COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10.12.1996
COM(96) 630 final

REPORT ON THE REVIEW OF DIRECTIVE 90/220/EEC IN THE CONTEXT OF THE COMMISSION'S COMMUNICATION ON BIOTECHNOLOGY AND THE WHITE PAPER

(presented by the Commission)

A: INTRODUCTION

In the European Union the safety of activities involving modern biotechnology is currently ensured through four horizontal Directives (Directives 90/219/EEC, 90/220/EEC, 90/679/EEC and 94/55/EC) and a number of other sectoral Directives/Regulations (see Annex I).

While Directive 90/219/EEC covers the contained use (i. e. use in research and industrial facilities) of genetically modified micro-organisms (GMMs), Directive 90/220/EEC covers the deliberate release into the environment of genetically modified organisms (GMOs). The latter covers both deliberate releases for experimental purposes, and deliberate releases for placing on the market of products. Directive 90/220 already foresees, in its article 10(2), that product legislation could replace the environmental risk assessment provided for by Part C of this Directive. This approach, known as "one door, one key" policy, aims at ensuring that one assessment and notification procedure are sufficient for the purposes of marketing products containing or consisting of GMOs. Under this policy, products containing or consisting of GMOs will be subject to specific product legislation, which will include a risk assessment similar to the one provided for by Directive 90/220/EEC, while being specific with regard to the intended use of product. Annexes I and II of this Report contain a list of Community legislation, adopted or under development, relevant for the purposes of the "one door, one key" policy.

In its Communication on Biotechnology and the White Paper on Growth, Competitiveness and Employment (June 1994), the Commission recognises the importance of modern biotechnology, and confirms that "in the future the whole network of interrelated biotechnological regulations needs to ensure that oversight is always appropriate to the risks involved, the building of public confidence and to the competitive development of the industries involved while guaranteeing the protection of human health and the environment.[1] "On this basis, the Commission confirmed its opinion" that the following two-track approach for the future development of the biotechnological regulatory framework should be applied:

- the exploitation of existing possibilities for revising measures/procedures/degree of oversight/requirements, through use of the "light" procedure of adaptation to technical progress (Regulatory Committee Procedure). (Internal amendment);

- the bringing forward of amendments to existing legislation in order to incorporate changes which cannot be achieved by technical adaptation while leaving the basic structure of the framework intact (external amendment)"[1].

---

1 Biotechnology and the White Paper on Growth, Competitiveness and Employment, preparing the next stage. Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee, p. 3

As far as Directive 90/220/EEC was concerned, the Communication concluded that this "Directive was flexible enough to satisfy the needs of the time for adaptation to technical progress and simplification of the procedures," but it concluded that "there were aspects of this Directive that might be improved in the future.[2]"

It is in this context that the Commission undertook to carry out a review of Directive 90/220/EEC with the aim of assessing the need for proposals in relation to the following objectives outlined in the Communication:

"1) extending the flexibility of Directive 90/220/EEC, so that its scope and the procedures to be followed are always appropriate to the risks involved, and are easily adaptable;

2) strengthening more uniform decision-taking between Member States in the case of research and development releases;

3) introducing further opportunities for notifiers (industry and researchers), so that they can benefit more from the existence of a uniform community system;

4) facilitating the link between this Directive and product legislation."[3]

Experience gained since the implementation of the Directive, has led to a better understanding of its functioning. In particular discussions with the Competent Authorities under this Directive as well as with interested parties has helped to identify problems and possible ways of addressing them. This experience was not sufficient to carry out a review of Directive 90/220/EEC during the first half of 1995 as foreseen in the Commission's Communication on Biotechnology and the White Paper on Growth, Competitiveness and Employment.[3]

This document presents the results of the review exercise which includes consultations with the Competent Authorities of Member States, Industrial and Research Associations, Environmental, Consumer and Trade Union Organisations. This Analysis carried out below has taken into account international experience in this field.

---

2 Biotechnology and the White Paper on Growth, Competitiveness and Employment, preparing the next stage. Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee, p. 5

3 Biotechnology and the White Paper on Growth, Competitiveness and Employment, preparing the next stage. Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee, p. 6

B. ANALYSIS OF THE FUNCTIONING OF DIRECTIVE 90/220

Directive 90/220/EEC came into force on 23 October 1991. Since then 747 experimental releases have been notified to Member States Authorities and 16 product notifications have been submitted so far (see Annex III). Although this might look impressive, it has to be seen in perspective of international experience elsewhere (see annexe IV.)

