouse experiments, to small scale and large scale fields tests up to market approval). This procedural implementation of the precautionary principle implies an ongoing scientific evaluation and identification of possible risks. The procedure also results in the accumulation of scientific data, which provides input to new evaluations.

4. Main features of precautionary regulation

4.1 Flexible Standards

Precautionary regulation always implies the regulation of a subject matter on the basis of standards that remain open for discussion. The regulation itself cannot define these standards. This is a completely new dimension in international environmental policy and not always appreciated. Directive 90/220, for instance, also leaves open what precisely can be considered as an `adverse effect on human health and the environment'. The Directive also leaves open what could be `a sufficient demonstration of safety'. The combination of a case by case evaluation and the absence of fixed standards for evaluating these cases provide the background for ongoing deliberations at national level and in scientific advisory committees.

Instead of fixed standards, individual Member States use flexible standards to define the acceptability of releases. "Reduction of biodiversity" or "comparison with the risks of conventional agricultural practices" are examples of such standards. These standards also do not predefine the outcome of the evaluation of scientific advisory committees.

Depending on the availability of scientific evidence and the location of releases of GMO's the evaluation on the basis of such a standard may differ over time. These standards may be called `flexible'. The state of the art in science concerning the knowledge of natural processes also determines the outcome of evaluations in the light of these standards. For instance the environmental effect of transfer of genes from GMOs to wild relatives may either be perceived as `genetic pollution' or as a natural (= acceptable) process depending on our knowledge of whether such a gene transfer would take place under natural circumstances. The standards to be applied can therefore transform previously defined unacceptable releases into acceptable releases if studies of natural processes provide us with a new understanding. Disagreements between Member States relate to the application of these standards whereas there is hardly any disagreement on the likelyhood of major environmental effects (Von Schomberg, 1998).

4.2 Proportionate regulatory requirements
Precautionary regulation is by definition (Agenda 21) a regulation, which cannot be based on a complete cost-benefit analysis. The scientific uncertainties concerning the subject matter do not make such an analysis possible. Precautionary regulation is constrained to cases in which it is plausible that irreversible environmental consequences are involved which are (internationally) predefined as unacceptable. Precautionary action does not relate directly to demonstrated actual risk but to anticipated plausible risks.

However, a general cost-benefit analysis could precede a political multilateral decision whether or not to translate the precautionary principle into proportionate regulatory requirements. For that purpose three points can be evaluated in relation to each other:

1. An assessment of the scope of the scientific uncertainties and the scope of possible environmental effects.
2. The costs and benefits for maintaining the status quo.
3. The costs and benefits for changing the status quo. The precautionary principle can be used to maintain or reverse the status quo.

Such a general analysis also remains important after the decision to implement precautionary regulation on a particular subject since the accumulation of scientific evidence during the time frame of such a regulation could make it appropriate to reconsider the scope of precautionary measures. The acknowledgement of the precautionary principle thus implies the evaluation of the scope of the measures to be taken and when they should be taken.

The scientific uncertainties concerning the subject matter also imply the impossibility of a full quantitative risk assessment whenever the precautionary regulation is implemented.

It is, however, possible to implement a precautionary regulation which is commensurate with the identified uncertainties or risks involved. Directive 90/220 is an potential example of proportionate regulatory requirements. The regulations facilitate ongoing revisions of the standards of risk assessment to be used. This means that these standards could be relaxed or strengthened over time depending on the accumulation of scientific evidence.

It is very important to note that precautionary regulation can never be aimed at a categorical ban on products or experiments. In the context of incomplete scientific knowledge, it is even necessary to gain practical experience with products or experiments in order to complete scientific knowledge and for identifying actual risks. The accumulation of scientific insight by precautionary use enables the update of standards for risk assessments. Thus precautionary regulation can facilitate guided introduction on the market of particular products.

Post-market technology assessments and monitoring of products/technologies by industry
could complement a precautionary regulation and would provide the necessary feedback for such a regulation.

