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BIOSAFETY REGULATIONS IN THE UNITED KINGDOM AND THE EUROPEAN UNION

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ABSTRACT

Regulations governing the production and use of genetically modified organisms have been developed in the United Kingdom since 1976. Regulations covering the release of transgenic organisms into the environment were initially voluntary. Since 1990, the European Economic Commission (EEC) Directive 90/219 and 90/220 (appears more frequently in the text) have been in operation for all European Union countries, and there are continuing efforts to harmonise standards of biosafety among the 15 members. Several genetically modified plant varieties have been approved, or are being considered for commercial use.

Key Words: **Biosafety regulation, European Union, UK**

RÉSUMÉ

Au Royaume-Uni d'Angleterre, les règles gouvernant la production et l'utilisation d'organismes génétiquement modifiés ont été développées depuis 1976. Au début, les règles sur la dissémination d'organismes transgéniques étaient volontaires. Depuis 1990, les directives de la Communanté Economique Européenne (CEE) 90/220 et 90/221 (apparaissant fréquemment sur les textes) sont utilisées pour tous les pays de l'union européenne et il y a constamment des efforts pour harmoniser les références de biosécurité parmi les 15 pays membres. Plusieurs variétés des plants génétiquement modifiés ont été approuvées, ou sont considerées pour la commercialisation.

Mots Clés: **Réglementation de biosécurité, Union Européenne, Royaume-Uni d'Angleterre**

INTRODUCTION

The regulations governing the use of genetically modified organisms within the European Union (EU) are based on EEC Directive 90/219 for contained use, and EEC Directive 90/220 for the deliberate release of transgenic organisms into the environment. Most countries within the EU have now transposed these two Directives into their own national laws, and there are significant moves towards achieving a harmonised regulatory system within the EU.

Before outlining the procedures that must be followed in preparing for an experimental or commercial release of a genetically modified organism (GMO), it is important to describe some features of the EU regulatory system. Directive 90/220 describes an essentially horizontal procedure which regulates any organism produced by recombinant DNA methods and genetic transformation. This is in contrast with vertical regulation, which attempts to define particular characteristics of organisms which make them worthy of regulation. The aim of the regulation is

to protect against unacceptable impacts to "human health and the environment". Each member state must have a "competent authority" (i.e., one or more designated government organisations responsible for the regulation of activities involving genetically modified organisms), and a committee of the competent authorities from the member states is involved in EU wide operational discussions and decisions.

DEVELOPMENT OF REGULATIONS IN THE UNITED KINGDOM

The development of regulations within the United Kingdom up to the point of adopting the unified EU system, is outlined as follows:

(1) The Genetic Manipulation Advisory Group (GMAG) was set up in 1976 to advise those involved in genetic modification work, to continually assess risks and precautions, and to advise on appropriate action (Royal Commission on Environmental Pollution, 1990).

(2) Powers under the Health and Safety at Work Act (1974) were used to protect people at work and members of public generally, against risks arising from work activities.

(3) The Health and Safety (Genetic Manipulation) Regulations were passed in 1978, and required anyone intending to carry out genetic manipulation to inform the Health and Safety Executive (HSE). Inspectors have powers, under the Health and Safety at Work Act, to ask for improvements in laboratory practices or to prohibit any work activity. These regulations apply to the contained use of GMOs. They can only be applied to cover the deliberate release of GMOs, to prevent harm to human health. This Act cannot be used to prevent harm to the natural environment.

(4) GMAG was replaced by the advisory committee on Genetic Manipulation (ACGM) in 1984 with the aim of advising the government health, agriculture, environment and industry ministers on aspects of genetic manipulation. This committee consists of representatives from employers, employees and members with specialist knowledge, and is largely concerned with contained experimental and industrial work involving GMOs.