Part A of Directive 90/220/EEC: General Provisions

Part A of Directive 90/220/EEC mainly defines:

a) the scope of this legal instrument. More specifically:

- the circumstances under which Directive 90/220/EEC applies (Article 1 and definitions for the terms "deliberate release", "product", " placing on the market", "use" provided in Article 2);
- organisms to which Directive 90/220/EEC applies (Article 2: definitions of "organism" and "GMO", Article 3 exemptions);

b) the obligations of Member States.

Regarding part A, the analysis carried out has identified the following points:

- Experience shows that some of the definitions in article 2, in particular those of "placing on the market" and "deliberate release", cause some implementation problems.

  More recently, it has been suggested that Article 1 paragraph 1 second indent, which is closely linked to the definition of "deliberate release", does not indicate unequivocally the circumstances under which products fall under Directive 90/220/EEC. The pragmatic approach followed so far should be adapted to address the issue, which involvesd a case-by-case examination.

- Although the whole Directive is supposed to be concerned with the assessment of risks for human and the environment, the risks covered and the criteria for such a risk assessment are not specified. It is to be noted that product legislation (pharmaceuticals, foods, etc.) has traditionally defined the objectives of the assessments to be performed under it. It is hence necessary to incorporate these objectives in the Directive and in product legislation, in order to strengthen harmonisation and to avoid that authorities of Member States reach different conclusions on the basis of the same information.

Furthermore, the principle of a scientific risk/benefit evaluation needs to be introduced in order to clarify which side - effects of certain types of releases would be acceptable, thus allowing authorities to establish the overall beneficial effect or the release.

Part B of Directive 90/220/EEC: Deliberate release of GMOs into the environment for research and development purposes or for any other purpose than for placing on the market

Part B of Directive 90/220/EEC defines the procedure that has to be followed in the case of experimental release into the environment of GMOs (i. e. submission of a notification, potential data requirements, risk evaluation, exchange of comments/information between Member States, granting of consent by the competent authority).

a) Risk categories and administrative procedures

At the time of the adoption of Directive 90/220/EEC there had been very little experience, and it was considered, that all GMO releases would potentially present similar risks. Against this background one administrative procedure for research and development releases was foreseen. The procedure has helped Member State Authorities to establish the infrastructure for overseeing this fast-moving sector, and has built confidence in the public that there is an instrument available to address risk issues.

However, the experience gained on the basis of practices already implemented at industrial level indicates that, while keeping a case-by-case approach, it is necessary to establish a classification commensurate with the identified risks involved in the release. Indeed, it is currently demonstrated that not all releases pose the same level of risk and, consequently, do not merit the same level of administrative oversight.

Such classification would allow to lay down administrative requirements that are in all cases proportionate to the risk identified, thereby eliminating unjustified administrative burden without lowering safety standards.

The current Directive does not allow for any classification of risk and for differentiation of administrative requirements according to the risks involved. Such a classification should be introduced and the administrative procedures commensurate to the risks involved. This approach has been already applied elsewhere in the world.

b) Simplified procedures

The Directive foresees the possibility to adopt simplified procedures (Article 6.5.), in cases where certain criteria are met. This possibly has only been used once, in order to allow for a single notification to cover the release of a combination of specific genetically modified plants on different sites. Although it is true that the possibilities for simplified procedures may not have been fully exploited, the present situation

illustrates the shortcomings of the possibilities for simplification as currently foreseen by the Directive:

- The fact that only one simplified procedure has been so far adopted demonstrates that the procedure for proposing and adopting them is cumbersome, and certainly does not meet the need for rapid adaptation in the biotechnology field.

- these simplified procedure cannot replace the need for a clear and well defined classification system linked to the risk involved. Furthermore the possibility for proposal of simplified procedure should be extended to all parties involved.

c) Multi-State procedures

Directive 90/220/EEC does not provide for the possibility of a single procedure for multi-State releases. As the field develops it becomes more and more necessary to test GMOs in more than one Member State. Such a procedure would be especially advantageous for SMEs, which are usually not based in more than one Member State.

