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A FRAMEWORK OF LAW FOR EUROPEAN BIOTECHNOLOGY(1)

Biotechnology promises to be one of the major industries of the future. It opens up vast new opportunities in major sectors of the economy such as agriculture, food processing, waste treatment, chemicals and medecine and could grow as much in the coming years as micro-electronics have done in the 1970s and '80s. If Europe's industries are unable to exploit its possibilities, they will seriously damage their ability to compete on world markets. Europe will also lose many of the benefits which genetic engineering has to offer.

It is nonetheless a development of technology which arouses strong public concern and neither industry nor public opinion will have the confidence to allow the creation of a major European biotechnology industry until there is a framework of legislation at the Community level.

The European Commission has now made proposals for the Community legal framework which industry needs and which can ensure technological progress while at the same time ensuring protection of public health and the environment by establishing the general principle of prior notification and endorsement. Public confidence is essential if European industry is to take advantage of the possibilities in this dynamic new field.

The Commission has proposed two directives:

- on the contained use of genetically modified micro-organisms, which would govern the use of biotechnology in the laboratory or as part of a manufacturing process;

- on the deliberate release of genetically modified organisms into the environment, which concerns both experimental releases or the marketing throughout the Community of new products containing or consisting of genetically modified organisms.

A confusion of national standards

The need for Community legislation is underlined by the varied way in which Member States have responded to the development of biotechnology. Faced with the need to ensure public confidence while providing a legal framework for industry, some governments have set up

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formal notification procedures for experimental work in contained conditions, especially to protect people at work. Others have relied on application of existing law governing dangerous substances. Almost all Member States are still undecided as to the ideal framework of regulation.

Deliberate release of genetically modified organisms is generally banned in certain Member States (Germany, Denmark). In one country (Netherlands) regulations are being prepared, others (France, United Kingdom) are relying on case-by-case authorisation. Some (Belgium, Italy) are using existing legislation to cover release into the environment.

Contained micro-organisms

The proposed directive differentiates between small scale processes involving micro-organisms, such as laboratory experiments or pilot applications, and large-scale, manufacturing processes. It also draws a distinction between group 1 micro-organisms which are generally safe, and group 2 which have a degree of risk.

For all contained uses of modified micro-organisms, whether they fall within group 1 or 2, the operator must notify the national authorities of his intentions and provide a safety assessment of the project. The competent authorities will verify the information given and the risk classification of the organisms involved. For non-industrial uses of group 1 organisms, the principles of Good Microbiological Practice will be applied to ensure good safety and hygiene conditions. For group 2 organisms, more stringent conditions are imposed. Special measures must be taken for containment such as air filtering, inactivation of waste, and emergency provisions to deal with any accidental escape of micro-organisms.

Contained industrial uses of group 1 micro-organisms are subject to wider controls, exercised by the competent national authorities, requiring provision of detailed information of the process planned, sufficient to allow the authorities to judge the correctness of the classification. With group 2 projects, the operator must provide full details of the micro-organisms involved, the installation, waste management, accident and emergency response plans and a safety assessment. If the plans are not blocked within 60 days, the contained use may go ahead.

Member States shall collect information on any accidents involving group 2 micro-organisms which may affect human health or the environment. This information would also be provided to the Commission which would in turn keep a register of accidents throughout the Community, analysing the causes and recommending ways of avoiding similar accidents in future.

Deliberate release of organisms

Genetic engineering will sharply increase the number of organisms with new characteristics being introduced into the environment. A system is therefore needed which will protect people and the environment from the possible risks related to the introduction of these new organisms.

Under the Commission proposals, competent authorities in the Member States would be responsible for overseeing projects for deliberate release of organisms for research and development purposes (as against the marketing of new products). However, these authorities would work within the context of Community law. All proposed releases in the research and development phase would be notified to them so they could review the proposals, endorsing the notification as long as it complied with the requirements of the directive and provided the risk associated with the release was considered acceptable.

An information exchange system would be established, under which a summary of each notification would be provided to the Commission and to all other Member States, which would be free to request further details and to make comments.

Commission proposals governing the marketing of products involving new organisms do not cover those which are already subject to Community legislation, such as medicinal products, veterinary products, foodstuffs, feedingstuffs and additives, plants and animals or any other products governed by Community legislation which includes a specific risk assessment. The proposals would apply to the marketing of other organisms such as pesticides, herbicides, nitrogen fixing bacteria, organisms for degrading toxic chemicals, recovering oil or treating waste.

The system proposed in analagous to the Community arrangements for the marketing of chemicals. Manufacturers would provide details of new products in confidence to the national competent authorities, together with a risk assessment, details of use and handling conditions and proposals for packaging and labelling. Once the competent authority was satisfied that the product could safely be placed on the market, it would send the dossier to the Commission, which would then forward a summary to all other Member States. They would have an opportunity to ask further information or to request changes in the marketing conditions. A special committee would be set up to deal with any disputes.

This Community process would be subject to strict time limits and to rules of confidentiality. Once a product had been endorsed, it could be marketed throughout the Community, although if evidence subsequently emerged that the product constituted a risk to people or to the environment, it might be provisionally restricted or prohibited by a Member State subject to a Commission decision.

A rapidly changing sector

The Commission has incorporated in its proposals various provisions allowing the legislation to be adapted to changing technologies and scientific knowledge and also to changes on the international level. It is anticipated that the OECD, for example, will develop new guidelines in this sector, which could be reflected in Community law.

Commenting on the new proposals, Commissioner Stanley Clinton Davis stressed the Commission's two essential aims: to protect people's health and avoid damage to the environment, while at the same time allowing Europe to exploit the enormous benefits of genetic

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engineering. "If we are to build a major biotechnology industry in the Community, we must retain the confidence of the public. We have proposed a legal framework which will establish effective safeguards for human health and the world around us, without unnecessarily cramping creative innovation in European industry."

Some uses of genetic engineering

Biotechnology in the form of genetic engineering, has an infinite range of applications. It essentially means changing the characteristics of micro-organisms such as viruses, bacteria, fungi, and living cell cultures, by modifying their genetic structure so that they can fulfil new functions.

In its proposals on contained use, the Commission provides for two groups of genetically modified micro-organisms. Most micro-organisms would be in the first group, which is of virtually zero risk. They would be used in the following types of process:

- production of rennet from yeast rather than from the stomach of a cow;
- production of citric acid from sugar;
- making of insulin or interferon;
- modifying the fermentation agent in yoghurt so it would no longer risk souring the product.

The second group covers applications where there is a higher degree of risk. A typical example here would be:

- production of vaccines where the pathogenic characteristic has been eliminated by the use of genetic engineering, so rendering the vaccine entirely safe.

Among the genetically modified organisms which might be deliberately released to the environment would be:

- potatoes which have been given improved disease resistance;
- cereal crops which have acquired the ability to create their own nitrogen;
- organisms with the power to disperse oil pollutants at sea;
- organisms able to extract metals from minerals, to break down household waste, to start compost heaps or to make silage;
- livestock with improved production or disease resistance characteristics produced by genetic modification.