COMMISSION
OF THE EUROPEAN
COMMUNITIES

Directorate-General
Environment, Nuclear Safety
and Civil Protection
XI/A/2

Brussels, 10.04.89 /XI/ 003710
JT/dg

Mr. W. SZYBALSKI
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University of Wisconsin
Madison, WI 53706

USA

4412.221

Dear Mr. Szybalski,

The rather polemic editorial published in Gene, No. 75 concerning the EEC proposed regulation on deliberate release and signed by Messrs. F. Young and H. Miller raises a number of issues which need to be answered. As Director General responsible for the draft proposal for the Directive on deliberate release of GMOs, I consider it appropriate for the Commission to have a right of reply and I would be grateful if you could publish the attached 'Letter to the editor' as soon as it is feasible in "Gene".

Yours sincerely,

L.J. BRINKHORST
Director General

TO THE EDITOR OF GENE

Dear Editor,

I recently read, with some surprise, the editorial in GENE No. 75 concerning the proposed European Community regulation on the deliberate release of genetically modified organisms. It is regrettable that a magazine of some international status and reputation publishes a rather sketchy, uninformed and highly selective evaluation of a major legislative proposal nine months after its publication, and adopts the blind polemic approach of FDA officials as its own view without reflecting on the context or the benefit of the legislation for industry and research.

In a European context of extremely diverse legislative provisions for the regulation of genetically modified organisms, where two important countries (Denmark and Germany) have a ban on deliberate releases, and where the political conditions are giving rise to growing public concern in the coutries where there is no legislation at all or only voluntary codes, an EEC Commission proposal for a notification of deliberate releases with only a 90-day waiting period for endorsement can hardly be considered as "over-regulation" or "irrational regulation".

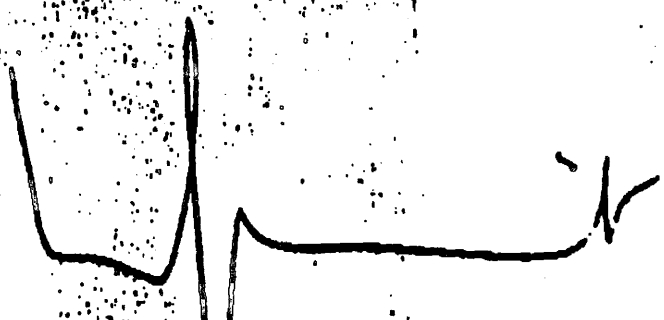
Rather than hinder research, the adoption of the Commission proposal will assist it and it will, in addition, provide a unified major market of 320 million people for those biotechnology products falling within its scope - since once a product has been placed on the market in one country, it will freely circulate throughout the 12 countries of the European Community. As for non-EEC products, their treatment will be exactly the same as for EEC products - with no discrimination of any kind.

The scientific basis for the proposal is clear, and in accordance both with scientific opinion and the majority opinion within the OECD. Modern biotechnology provides the opportunity to create entirely novel organisms and products which were not previously possible. The new opportunities are accompanied by new potential risks to the eco-system if insufficient care is taken. Our limited experience with released organisms and limited understanding of some of the possible effects on the eco-systems require us to proceed responsibly and with caution on a case-by-case basis (as recommended by the OECD) - in the interest of the biotechnology sector itself, as well as in the interest of the public.

The proposed EC directive, which does not need to be approved by the European Parliament as you mention but by the Council of Ministers, has not attracted the kind of opposition you refer to either inside the Parliament or outside it. It has, in fact, been well received both by industry and by the "enlightened authorities of the European nations" your editorial refers to. The European Parliament has not yet given its opinion, but first reactions would indicate that it considers that the proposal does not go far enough.

I hope your readers have been somewhat more enlightened by reading this letter. They can rest assured that the "bright promises of new biotechnology" are not "dimmed by the shadow of irrational regulation" as your editorial would have them believe. It is a pity that some people who are in a position to know better are too short sighted to see the longer-term benefits of harmonised and appropriate regulation for the biotechnology sector.

Yours sincerely,



L.J. BRINKHORST
Director General

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Elsevier

GEN 02250

Editorial

'Deliberate releases' in Europe: over-regulation may be the biggest threat of all

The European Commission (EC) recently approved a directive addressing planned introductions ('deliberate releases') of microorganisms into the environment. It has attracted strong opposition within the European Parliament, which must approve directives, and has stimulated concerns abroad.