It is therefore necessary to have such a provision introduced.

d) Risk assessment

At the time of adoption of the Directive it was not possible to specify the basis of the risk assessment, that has to be carried out, (see above) or the methodology to be followed and the safety standards that have to be satisfied in the text of the Directive. Although the system of the Directive works even in the absence of commonly accepted objectives and methodology, it has to some degree led to lack of harmonization in safety standards in Member States. Consequently, a notifier has to comply with different requirements when releasing in different Member States.

With the accumulated knowledge and experience it is now possible and necessary to establish centralised definition of the objectives and methodology of the risk assessment.

e) Exchange of information between Member States

Article 9 specifies that exchange of information on experimental releases should take place. This is already happening, and the Commission intends to set up a database. Experience gained with over 700 experimental releases notified to Member State authorities shows that it would be useful for the Commission to receive appropriate information concerning the subsequent approval of products in order to circulate this to Member States. This would enable Member States to have information about assessment on safety of products and more specifically the results of the releases.

Therefore strengthened provisions on the issue of exchange of information between Member States should be introduced.

f) Link between experimental and product releases

The Directive foresees that experimental releases of GMOs should pose no risk to human health and the environment under the purpose or conditions in accordance with Article 6. It could be explored how the experience gained under part B could be used for possible environmental problems that could arise at the stage of commercialisation. This could be done by collecting information or data to address them. (See paragraph e) above.)

Therefore, the possibility could be explored of introducing in the Directive an incentive or an obligation to gather data/information which could be of relevance to the subsequent evaluation of the GMO in view of its placing on the market as product under part C of Directive 90/220/EEC or under the relevant product legislation, as appropriate.

It is worth underlining that in the case of placing on the market of GMOs, Community legislation on products currently discussed in the Council and the Parliament does not foresee a specific environmental risk assessment for research and experimental releases of GMOs and refers to "authorisations that have been given to part B releases under Directive 90/220/EEC". Therefore, it could be useful that the assessment of the environmental effects of GMOs to be placed on the market, be prepared and, if possible, be completed at the research and development stage under Directive 90/220/EEC. Therefore, in certain cases the possibility should be explored of including into product legislation which already foresees an environmental and human health assessment for experimental releases of products under development, a risk assessment similar to that laid down in part B of Directive 90/220/EEC.

Part C of Directive 90/220/EEC: Placing on the market of products containing GMOs

Part C of Directive 90/220/EEC defines the procedure to be followed in the case of the placing on the market of products containing or consisting of GMOs. This procedure involves the submission of a notification to a competent authority of the choice of the notifier, and in the case of a favourable opinion by this authority, involvement of all the other authorities and possibility to raise objections within a set deadline. In the case of an objection being raised the Commission has to table a proposal for a decision.

a) Risk categorisation and administrative procedures

Since the entry into force of the Directive, 16 applications for placing on the market of products containing or consisting of GMOs have been submitted under this Directive. The administrative procedure which the Directive foresaw as the general rule (marketing possible after the 90-days period during which CAs may comment) has not been used a single time.

In one case, it has even be necessary for the Commission to submit to the Council a proposal for a Council decision (Maize). So far the assessment carried out by one Competent Authority to which the notification was submitted, has not been able to satisfy all other Competent Authorities, which again carry out their own assessment, often on the basis of different criteria (see analysis concerning part A). It should also be noted, that although deadlines are given to Member States for examining the dossiers and pronouncing their opinion, no deadlines are given to the Commission despite its crucial role in the granting of consents for products. Experience has shown that the procedure followed is difficult to implement, time-consuming, and cumbersome to follow both for users and authorities.

Furthermore, the Directive foresees only one procedure which is indistinctly applied to all types of products, irrespective of the risk identified or whether similar products are already on the market. It has to be remembered that in this fast-moving, high-tech field, not only future notifications but also current ones already concern products which are similar to authorised ones in the EU, as well as products which themselves have been used elsewhere in the world and which have proven to be safe.

There is therefore a need to provide for streamlined procedures for those products posing no, negligible or low risk. Such a possibility exists elsewhere in the world. For example, there are GMOs - with which familiarity exists (along the lines of the concept of familiarity as defined within OECD work, especially for the assessment of genetically modified crop plants).

The establishment of categories according to the risk identified, the streamlining of administrative procedures in those cases where no, negligible or low risk is involved, without lowering the safety level, should be introduced. In the same time, the Commission should consider an adaptation of its internal rules in order to speed its stage of the procedure.

