4. In view of the fundamental problems which have also emerged in the negotiations, the Committee wonders whether the time might have come for a careful review of the Community’s transport policy, as the achievements of the current policy have sometimes been less than outstanding.


The Chairman
of the Economic and Social Committee
Alberto MASPRONE

Opinion on:
— the proposal for a Council Directive on the contained use of genetically modified microorganisms, and
— the proposal for a Council Directive on the deliberate release to the environment of genetically modified organisms

(89/C 23/15)

On 30 May 1988 the Council decided to consult the Economic and Social Committee, under Article 100 a of the Treaty establishing the European Economic Community, on the abovementioned proposals.

The Section for Protection of the Environment, Public Health and Consumer Affairs, which was responsible for preparing the Committee’s work on the subject, adopted its Opinion on 8 November 1988. The Rapporteur was Mr von der Decken.

At its 260th plenary session (meeting of 24 November 1988), the Economic and Social Committee unanimously adopted the following Opinion.

Although evidently connected, the two proposals differ in their scope and raise different problems. They will therefore be examined separately, in order.

1. Proposal on contained use

1.1. General comments

1.1.1. The proposal responds to the need to harmonize the different provisions in the Member States. The Committee supports this proposal, subject to the comments which follow.

1.1.2. Since 1972, the ‘in-vitro recombination’ of genes or what we now call ‘genetic engineering’ has become firmly established in biological, biochemical and medical research. This technology is also increasingly used for industrial and agricultural purposes.

1.1.3. The main aim of these guidelines, which exist in all countries engaged in research, has been to protect people who are directly involved in experiments or industrial uses and the environment from harm or potential harm. Two measures were combined in order to guarantee maximum safety.

a) The in-vitro recombination of genes and work with genetically modified organisms must take place under conditions which have already been proved to provide a hazard-free setting for work with microorganisms and especially pathogens. A wealth of experience can be drawn on regarding work with even highly pathogenic agents, both in laboratories

and on an industrial scale, e.g. for the production of vaccines. Such techniques are now described as 'contained' and are largely standardized. Pathogens are classified into different categories of risk depending on the gravity of the disease they cause and the way they cause infection and spread. Specific graded safety measures have been prescribed for these risk categories.

b) In addition to these 'physical' safety measures, biological safety measures were introduced for the first time in genetic engineering. According to this concept, where dangerous procedures are involved, only those host organisms should be genetically modified and used which are no longer capable of establishing themselves permanently in the environment. To this end, many 'safe' strains have been developed, tested and made available for use. Further biological safety measures are (1) the requirement that the constructs of genetic engineering cannot be mobilized, i.e. transferred to other organisms in the environment, and (2) the ban on using certain resistance markers for selecting manipulated organisms.

1.1.4. Within the confines of these guidelines, genetic engineering has, in the space of over 15 years, developed into an important method especially for analysing the structure and function of the genetic system. From very early on, genetic engineering has also been used to make certain biological products. For example, large quantities of HIV-virus antigens can be produced at no risk whatsoever. These antigens are used for screening donated blood—an application that is important for the public at large. Another example is producing antigens for the hepatitis-B vaccine, which would not be available for the majority of the population without genetic engineering, since the production costs would otherwise be too high.

1.1.5. The present proposal sets out regulatory measures for genetic engineering based on the experience to date. The proposal draws extensively on a report of the Organization for Economic Co-operation and Development (OECD) which was prepared jointly by OECD Member States. It takes account of the interests of research and user industries but not at the price of neglecting protection of man and the environment.

1.1.6. The experience gained from hundreds of thousands of genetic engineering experiments which have been carried out without danger over the past 15 years provides a good basis for assessing these guidelines.

1.2. Specific comments

The Committee would make the following comments and raise the following questions regarding the individual Articles:

1.2.1. Article 1

— ad b): The word 'organism' is used here instead of 'microorganism', thus broadening the scope of the Directive. The Committee invites the Commission to clarify this point.

— ad f): In the present version, there is a contradiction between f) and Article 12. The following wording is proposed: 'Accident' means any incident involving significant and unintended emission of genetically modified microorganisms in the course of their contained use that leads or could lead to a serious danger, immediate or delayed, to the health and safety of the general population or the environment.'

— ad g): The term 'user' could be misinterpreted, despite the definition provided. A less generic term would be preferable.

1.2.2. Article 2

It is unfortunate that no definition of 'pathogenic' is provided here. Classification of genetically-modified organisms into only two groups does not do justice to the realities. This Article should at least lay down the criteria for assessing the points listed in Annex II and indicate the consequences with regard to a graded choice of safety measures in Annex III.

1.2.3. Article 3

The exclusion of transport may create a legislative vacuum at EC level. Measures therefore are needed to guarantee adequate safety requirements as regards transport of GMO. The Commission is urged to take the necessary steps to revise transport regulations to cover this field.