There are three general areas of concern about the directive: the underlying premises on which it is based; the risk of a regulatory approach that will hinder research and development activities; and the possible use of such provisions for the erection of non-tariff trade barriers to foreign products. With respect to the latter point, many of the provisions may prove anti-competitive even within the EC nations themselves. These concerns are developed below.

First, there are underlying premises of the directive that are scientifically flawed. The directive is focused on the regulation of 'genetically modified organisms (GMOs)', which are defined as those manipulated with only certain recently developed techniques, including recombinant DNA. Thus the directive preferentially singles out for stringent regulation the newest techniques of genetic manipulation that enable the most precise and predictable genetic changes. This is at odds with the broad consensus that these newest techniques represent a clear refinement, an improvement on conventional techniques of genetic manipulation that enhances the precision and predictability of the effects of intervention. Such GMOs are clearly not a functional category, and most certainly not one correlated to risk. Additionally, we would cite one of the salient conclusions of the white paper by the U.S. National Academy of Sciences (1987)—'[t]he risks associated with the introduction of R-DNA-engineered organisms are the same in kind as those associated with the introduction of unmodified organisms and organisms modified by other methods'—a view that has been widely adopted by various national and international bodies.

Second, the directive may seriously impede research and development. It proposes such all-compassing regulation of research that the review process is likely to become either too burdensome to allow progress, or too superficial to protect against abuse (a bureaucracy overwhelmed with trivial cases may resort to 'quick and dirty' reviews). The directive assumes without explanation that there must be evaluations by national authorities for each and every field trial of GMOs for research purposes; such an assumption departs from good science and from the lessons of experience. For example, one provision of the directive encompasses all introductions of GMOs without reference to the likely risk of such uses. In addition, even testing subsequent to an already approved introduction that is part of the same research program requires a new application to the national authority, a substantial potential burden to academic investigators in particular. This insistence of the directive upon 'every case' evaluation is, in our view, a departure from good science and is inconsistent with past experience. The approach is also at odds with the published statements of the OECD, with U.S. policy, and with widespread enthusiasm for establishing criteria for low- or minimal-risk organisms for field trials. It appears to derive from a serious misapprehension of the meaning of 'case by case' as set forth by the OECD (Recombinant DNA Safety Considerations, Organization for Economic Cooperation and Development, Paris, France, 1986). Their definition was carefully qualified to mean, 'an individual review of a proposal against assessment criteria which are relevant to the particular proposal; this is not intended to imply that every case will require review by a national or other authority since various classes of proposals may be excluded' (emphasis added).

Third, the directive presents an invitation for the erection of non-tariff trade barriers. These aspects of the directive will not be examined at length here, but they include; the ability of one EC nation to delay

Abbreviations: EC, European Commission; GMOs, genetically modified organisms; OEDC, Organization for Economic Cooperation and Development.

marketing approvals indefinitely; and the possibility of discriminating against data generated outside the EC. Some aspects of the directive may even prove potentially anti-competitive for the EC nations themselves, if they are preferentially (and unnecessarily) over-regulating products at the cutting edge of new technology.

It would be unfortunate for the bright promises of new biotechnology to be dimmed by the shadow of irrational regulation. Let us hope that the enlightened authorities of the European nations return regulation to a scientific, truly risk-based approach.

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TO : Mr. van Hoeck, DG XII
FROM : R.Roy
REF. : RR/T272
DATE : May 23, 1989

RR

ADDRESSEE PLEASE COPY TO : Messrs.:
Fasella, Valentini, Boggio,
Cantley, DG XII
Brinkhorst, Del Bino, DG XI
Lennon, Sauer, DG III
Miranda, DG I

SUBJECT : Proposition de directive sur l'introduction de micro-organismes dans l'environnement.

Vous trouverez peut-être intéressant d'apprendre que Mrs. Dorigan de l'Office of Science and Technology Policy (OSTP) s'est adressée à la Délégation afin de savoir, en préparation à la réunion d'experts de l'OCDE sur la biotechnologie, quelles avaient été les réactions de la DG XII principalement, ainsi que celles de la DG III à l'article de Young et Miller de la Food and Drug Administration (FDA) dans Gene (ci-joint). Il semble, en effet, que la FDA tente de convaincre les autres agences que la réponse de M. Brinkhorst (ci-jointe également) ne représente que la DG XI et que la Commission, divisée à ce sujet, n'a pas, dans son ensemble, mal accueilli l'article. La Délégation a bien entendu souligner la solidarité de la Commission.

Roy Denman

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