

COMMISSION OF THE EUROPEAN COMMUNITIES

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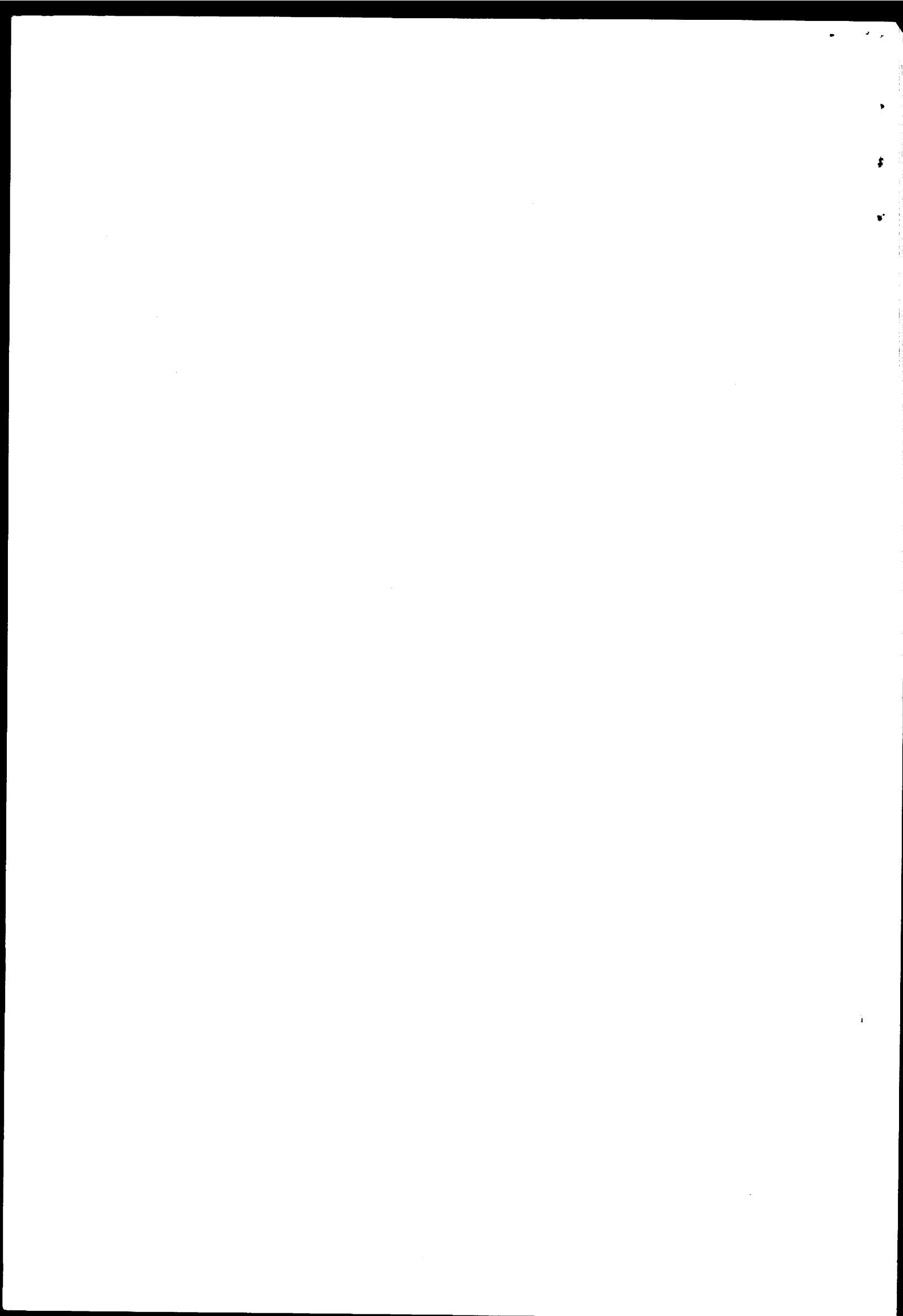
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COMMUNICATION FROM THE COMMISSION TO THE COUNCIL

A COMMUNITY FRAMEWORK FOR THE
REGULATION OF BIOTECHNOLOGY

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1. Traditional biotechnology, achieving genetic modification by such techniques as hybridization and selective breeding, has always played an essential role in the development and improvement of plants, animals and in manufacturing processes. Within the last decade new techniques of genetic modification have been developed to make possible major advances in animal and plant breeding, and in the modification and the use of microorganisms and cell lines to manufacture medicines, fine chemicals, and many other products. These new techniques, such as recombinant DNA or RNA, and cell fusion, are now generally known as genetic engineering.

2. The question has been posed as to whether these newer genetic modification techniques bring with them extra or new risks for consumer/worker health and safety or the environment. In that they enable much more precise genetic modification, there is no a priori reason to believe that their use in enclosed manufacturing processes entails any extra or new risks. Nevertheless, the use of genetically engineered organisms in both laboratory and industrial conditions has been subject to regulatory oversight in the Community and in the U.S. Moreover, in recent years, the planned release of genetically engineered organisms in agricultural and environmental applications has given rise to further debate about the possible risks involved.

3. Several countries have therefore been reviewing existing regulations, and generally assessing the risks to human and environmental safety from genetic engineering. A major study-report prepared by leading international experts for the OECD entitled "Recombinant DNA Safety Considerations" has been recently published.

