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BIOTECHNOLOGY MUST BE CONTROLLED ON A COMMUNITY BASIS

Extracts from the opening address given by
Commissioner Stanley Clinton Davis at the
CEPS business policy seminar on biotechnology,
February 23, 1988

"Public concern about the potential environmental impacts of genetically modified organisms has been rising steadily for almost a decade. Several Member States have responded with voluntary testing and permit schemes, while others have adopted more formal bans on the release of genetically modified organisms to the environment.

"Living organisms can reproduce and spread across the earth, ignoring national frontiers in the process. National legislation may help to control domestic releases, but can do nothing to protect one State against the releases of organisms in other States.

"Hence, Community legislation is vital for two reasons: the vulnerable growth industries need access to the entire Community market of 320 million people. And only Community legislation can begin to achieve comprehensive protection of the environment. Of course, we do not intend to stop at only the Community level. We will collaborate with other industrial countries within the scope of the OECD as well.

"In contrast to the United States, the Community does not have a comprehensive web of product licensing laws that can be applied to cover all potential applications of biotechnology. Because the Community's regulatory slate is comparatively blank in the field of biotechnology we have a unique opportunity to tailor our regulatory requirements closely to the needs of the time - and find a sensible balance between the concerns of industry, government, science and the public.

"Only a strong framework of legislation that guarantees the careful assessment of risks before genetically modified organisms are released, the monitoring of uses, and the maintenance of reliable controls can give the necessary reassurance that the authorities are fulfilling their responsibilities.

"Our goals in this situation are:

- to create a stable regulatory framework that gives the maximum possible assurance that those applications offer no threat to human health or the environment;
- to provide legal sanctions for the enforcement of these regulations throughout the Community; and, as a result of these actions,
- to ensure access for those industries to the entire Community market.

"The problem of contained use is in many ways the least difficult. The use of genetically modified microorganisms in contained systems is most unlikely to give rise to types of risks beyond those already encountered in the traditional uses of microorganisms. The levels of physical containment that have been developed over the years should be sufficient to control hazards or potential risks.

"The regulatory focus, therefore, both for research and industrial uses must be on ensuring that the risks are identified and that appropriate levels of containment are implemented, on monitoring the use of these microorganisms, on deactivating wastes, on preventing accidents, and providing for rapid emergency response where it may be necessary.

"In the case of the release to the environment of genetically modified organisms we are in quite a different situation. We do not yet have much experience in assessing the risks and ecological impacts of new organisms released to the environment.

"Given the already high level of public concern about the safety and social impacts of biotechnology, and the reflection of this concern in the highly restrictive policies of Denmark and the Federal Republic of Germany; bearing in mind the lessons taught by, for example, the unforeseen impact of chemical pollution, we must avoid repeating the mistakes of the past and rushing into the technological future without considering its effects on our whole society and on our planet.

"If we are to foster public confidence and trust in these industries, we must proceed openly and deliberately. That is why the Commission established the Biotechnology Regulation Interservice Committee in 1985 to draw upon all of the resources of its different services from the very beginning in drafting a regulatory framework and why we published our approach to regulation in 1986.

"In the last analysis, we believe that a strong structure combining risk assessment and risk control by industry; government notification, monitoring and enforcement; and transparency of the decision-making process to the public, will provide an essential foundation for the healthy development of these industries, public confidence in their activities, and the quality of the environment in Europe."