(5) A working group of ACGM, which became known as the Planned Release Sub-Committee of ACGM, established guidelines in 1986, for the release of GMOs into the environment. The recommendations were that: (a) the Health and Safety Commission (HSC) should be notified of any release of GMOs; (b) the notifier should be advised by a local (institute or company) biosafety committee, on the environmental consequences of a release and; (c) case by case examination of a proposal should be carried out on behalf of HSC using the risk assessment material provided by the proposer. These arrangements were initially (largely) voluntary, but no release of a genetically modified organism is known to have taken place without prior notification of, and endorsement by, the Planned Release Sub-Committee.

(6) Advances in genetic modification techniques and an increasing awareness of their potential for use in agriculture, led to the view that there should be statutory control of the release of GMOs into the environment. Because there is no clear dividing line between containment work and release of GMOs into the environment, it was considered that the regulations should cover risks both to human health and the environment. It was, therefore, proposed that the Secretary of State for the Environment should be given a range of powers, including: (a) to set up an advisory committee; (b) to publish codes of practice; (c) to make information available to the public; (d) to carry out appropriate monitoring; and (e) to inspect the release premises.

(7) In 1990 the European Community (EC) issued directives on the contained use (directive 90/219) and the release to the environment (directive 90/220) of GMOs.

It is the responsibility of each member state within the community to pass legislation to comply with the directives. The legal basis of the release directive (90/220) implies that member states do not have the option to adopt more stringent rules and criteria when the directive is transposed into national law. This is considered important for the harmonisation of laws and rules for establishing the EC internal market. In the United Kingdom, national regulations for both contained use and deliberate release, came into force in February 1993.

PROCEDURES FOR EXPERIMENTAL AND COMMERCIAL RELEASE

The proposer. The proposer must first prepare a description of the release and provide a risk assessment. This involves responding to the questions outlined in EC Directive 90/220, about the nature of the gene donor organism, the recipient organism, the modified organism and its interaction with the environment (Dale *et al.*, 1993). There are 89 questions in the Directive, but not all are relevant to each release, and guidance notes help to identify questions to be answered.

The local biosafety committee. It is usual for the proposal to be discussed and approved by an institutional or company biosafety committee. This has the merit of involving in the decision making people with a range of expertise, and of spreading responsibility and accountability to people in addition to the person directly responsible for the proposal. Members of the local biosafety committee will usually have local knowledge of the environment, the scientific objectives and the crop being modified, and can often play a valuable role in identifying important biosafety issues.

The national biosafety committee. The United Kingdom has an advisory committee (Advisory Committee on Release to the Environment, ACRE) which advises the Secretary of State (i.e., Government) on whether a release proposal should be accepted, modified or rejected. ACRE consists of 12 members with a range of expertise, along with observers from different government ministries. The response time for considering proposals is a maximum of 90 days, but the "clock" can be stopped if the proposer needs to be asked for further information. For experimental releases (see below for commercial releases) the competent authority communicates the decision to the European Commission and to the other member states. Various actions to streamline and simplify procedures have been adopted by the EU, and last year the UK introduced a fast-track procedure for crops and transgenes that are considered to be low risk. For the fast-track procedure, a decision from the UK Regulatory Authority is obtained within 30 days.

For commercial releases, a proposal is sent to the competent authority in one member state. That competent authority reaches a decision in 90 days (the "stopped clock rule" also applies) and when approved the proposal is sent to the Commission and the other member states. The other member states approve or refuse the release in 60 days. If there is not a unanimous decision, a qualified majority voting system is used. If the consent to commercialise is given, the approval is valid across the whole European Union (Kioussi, 1994).

International biosafety responsibilities. International responsibility within the EU is organised by staff in DG XI, which act as a Secretariat for the committee comprising of the competent authorities from each member state. The competent authority in the UK is the Secretariat of ACRE and is based in the Department of the Environment.

Public information. There is an obligation on proposers to inform the public of a transgenic release experiments, which is usually done by publishing details in a Public Notice in the local newspaper. There is public access to summaries of proposals through a Public Register. Members of the public can also have access to the full

release proposal (minus confidential business information) by making a request to the Department of the Environment.

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