THE ROYAL SOCIETY

February 1999
Ref: 3/99

Regulation of Biotechnology in the UK

A response to the Government's consultation exercise

Contents

Introduction

The Cabinet Office and the Office of Science and Technology initiated a joint consultation exercise in December 1998 requesting comments on the current regulatory and advisory framework for overseeing developments in biotechnology. The Royal Society welcomes the opportunity to comment and would like to stress the importance of providing sound scientific advice to policy makers.

The Society has already produced statements on genetically modified organisms (GMOs) in September 1998 and the scientific advisory system, in June 1998. This paper covers current gaps and overlaps in the advisory system, transparency of scientific advice to Government and the proposal for an environmental stakeholders panel. The response has been endorsed by the Council of the Society, and was prepared by a group chaired by Professor Patrick Bateson FRS (Biological Secretary and Vice-President, Royal Society). The other members were Professor Derek Burke (ex-Chairman of ACNFP), Professor Ted Cocking FRS (University of Nottingham), Professor Mike Gale FRS (John Innes Centre), Professor Don Grierson (University of Nottingham), Professor Chris Leaver FRS (University of Oxford), Dr Terry Rabbitts FRS (Cambridge University) and Dr Rebecca Bowden (Secretary).

It is particularly important to take account of public values, and how these are formed, at all stages in any process of setting standards, as was outlined in the report of the Royal Commission on Environmental Pollution, published in 1998. The application of biotechnology has the potential to offer real benefits in human and veterinary medicine, agricultural practice, food quality, nutrition manufacturing and environmental protection. As a result it may also have immense potential industrial potential. Nevertheless, it is necessary to have adequate regulatory procedures in place to ensure all aspects of the technology are addressed.

The four main issues that the Society recommends be addressed by Government in order to improve the current framework are as follows:

1. Improvement of communication and coordination between Government departments involved in the regulatory process.
2. Use of an overarching body, to which specialist advisory committees would report, to take a broad overview of developments and concerns related to biotechnology.
3. A presumption that scientific advice to Government will be made publicly available unless it is demonstrably against the national interest to do so.
4. Increased use of *ad hoc* working parties to enable greater flexibility and rapid adaptation to scientific advances and to provide advice on specific issues of concern.

In the remainder of the document the Society lists its responses to the specific questions raised in the consultation.

(i) What gaps exist in coverage of biotechnology by the existing advisory committees and how might these be remedied?

Although genetic modification and the release of GMOs are tightly regulated in the UK, concerns have been expressed that there is no over-arching body to monitor the impact of GM crops on agronomic practices or to look at the cumulative effects of such crops, since applications are reviewed on a case by case basis. In 1994 the BBSRC held a Consensus Conference on plant biotechnology at which a cross-section of lay persons considered the implications of these technologies. We agree with the recommendation of this panel that the regulatory authorities should address the wider issues surrounding

the introduction of GM commodity crops by putting in place a monitoring mechanism or over-arching organisation (as set out in our recent publication 'Genetically Modified Plants for Food Use'). We welcome recent moves by the Government to establish a Ministerial committee to oversee biotechnology. However such a body is likely to be concerned mainly with coordination of policy across departments. It will also be necessary to ensure that there is also some mechanism for taking a broad overview of developments and concerns.

The reliance on a case by case approach in obtaining expert advice for policy makers may result in a lack of analysis of the overall impact of the technology on agriculture and the environment, and of the long-term effects of GMOs. In particular, the following points are not adequately covered by the current advisory committee system:

- review of enforcement mechanisms for current regulations
- review of mechanisms by which GM crop plants could be monitored in the environment and recommendations for long-term monitoring of impact on ecosystems
- review of current guidelines for isolation of certified seed crops and high erucic acid oilseed rape and provision of recommendations regarding isolation of specific GM crops of concern and possible statutory provisions
- review of available methods for minimising gene transfer and recommendations regarding further research
- consideration of possible effects of insect tolerant crops on the ecosystem and provision of guidelines for growth of such crops and recommendations for further research, as applicable
- consideration of current guidelines for growth of herbicide tolerant crops and the potential for statutory measures
- regular review of advisory committee membership
- analysis of the current regulations, with particular attention to consideration of whether allergenicity and toxicity of GMOs receive adequate consideration
- applications for herbicide use on a crop should be considered in conjunction with applications for release of herbicide tolerant crops. There should also be a mechanism by which the long-term impact of such crops on agricultural practises could be monitored
- consideration of the potential effects of GM crops in comparison with the effects of current agricultural practices in general on ecosystems and the environment as a whole.

