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Société Suisse des Industries Chimiques
SSIC Società Svizzera delle Industrie Chimiche
Swiss Society of Chemical Industries

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Sicherheitsvorschriften in der Biotechnologie

Sehr geehrte Herren

wir danken Ihnen für Ihr Schreiben vom 21. Januar 1983 und die uns gebotene Möglichkeit, zum vorgelegten Arbeitsprogramm der OECD Stellung zu nehmen.

Die Kommentare der drei grossen Basler Firmen lauten grundsätzlich positiv, wenngleich gewisse Bedenken bezüglich der Beschränkung des Arbeitsprogramms auf "genetically engineered microorganisms" und bezüglich der praktischen Durchsetzbarkeit allfälliger behördlicher Vorschriften geäussert werden. Andererseits hätte eine internationale Harmonisierung dieser Vorschriften den Vorteil, dass alle Unternehmungen gleichgestellt wären (so wie dies offenbar beim Strahlenschutz erreicht worden sei). Die Vorschriften müssten auf möglichst klar ausgearbeiteten Definitionen der denkbaren Gefahren basieren. Dies dürfte eine heikle Aufgabe darstellen, sind doch erhebliche Differenzen in den Formulierungen der Experten je nach den nationalen oder firmenspezifischen Interessen und Schwerpunkten der Projekte zu gewärtigen.

Besondere Bedeutung wird der Ausarbeitung von Prüfmethoden zur periodischen Risikoanalyse bei den verwendeten pathogenen Keimen zugemessen, wie Sie aus dem beiliegenden Schreiben von Prof. Dr. J. Nüesch, CIBA-GEIGY ersehen können.

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Eine sorgfältig abgewogene Oeffentlichkeitsarbeit - etwa im Sinne der gut eingespielten, lokalen "Biosafety Committees" (U.S.A.) in Gemeinden mit biotechnischen Anlagen - wird als notwendig erachtet. Gerade dadurch könnten in gewissen Fällen eine breite Publizität und ein Hochspielen der biotechnologischen Sicherheitsfragen vermieden werden.

Im übrigen möchten wir Sie darauf aufmerksam machen, dass von der Schweizerischen Akademie der technischen Wissenschaften soeben eine "Schweizerische Expertenkommission für die Sicherheit in der industriellen Anwendung der Biotechnik" unter dem Vorsitz von Herrn Prof. Dr. A. Fiechter, ETH Zürich geschaffen worden ist.

Wir hoffen, Ihnen die Vorbereitung der OECD-Sitzung mit diesen Angaben erleichtert zu haben und verbleiben

mit freundlichen Grüssen

SCHWEIZERISCHE GESELLSCHAFT FUER
CHEMISCHE INDUSTRIE

pp. Lauer i.V. A. Sieber

Beilage erwähnt

J. Nüesch

2.2.1983

OECD / Safety and Regulations in Biotechnology

General Views

The OECD report contains a great deal of general information on safety in Biotechnology. The attitude of the authors also reflects that of the majority of scientists to-day.

As a primary essential, the various hazards of Biotechnology should be placed in groups according to the field in which they occur. The types of hazard fall into four natural categories:

- Biological
- Physical
- Ecological
- "Socio-economic"

In particular, care should be taken not to use the word Biotechnology as a synonym for genetic engineering which tends to confuse the issue. The emergence of genetic engineering technology has made the general public more concious of the existence of Biotechnology as a whole but they tend only to think of genetic engineering in this connection.

Even before the birth of genetic engineering there was an awareness among biotechnologists of the necessity for adequate safety precautions, though the excellent record of the biochemical industry as a whole may have given rise to undue complacency. Laboratory precautions may become lax unless carefully controlled and the staff is well trained and educated in the use of pathogenic organisms and mutagens for instance. Most if not all responsible firms drew up careful instructions on how to work with microorganisms long ago. The advent of genetic engineering has caused everyone to think again; but it is only one aspect of the complex problems of safety in biotechnology.

It would seem that OECD has the opportunity to assess these problems in the broadest possible way. There is more to genetic engineering than creating genetically engineered organisms using

various plasmid vectors. The genetic manipulation of plants and animals using continuously developing new methods e.g. successful in vitro introduction of the rat growth hormone gene into fertilized eggs of mice, techniques for cloning in animals etc., are areas of research which are much in need of monitoring, not only because of the moral issues involved, but also because of the long term ecological consequences the successful realisation of such experiments might have. Thus in focussing its attention on biosafety in industrial production the OECD might attempt to bring about a degree of uniformity of policy amongst its member countries. This will of course in no way be simplified by the fact that so many other organisations already exist with very similar terms of reference. It is also clear that the responsibility for individual projects cannot be centralised will and have to be left to the individual. The organisation of suitable approved courses on the various aspects of biosafety would surely contribute to a greater awareness of the problems involved. Finally, as the results of genetic engineering become more dramatic, the media will tend to distort them with the standard effect of over-reaction among the public. This is a completely different kind of hazard but very actual nevertheless. This kind of thing can only be overcome by sensible anticipation and good public relations.

Comments on Conclusions and Recommendations (pages 16-18)

Effective enforcement of industrial guidelines and international harmony

Guidelines should be general and not specific to rDNA research and production. It will be difficult or impossible to turn guidelines into legally enforceable regulations. The obvious idea behind this is largely economic and, as is stated, the fear is that a country with lax regulations should gain an economic advantage in this way. (e.g. The former Italian pharmaceutical Patent regulations.) However the implication would be

that written application for permission to produce a new product would be necessary in each case with all the bureaucratic delays involved, and such regulations would be extremely difficult to enforce.

Public acceptance of large-scale production

This is indeed an important aspect and the suggestions made here are sensible. However the proliferation of international organisations discussing the same thing is liable to be contra-productive.

Safety of industrial mass-production and release into the environment

The great necessity here is to develop tests for risk assessment. This is difficult because of the very broad scope of biotechnology. However if one is using a pathogen (animal or plant) it would be of interest to examine its degree of pathogenity from time to time. This is of course a very simple example. To establish tests for potential danger from cloned organisms would be far more difficult.

Work proposals

The decision to confine the study to genetically engineered micro-organisms in industrial mass production and their release into the environment is perhaps to be regretted. The other aspects we have mentioned would seem to present, at least in some cases, new hazards of at least equal potential and importance. However it might indeed be more practical to consider these aspects separately.

2. (ii) The intention here is not clear and could be usefully rephrased.

In conclusion, it is really questionable if the proposed very narrow terms of this investigation will really serve the purpose of improving the present general safety standards in Biotechnology.