5. Trade Aspects of precautionary regulation

5.1 Internal market

The Maastricht Treaty allows individual Member States to take all `appropriate measures to avoid adverse effects on human health and the environment'. However, this statement may be linked to other statements concerning the internal market in specific EC Directives or regulations, such as is the case of the Directive 90/220/EEC. The new Amsterdam Treaty remains ambiguous on this point. The Amsterdam Treaty allows an individual Member State to apply stricter environmental measures than those provided by European legislation in so far as the country does thereby not impose trade barriers. Only a ruling by the European Court of Justice could clarify what this will mean in cases where precautionary regulation is linked to an obligation of the internal market.

However, from a policy point of view, it would be consistent to complement precautionary regulation with a European policy that allows for flexible trade barriers. Precautionary regulation always needs ongoing deliberation at national level which inevitably will cause divergent ideas about the acceptability of uncertainties. If we wish to respect these differences, we have to accept flexible trade barriers as we do accept flexible standards for assessing uncertainties. These trade `barriers' would then be restricted to the areas for which we wish to implement precautionary regulation.

European biotechnology regulation has indeed resulted in the use of different standards by different countries which has indeed has become the case in the framework of Directive 90/220. Austria and Luxembourg have imposed a ban on EC approved products and the European Council has repeatedly postponed a European Commission proposal to enforce a lifting of these bans. These conflicts among Member States reflect an inadequate understanding of the meaning of precautionary regulation since such regulation cannot be scientifically aimed at a zero-risk level. Therefore, it is not appropriate to reverse the burden of proof and call for demonstrated proof of safety instead of a demonstration of actual risks in case by case assessments. In fact, precautionary regulation has been implemented to postpone a burden of proof both on the side who claim the plausibility of adverse effects and those who claim plausibility of sufficient safety.

5.2 General conclusions for Policy Options for the revision of Directive 90/220/EEC

The implementation of the Directive has been laborious. In 1992 only 4 countries managed to implement the Directive within obligatory 18 months time frame (UK, NL, DK and D) and Luxembourg implemented the Directive as the last country only in early 1997; No
country was brought for the European Court of Justice for not implementing the Directive. Subsequently, the policy and societal discussion on the release of GMOs has shifted to the meaningful implementation of a precautionary practice in the context of member states. Despite all the controversies, no political actor, organisation or member state has questioned the necessity of a precautionary approach. Now that a revision of the Directive is approaching, all major parties involved in the policy process, such as national competent authorities, bioindustry and NGOs have reaffirmed the precautionary approach (Von Schomberg, 1998). The precautionary principle has been formalized in the procedure by a case by case and step by step approach. Differences between Member States reflect how far this formal procedure has been materialized in the Member State in the absence of pre-given definitions for environmental harm and risk, but most importantly in the absence of harmonized standards for what would count as (un)acceptable environmental or health effects.

Precautionary regulation facilitates:

1. An ongoing scientific deliberation within the policy context- this means a shift in science based policy, as presupposed to be possible by the current Directive, towards a scientific debate on uncertainties within the policy context): this means that decisions should not only be based on available data but also on plausible notions of what could be the case.

2. An ongoing discussion on transformable/flexible standards within the regulatory framework but also in the societal context of this regulatory framework.

3. The awareness of the need of monitoring and continuous interest in the experience with releases and market product

4. The awareness for the need for a long-term perspective, which is implemented by a precautionary and flexible practice.

All member states and the major interest groups embrace a precautionary approach. Therefore only minor changes of the current Directive in so far the Directive serves as a safety net are acceptable. The most prevailing problem resulting from the Europe-wide acceptance of the precautionary approach is that this can only be practised by a continuous deliberation on flexible standards. These discussions materialize differently in the different member states. From this state of affairs arises the problem whether it is a legitimate way of acting to impose decisions on countries in which this process of deliberation deviates from other countries.

5.3 Conclusion on recent proposals of the European Commission to modify Directive 90/220
Across the member states and among experts of advisory committees, disagreements arose on the application of the standards of risk assessments rather than on the plausibility of environmental harm which can be caused by releases of genetically modified organisms. To achieve a consensus among experts in advisory committees as well as among the competent authorities of the Member States a clarification is needed on how to review releases in the light of one of the following standards which determine the outcome of risk assessments and the decision of competent authorities.