1.2.4. Article 4 (2) and (3)

Cf. comments on Article 2.

1.2.5. Article 7 (2)

Experience has shown that there are considerable differences in the assessment of microorganisms according to the criteria in Annex I. A liberal interpretation by, for example, an industrial user could cause irreparable damage if the physical and biological safety measures are inadequate. The competent authority should therefore be allowed a period for raising objections in the case of this group of projects too.
1.2.6. Article 8 (1)

The period of 15 days for raising objections is too short, given the many criteria to be considered. The period should be doubled.

1.2.7. Article 11

The second indent should be expanded to say that, as well as being informed of the hazards, the emergency services should be prepared for tackling an accident and hence equipped with suitable means.

1.2.8. Article 15

Given the extreme sensitivity of the subject in question, serious consideration ought to be given as to how involve both the public at large and the social partners and experts in the consultative procedures. The Advisory Committee proposed ought to be receptive to the views of such groups, for example through preliminary consultations at national, regional and local level. Only if the public at large is involved in the deliberations can this important new technology develop for the benefit of all.

2. Proposal on release to the environment

2.1. General comments

2.1.1. While experience has been gained with the use of genetically modified organisms in contained systems, little experience is available as yet regarding the consequences of the deliberate release of genetically modified organisms into the environment. The release of genetically modified organisms into the environment of necessity involves abandonment of the safety measures which have so far proved satisfactory for minimizing risks in genetic engineering, i.e. working in contained systems and the use of biological safety measures. This difference vis-à-vis the previous Directive cannot be emphasized too strongly.

2.1.2. The Committee understands the need to adopt a preventive common approach as regards sensitive new technological developments that are already taking place at international and Community level and are subject to different rules varying from a general ban to a total lack of rules.

2.1.3. The Committee agrees with the statement of the explanatory memorandum that 'citizens and the environment throughout the Community need to be provided with adequate protection from any potential hazards arising from the application of genetic engineering', and that, 'from an environmental viewpoint, organisms are no respecters of national frontiers, and nothing short of Communitywide regulation can offer the necessary human and environmental protection'.

2.1.4. However, in the light of the limited experience and knowledge available, the proposed Directive should be seen only as a first step setting down general minimum requirements deemed necessary, and as a reference framework with a view to completing and adapting knowledge in this field.

2.1.5. Therefore, the Directive must be reassessed very carefully and redrafted in the light of the comments which follow.

2.1.6. Many citizens, including a large number who are well informed, take the view that the release of genetically modified organisms introduces a new dimension into man's relationship with the environment. In this situation, consideration should be given to how the citizens of the Community can be appropriately involved in evaluating this expansion of technology and its application in the environment. For instance, measures could be taken by the competent authorities to inform the public concerned of any endorsement granted for deliberate release prior to the release.

2.1.7. Account must be taken of the fact that many Member States now have strict rules, including prohibitions (under their anti-epidemic and plant protection legislation) on the importation and release of certain organisms.

The release of genetically modified organisms and the consequences thereof can best be compared with the introduction of organisms that are foreign to the environment in question, and also with experiences in 'classical' genetic research or the use of 'live' vaccines.

It is not clear whether and, if so, how these various experiences have been taken into account in the Directive or whether experts in these fields were consulted during its preparation.

2.1.8. The Commission's aim with the proposal is to lay down a procedure to be observed in making decisions on the release of genetically modified organisms. It is expressly stated that the decisions should be made on a case-by-case basis—in other words, no binding criteria are specified for determining when organisms may be released and when not. This is to be welcomed.

Bearing in mind the OECD recommendations the Committee suggests that a step-by-step procedure should be followed, moving gradually from the laboratory stage to the greenhouse, to small-scale field testing and finally to large-scale field testing, in order to keep risks to a minimum and to ensure adequate monitoring. No explicit link are made in the Commission proposal between the different stages.
2.1.9. The organisms which come into consideration for release vary greatly. They include, for example, genetically modified viruses intended for use as vaccines, brewers' yeasts, plants to which genes for nitrogen fixation from bacteria have been added and transgenic animals. At this point in time, it is not possible to give in any way adequate assessments of these organisms.

2.1.10. Whether an organism may be released should be decided in a dialogue between the competent authorities and the person or institution wishing to effect the release. The competent authority should agree to the proposal. The responsibility for the consequences of the release should lie with the applicant. This, too, seems to be appropriate provided that the dialogue is also pursued in the follow-up stage.

Consideration should be given also to the fact that competent authorities may approach problems differently in different Member States.

2.1.11. The proposal distinguishes between experimental releases and commercial releases. In the case of the former, the competent authority of the Member State has to give its approval, and in the case of the latter the Commission and other Member States have the right to raise objections. This dual system does not seem justified, considering that some types of released organisms can be prevented from spreading further and indeed across frontiers only if the conditions are very strictly controlled. Article 7 provides for the participation of other countries in the approval procedure for experimental releases, but overall these provisions remain vague. Other countries can at the most ask for and provide information.