We therefore recommend that these issues be covered via extending the remit of the appropriate advisory committees. In addition, an overarching body is needed to have an ongoing role in monitoring the wider issues associated with the development of GM plants. Such a body should consider those of the above issues which cannot be considered by individual advisory committees for practical reasons. In addition, the proposed Food Standards Agency and Ministerial Committee will have an overseeing role to play on some aspects of biotechnology. We acknowledge that many of the concerns raised cannot be addressed without the information gained from long-term small-scale field trials and laboratory work.

In addition to the above areas of concern which are not adequately covered at present, there is a degree of discrepancy in both membership and remit of the advisory committees. For example, the Advisory Committee on Novel Foods and Processes (ACNFP) currently has a member to provide advice on consumer issues, whereas the Advisory Committee on Release to the Environment (ACRE) does not, although it gives advice to Government on applications to market GMOs. In addition, members are occasionally common to more than one non-departmental public body. Whilst this has obvious advantages for the coordination of advice (eg membership of both ACNFP and ACRE), it has the disadvantage of limiting the number of independent advisors. We recommend increased use of co-opted members of advisory committees on an ad hoc basis, with individuals appointed on a personal basis to provide advice on specific issues. In addition, advisory committee should make use of ad hoc working groups to consider specific issues of concern and report back to the committee. We also recommend the consultation of independent bodies of international reputation and widespread consultation for specific purposes such as determining the degree of public confidence in the current regulatory framework.

(ii) What overlaps exist and are they justified? If not, how might they be remedied?

There are currently several overlaps in the advisory system, most notably between those advising on applications to market different GM products. The introduction of the Novel Food Regulation at European level was intended to streamline the process of marketing GM foods and food ingredients in the EU. All such applications are reviewed by MAFF in the UK. However, current arrangements are far from clear, since many food products are also intended for other uses such as animal feed or growth for seed. Such uses are regulated by Directive 90/220/EEC which covers the deliberate release and marketing of GMOs. This overlap may necessitate the submission of an additional application under 90/220/EEC; all such applications are reviewed by DETR in the UK. Advisory committees to MAFF primarily dealing with applications under the Novel Foods Regulation may also be required to review applications made to DETR under 90/220. Conversely, applications made via DETR under 90/220/EEC may also have to be reviewed by MAFF. Hence there is a great potential for repetition and overlap unless there is strict top-down coordination of the regulatory process.

Matters are further confused by the existence of separate legislation for medicinal products containing GMOs, and the proposal for further vertical legislation such as that governing GM seeds. Any such overlaps would be identified if there were an overarching body monitoring the development of governmental policy on biotechnology as a whole.

(iii) Could the current system be structured in a more simple way?

The current system could be simplified in the ways set out above by removing overlaps in advisory committee remits and ensuring membership is more flexible. Regarding the provision of scientific advice, the current use of a number of

specialised advisory committees could be more efficiently coordinated if the Chairs of such committees had an official forum in which to discuss concerns raised by their committees with respect to individual applications. Such a forum could take the form of an overarching body as set out above. The Chairs of all advisory committees, in addition to consumer and environmental representatives would provide a suitable breadth of knowledge to monitor wider issues and long term developments. Such a committee could then give advice to the Ministerial Committee set up to monitor Government policy in biotechnology.

The system could also be further simplified for companies wishing to make applications and those wishing to find out information on such applications. Currently several Government departments are responsible for different aspects of the legislation governing biotechnology. A single enquiry point providing advice on the regulatory framework and applications currently under consideration would simplify the process dramatically and aid transparency of regulation. A single 'post-box' for applications to produce, use, release or market GMOs would simplify the process for those working with GMOs.