The report distinguishes between

- the use of genetically engineered organisms in enclosed manufacturing systems, and the products produced by such methods,
and
- the planned release of genetically engineered organisms in agricultural and environmental applications.

4. The report concludes that genetically engineered organisms used in manufacturing systems contained or enclosed to the appropriate standards and not at any stage inappropriately exposed to or released into the environment, give rise to no new or additional risks, either for the workers involved, the environment or in respect of the resultant products.

It states that, for the majority of cases, the levels of physical and biological containment laid down by the principles of Good Industrial Large-Scale Production (GILSP) would provide adequate safeguards for worker and environmental protection. In those few cases where higher risk organisms have to be used (e.g. vaccines) well-known containment measures would be applied in addition to GILSP.

5. On the question of planned release of genetically engineered organisms in agricultural and environmental applications, the report concludes that while risks exist, they can be assessed to some extent by analogy with information about existing organisms. However, there is insufficient experience at this stage to lay down a coherent set of regulations. Instead the report recommends a prior case-by-case evaluation of all planned release applications.
6. The Community took a first step in biotechnology regulation in 1982 with the adoption of a Council Recommendation on laboratory safety measures in relation to rDNA experimentation. A new coordination procedure for Community evaluation of biotech medicines was proposed in October 1984 and is currently before Council. Existing Community legislation already covers the protection of workers from the risks related to exposure to biological agents at work, and work is in progress on specific norms for pathogenic biological agents. In July 1985, the Biotechnology Regulation Interservice Committee (BRIC) was set up, and has been assessing the need for Community regulation in this area. Existing Community legislation in respect of products, worker protection and environmental protection is being re-evaluated as to its adequacy. BRIC was involved in the preparation of the OECD report referred to above, and organized on 29-30 April 1986 a high-level meeting with Member States officials to discuss the regulation of biotechnology in the Community, taking account inter alia the OECD report. Following this meeting, Member State officials have been requested to keep the Commission services informed of national

activities and intentions in regard to biotechnology regulation. The Commission services involved have also been in consultation with the industries most involved with modern biotechnology - indeed the chemical, agrochemical, pharmaceutical and food industries have submitted a joint report to the Commission, setting out their views on the need for Community-wide regulation of biotechnology. At the same time, Community research is being undertaken in the framework of the Biotechnology Research Action Programme to develop further the scientific basis for the assessment of risks resulting from the release (accidental or deliberate) of genetically engineered organisms. Member State representatives on the Advisory Committee ("CGC") for the Biotechnology Research Action Programme have been requested to prepare a summary of relevant research in national programmes.

7. In the light of the examination which has been undertaken by the services, the Commission believes the rapid elaboration of a Community framework of biotechnology regulation to be of crucial importance to the industrialization of this new technology in the Community. Equally, citizens, industrial workers, and the environment, need to be provided with adequate protection throughout the Community from any potential hazards arising from the applications of these technologies. The internal market arguments for Community-wide regulation of biotechnology are clear. Microorganisms are no respecters of national frontiers, and nothing short of Community-wide regulation can offer the necessary consumer and environmental protection.
8. The Commission therefore intends to introduce proposals for Community regulation of biotechnology by Summer 1987 with a view to providing a high and common level of human and environmental protection throughout the Community, and so as to prevent market fragmentation by separate unilateral actions by Member States. The Commission's proposals will address two distinct aspects of the use of genetic engineering, viz :
 - A. Levels of physical and biological containment, accident control, and waste management in industrial applications, and,
 - B. Authorization of planned release of genetically engineered organisms into the environment.

9. The purpose of the first proposals (A) would be to ensure adequate Community-wide levels of containment, accident procedures and waste management in respect of the use of genetically engineered organisms in enclosed manufacturing systems. This measure would ensure adequate standards, while at the same time comparable conditions of industrial production as between Member States. It will be based on usual requirements of good manufacturing practice - and may in its scope cover other biological agents used in industry.
10. Because international experience of risk assessment in the field of "planned release" is still limited, it is not possible to propose any general guidelines or testing requirements for the time being. The Commission will be proposing a Community case-by-case evaluation and authorization procedure based on mandatory phased notification by industry. This is in line with industry's own proposals and with the recommendation of the OECD report. The stages at which Community notification would be mandatory, the procedures for dealing with agricultural and environmental applications, and the general question of a priori exemptions, have yet to be agreed and will be a matter for further discussion with experts and with Member States officials in the light of the reevaluation of existing Community legislation referred to in para 6.
11. These new technologies have a significant international impact and the market for the new biotechnology is worldwide. The Commission therefore considers it to be of importance that in the elaboration of Community regulations care is taken to achieve and maintain a broad measure of harmonization with other countries, in particular with the practices of our principal trade partners. The Commission is prepared to sponsor or co-sponsor general and technical international meetings on aspects of the regulation of genetically engineered organisms.
12. The Commission is convinced that the development of a Community regulatory framework, which will both provide a clear, rational and evolving basis for the development of biotechnology and also ensure adequate protection of human health and the environment is an urgent necessity. To this end the Commission services, working together in the framework of BRIC, are launching the necessary work to draft proposals for legislation on genetically engineered organisms to be presented to the Council by Summer

1987. In the meantime, the Member States are requested to inform the Commission of their activities and intentions in the fields of biotechnology regulation and risk assessment research.