2.1.12. Articles 8-16 lay down the procedure for the placing on the market of genetically modified organisms. Cooperation between all Member States and possibly the Commission is provided for in these cases. The provisions do not, however, apply to organisms from product groups which are already covered by Community legislation. This implies that the authorities responsible for these groups of products will have the necessary expertise concerning releases. Whether such confidence is justified would appear at least doubtful.

In the interests of uniform monitoring, the products listed in Article 8 should also be included in the Directive in a form to be determined. At all events the Committee urges a coordination approach by the Commission Services so as to guarantee that the same safety provisions are ensured for the excluded products.

2.2. Specific comments

Apart from these more fundamental comments concerning the spirit and structure of the Directive, the Committee would make the following points.

2.2.1. Article 1

The exclusion of transport may create a legislative vacuum at EC level. Measures therefore are needed to guarantee adequate safety requirements as regards transport of GMO. The Commission is urged to take the necessary steps to revise transport regulations to cover this field.

2.2.2. Article 2

The definition provided in Article 2 (2) is not very precise and consequently inadequate. In classical genetic research, genetic modification plays an important role and has been tested over decades if not centuries. Organisms which have been modified in this way must be clearly excluded from the Directive.

The following definition is proposed instead:

```
'Genetically modified organism' means any organism obtained by such techniques as in-vitro DNA recombination, microinjection, macroinjection, microencapsulation, nuclear and organel transplantion or genetic manipulation of viruses. It does not comprise organisms produced by processes such as deletion, mutagenesis, conjugation, transformation, transduction, in-vitro fertilization or any other process if they are carried out under normal physiological conditions and do not involve the use of recombinant DNA techniques or genetically organisms.'
```

The definition in Annex I can then be deleted.

2.2.3. Article 3

In its present form, Article 3 does not seem acceptable. The provision that 'all measures reasonably practicable' are to be taken runs counter to the intentions of the Directive. No organism should be released unless suitable state-of-the-art measures can be adopted to prevent foreseeable risks to man and the environment.

2.2.4. Article 7.2

There should be adequate provision to ensure that this procedure is carried out in a manner which will ensure the commercial confidentiality of information in order that the unauthorized spread of knowledge to competitors both within and outside the EC is prevented.

2.2.5. Article 16

In Article 16 no provision is made for involving the ESC. The follow-up report should be sent not only to the European Parliament but also to the ESC.
2.2.6. Article 18

The updating of the Directives provided for in Article 18 should be spelt out more clearly.

2.2.7. Article 19

Given the extreme sensitivity of the subject in question, serious consideration ought to be given as to how involve both the public at large and the social partners and experts in the consultative procedures. The Advisory Committee proposed ought to be receptive to the views of such groups, for example through preliminary consultations at national, regional and local level. Only if the public at large is involved in the deliberations can this important new technology develop for the benefit of all.

2.2.8. Article 22

The Committee is concerned that no obligation is placed on Member States to make the financial provision needed to comply with the Directive.

2.3. Conclusions

2.3.1. With this proposal the Commission attempts to regulate a very difficult and controversial area. The Directive has many elements which point the way forward, and it can form a basis for a systematic accumulation and evaluation of the experience which has hitherto been lacking.

2.3.2. It is hardly possible to make a final assessment of the proposal in the absence of the relevant experience. If releases are conducted responsibly, if those concerned are prepared to engage in an unbiased dialogue and if the provisions are swiftly updated as new knowledge is gained, this Directive can be a path to utilization of this potentially very important new technology.


The Chairman

of the Economic and Social Committee

Alberto MASPRONE

Opinion on the proposal for a Council Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community and Regulation (EEC) No 574/72 laying down the procedure for implementing Regulation (EEC) No 1408/71

(89/C 23/16)

On 29 October 1988, the Council decided to consult the Economic and Social Committee, under Article 198 of the Treaty establishing the European Economic Community, on the abovementioned proposal.

The Economic and Social Committee decided to appoint Mr Pearson Rapporteur-General to prepare work on the matter.

At its 260th plenary session (meeting of 24 November 1988) the Economic and Social Committee unanimously adopted the following Opinion.

1. The Committee acknowledges the wisdom of the Commission in updating the Regulation and amending Regulations concerning the application of social security schemes for employed, self-employed and members of their families moving within the Community. Inevitably, since the initial Regulation (EEC) No 1408/71 there have been many changes in the benefits of the Member States, and with the membership of the Community doubling since then, a large number of anomalies have come about.

2. The current proposal is an updating document which claims to adjust the anomalies so that the present position is correctly reflected. The Committee suggests that the Commission be asked to propose a routine