- conventional agricultural practice
- biodiversity
- sustainable development
- agronomic effects

Individual standards have been used by the Member States to differing extents, thereby creating dissent among experts and among competent authorities. An open discussion of these standards was hindered by the dominant interpretation of the Directive that only allows for an assessment of the scientific-technical safety aspects of releases. However, the working in practice of the Directive has shown that the application and choice for a standard is necessary in order to substantiate a claim for the acceptability of individual releases and market products. The standard of `conventional agricultural practice' is a too small basis for a precautionary approach and belongs to the option of those who would favour a product-legislation. To envisage the Directive as a precautionary safety net would favour the option to focus on safety/biodiversity (which already has a consensus in the European Union through the biodiversity declarations on the 1992 UNCED conference in Rio de Janeiro). H. Martin of the European Commission confirmed in an interview that this would be a possible policy, but disagreements might remain since biodiversity is interpreted differently by some member states through the application of different thresholds for effects on biodiversity. Sustainable development and agronomic effects are standards which are likely not to achieve a consensual basis among the member states. These two standards reflect a more integrative approach to environmental issues but are difficult to apply within the specific context of a process-based legislation. The European Commission is not willing to consider these standards for amending the Directive.


Member States have interpreted the current Directive differently and it did not establish a procedure to resolve these disagreements. Scientific risk assessments could not produce a
consensus on the risks of genetically modified organisms (GMOs). The approval for marketing of products has been delayed in almost all cases. Proposals to amend the Directive have come from competent authorities of the member states, industrial organisations and non-governmental organisations. Below I will summarize the most significant proposals of the European Commission.

The Commission proposes to amend the Directive to include an obligation to implement of a risk management strategy. It remains unclear how such a strategy could be implemented without using standards which are derived from current agricultural practices. Without defining a standard, a contradiction will be created in the implementation of the Directive, since at the moment an appeal to agronomic effects is not accepted.

However, the recent agreement of the Italian authorities to lift the ban on Novartis' Bt-Maize, after an agreement with Novartis to conduct monitoring experiments with this particular maize, is an important policy-precedent of how to combine acceptability with management strategies.

The establishment of an independent Risk Assessment Committee at European Level is expected to override the advisory committees of the national member states. However, disagreement will also appear in such a committee if no clear agreement is achieved on the application of definitions of acceptability. Some member state could be encouraged to use article 16 to ban certain products, if they feel excluded in the deliberations on these standards.

The Commission has now proposed to amend article 16 by restricting its use to those cases when *during the approval procedure* new information has become available which would make a reconsideration necessary. This proposal does not reflect the essence of a precautionary approach in which the *lack* of such information could be a reasonable ground to reconsider a case. The Commission seems to reject any proposal for a qualitative `risk' assessment. This constitutes a major conflict with environmental and consumer organisations and makes negotiations with these organisations very difficult.

The development of policy by competent authorities of the member states has moved from Risk-based regulation to Uncertainty-based regulation. There is a growing awareness that the issue of deliberate release has to be seen in the context of an uncertainty-based regulation which is characterized, *inter alia*, by the application of deliberations-based standards of risk assessment. In our analysis, this is adequate for the current situation. A precautionary approach is determined by both the absence of a definition of environmental harm and an ongoing acquisition of scientific knowledge which may change the acceptability of individual releases over time. Therefore, an ongoing discussion among experts of scientific advisory committees as well as among competent authorities of member states is unavoidable and necessary to cope with uncertainties and define the
meaning of standards of risk assessment in concrete cases. Therefore, the interaction between member states and advisory committees should be encouraged rather than abolished: for effective decision making, administrative procedures should be facilitated to make decision possible within a certain frame, but also the possibility of the reversibility of decisions should be considered. Countries might have less problems with certain products or releases if they are confirmed that these decisions can be reversed once environmental harm could be demonstrated. It is therefore a significant step that the Commission proposes to link the market consents with mandatory monitoring strategies.

ACKNOWLEDGEMENTS:

In the preparation of the report I have made use of helpful comments from officials of the European Commission and Members of European Parliament. Of course, this does not imply acceptance of the ideas expressed in this paper by the European Commission or by Members of the European Parliament.

REFERENCES:


Copyright remains with the author.

Published by Bioline Publications.
Editorial Office biosafe@biostrat.demon.co.uk