It should also be noted that the current procedure according to which notifiers have no other option but to submit a new notification to another Member State in case of an unfavourable opinion by the authorities to which they had first submitted the notification, is disadvantageous for SMEs as they are not based in more than one country.

b) Risk assessment and scientific advice

The lack of a common definition of the objectives and the methodology of the risk assessment (see analysis concerning part B) allows Member States to carry out a risk assessment on the basis of different criteria. This is one reason for the delivery of diverging opinions and the difficulty in reaching consensus among Member States.

These questions, have to be further clarified in particular, by including, along the lines of what is proposed for Part B, a clear definition of the objectives and methodology of the risk assessment.

In any case, and in view of the fact that in the future the environmental assessment for many products currently covered by part C of Directive 90/220/EEC, will be carried out under appropriate sectoral legislation (where it exists), it is of utmost importance that the objectives of the risk assessment be clearly defined for the following reasons:

i) sectoral Community legislation will foresee an environmental risk assessment "similar to that foreseen by Directive 90/220/EEC" (i.e. without lowering safety standards). If the objectives of this assessment is not clarified enough in Directive 90/220/EEC, the current problems concerning the assessment of risks of GMOs will be transferred to sectoral legislation;

ii) well defined objectives in Directive 90/220/EEC will ensure that the risk assessment is carried out on the same basis throughout all stages of the development of a product containing GMOs.

Currently, the Directive does not provide the possibility to discuss, at Community level, scientific controversy within an independent scientific group, as it is the case in Community legislation dealing with marketing authorisations (foods, pharmaceuticals, feed, etc.). This leads to an anomalous situation where application controversy cannot be dealt with by an independent system of conflict resolution which would allow to discuss and solve problems on a scientific basis. This specific issue merits to be specifically considered in the context of developing a proposal for amendment to the Directive.

c) Labelling

The issue of labelling of products under Directive 90/220/EEC has been the subject of controversy. Some Member State Authorities object to the placing on the market of a product whose labelling will not indicate that it is genetically modified. The current provisions of the Directive do not allow the imposition of such labelling in the absence of any link to risk assessment. Specific provisions on labelling are, however, foreseen in product legislation.

It will be essential to address this issue in order to take into account the need to inform consumers and to comply with the international obligations of the Community. The issue of labelling will be considered when preparing the amendment of Directive 90/220/EEC and the final provisions of other relevant product legislation will be taken into account.

Part D and Annexes of Directive 90/220/EEC:

The flexibility of the Directive appears to be limited as it does not provide for easy adaptation to technical progress of one of its Technical Annexes. In a so fast-moving and continually evolving field, it is important to ensure that Community provisions are always based on the latest stage of experience and scientific knowledge. Therefore, the possibility of adapting all annexes of the Directive though a Regulatory Committee Procedure, could enhance flexibility and permit timely adaptation of these highly technical parts of the Directive to rapidly advancing scientific and technical progress.

C. CONCLUSIONS

Directive 90/220/EEC regulates a high-technology field, which is developing rapidly. The Directive covers both the stages of development and placing on the market of products containing GMOs. In this light, there is a need for regular updating and adaptation of this Directive in order to keep pace with scientific and technological progress.

Directive 90/220/EEC has helped Member States to introduce the infrastructure for assessing potential human health and environmental effects from the placing on the market of products containing GMOs, but its implementation has revealed a number of problem areas. These include

- insufficient clarification concerning the objectives for risk assessment, which has hindered full harmonisation between Member States at the research and development stages and which has led to disagreements between Member States at the stage of placing on the market of products;
- absence of a risk classification as well as of a link between administrative procedures and identified risk, which may result in cumbersome procedures for low risk releases;
- weak link between parts B and C of the Directive, which means that experimental releases under part B do not always provide the relevant data for the environmental assessment necessary for the placing on the market under part C;
- cumbersome administrative procedures and approval system for placing on the market of products, which have led to delays in approving products;
- absence of an active role for the Commission on a number of aspects, including the right to propose simplified procedures and to acknowledge part C dossiers and objections, which has led to delays in exploiting existing possibilities for simplification and to problems in implementing part C;
- absence of a possibility to resolve controversy through consultation of independent Scientific Committee(s), which has caused problems in implementing part C;
- absence of sufficient flexibility for technical adaptation, which prevents regular updating of the Directive to scientific and technical progress;
- current labelling requirements.