(iv) Could the current system for providing advice to Government be made more transparent?

We welcome indications that the current Government is seeking to conduct its affairs more openly. We recognise that confidentiality can often be important, but believe that a policy that favours extensive use of confidentiality and the Official Secrets Act irrespective of need is unhealthy and counterproductive. We support the approach set out by the Chief scientific Advisor in 'The use of scientific advice in policy making' regarding transparency.

We also welcome moves by ACNFP and ACRE to increase transparency in the regulatory system by the publication of agenda and minutes and ACNFP's initiative to convene open meetings. We recommend that other advisory committees involved in the regulation of biotechnology consider such measures.

We also recommend that greater information should be made available on the Internet. Web Sites for individual Government departments involved in biotechnology regulation should be linked and should contain sufficient detail on the regulatory process, applications received and advice given to Government by non-departmental public bodies.

We strongly endorse the recommendation of the Chief Scientific Advisor that there should be a presumption that scientific advice to Government will be made openly available, unless it is demonstrably against the national interest to do so.

Where public comment is possible within the regulatory system, for example under the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (as amended 1995, 1997 and 1998), we recommend that sufficient time be made available for such comment to be received and considered. Currently periods in which comments may be submitted are very limited and we urge the Government to press for the inclusion of adequate consultation periods in the revised European Directive currently under discussion at EC level.

We also urge the Government to press for greater transparency in the provision of scientific advice by expert committees at the European level.

(v) Are ethical and other wider issues addressed fully within the current system?

Ethical issues are not considered under the current regulatory framework for release and marketing of GMOs. There is widespread concern at this lack of consideration and we support the possible revision of directive 90/220/EEC to include consideration of such issues. Nevertheless, such issues may not be best considered by advisory committees in their current structure since they have been formulated to provided a scientific evaluation of the risk of an individual GMO.

(vi) Are stakeholders given the appropriate opportunities to make their views known? For example, would an environmental stakeholders forum be a valuable addition to the current framework?

It is of the greatest importance to develop a mechanism by which public values can be taken into account at all stages of the process and the proposed overarching body should consider ways in which this may be accomplished. It is unclear from the information issued to date in what way an 'environmental stakeholders' forum would contribute to the regulatory framework for biotechnology, and in any case, it would be advantageous to ensure that both environmental and industrial interests are adequately represented in any advisory committee considering biotechnology, at all levels of the regulatory process. If the stakeholders forum is to review individual applications for the production, use, release, or marketing of GMOs then it will be duplicating the work of the existing committees rather than promoting a dialogue between interested parties. If, on the other hand, the forum will advise the Ministerial Group on biotechnology directly, this should be complemented by an industrial stakeholders forum to give a balance of opinion.

(vii) Is the framework flexible enough to cope with the rapid development of this technology which is likely in the future?

As discussed above, we recommend increased flexibility in the advisory committee system by the use of ad hoc membership as required when specific expertise is necessary. Such members could be drafted in to assist a core committee as required, which would allow greater flexibility and faster adaptation to future developments.

(viii) Does the public have confidence in the system currently in place?

The use of GMOs in food may offer benefits in food supply, food quality, nutrition and health, and we support ongoing research in this field. However, we recognise that the technology and current regulatory system have aroused concern amongst some consumers, coming at the same time as other, unrelated, concerns about food safety, notably BSE and *E.coli* O157 food poisoning. It is

important that such concerns are respected and accurate information made available which will help consumers to make informed choices.

Additional information

The Society would like to draw attention to the following Royal Society publications which are of relevance to this subject: *The Scientific Advisory System (June 1998)* and *Genetically Modified Plants for Food Use (September 1998).* Additional copies of this response and the above publications are available from The Science Advice Section at the Royal Society (rebecca.bowden@royalsoc.ac.uk tel: 0171 451 2588 fax: 0171 451 2692).

Royal Society Statement: 3/99; 18 February 1999