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Foreward

Mr. Noel Dempsey, T.D.,
Minister for the Environment and Local Government.

Minister

I have pleasure in submitting the Report of the Chairing Panel you set up for the national consultation debate on Genetically Modified Organisms and the Environment.

The Panel consisted of the following members -

The Right Hon. Dr. Turlough O'Donnell, Q.C.
Member of the Law Reform Commission, and former Lord Justice of Appeal in Northern Ireland and former Chairman of the Bar Council of Northern Ireland.

Ms. Evelyn Owens
Chairperson of the National Centre for Partnership and former Chairperson of the Labour Court.

Professor Dervilla Donnelly
Emeritus Professor of Chemistry in UCD and Chairman of Council, Dublin Institute for Advanced Studies.

Mr. Seán Cromien
Former Secretary General of the Department of Finance.

Our terms of reference were to manage a two-part debate and to report our conclusions on:

- the identification and prioritisation of the key environmental issues which should inform the development of national policy on the deliberate release of genetically modified organisms to the environment; and
- the considerations raised in relation to each of the environmental issues examined in the substantive discussion in Part II of the debate.

Although we were primarily concerned with the possible impact of genetically modified organisms on the environment, considerations raised in the course of the debate will apply in any examination of related areas including food safety.

We heard the views of the industry, academics, non-Governmental organisations and members of the public who had responded to your discussion paper.

We gave everyone present an opportunity to offer such evidence as they wished, and to express their concerns and anxieties.

We hope that we have considered all of the issues raised in a fair and reasonable manner and that this report will be of use to you in formulating national policy.

We had hoped that our report would have been available to you before you attended the meeting of the European Council of Environment Ministers on 24 June 1999. Unfortunately because of the postponement of the debates, we were unable to finalise the report in time. We did, however, furnish our interim conclusions, a copy of which we have included in Annex III to this report.

In conclusion, we wish to express our gratitude to Mr. Owen Ryan, who acted as Secretary to the Panel, for his assistance in the preparation of this report.

Dr. Turlough O'Donnell, Q.C.,
Chairman.
28 July 1999.

Executive Summary

We were invited to manage and report on the debate stage of the national consultation on "Genetically Modified Organisms & the Environment" which the Minister for the Environment and Local Government initiated when he issued a consultation paper in August 1998. His remit in this area stems from his responsibility for the implementation of two EU Directives in this country, Directive 90/219/EEC on the contained use of genetically modified micro-organisms and 90/220/EEC on the deliberate release of genetically modified organisms (GMOs) to the environment.

The consultation paper attracted almost two hundred responses from organisations and individual members of the public. To conclude the consultation, the Minister decided on the two-part debate which we managed. Identification and prioritisation of issues in part one of the debate (see Annex I to this report) were to be followed by an analysis of the key issues in part two. The structure of the debate included a Stakeholder Panel, comprising representatives of industry, academia and non-Governmental organisations, to assist us by leading and responding to the debate. The exploratory exercise was held on 25 May and the substantive discussion on 3 June 1999.

It was hoped that a clear agenda of four or five key issues for substantive discussion would emerge from the exploratory debate. That did not happen and the task of preparing the agenda for the second part fell to us. This agenda dealt with what we considered were the major issues raised in part one and was aimed at ensuring a balanced and well structured analysis of issues from all perspectives. A copy of the agenda is provided at Annex II to this report.

Food products derived from GMOs, such as bacteria and yeast, are receiving wide press coverage but GMOs have been used to make commodities including yoghurt, cheese, and certain vaccines from as early as 1982. In addition, this relatively new technology (biotechnology), based on the properties of micro-organisms, is revolutionising the pharmaceutical industry, e.g. by the production of insulin and the anti-cancer drug interferon.

In the aspect of biotechnology with which the public consultation was concerned, namely products covered by the deliberate release directive, particularly crops, genetic engineering has been used for over 20 years in the United States. At present there are 70,000,000 acres of genetically modified crops growing in the US, Canada and Argentina, and 56,000 acres in Europe. The scientific evidence presented to us does not suggest that, so far, the use of genetic modification technologies in agricultural crops has produced any harmful effects on human health or the environment.

One of the features of our debate was how muted the criticism was of pharmaceuticals produced by biotechnology, whether this was due to the respect in which the drug testing agencies are held, the intensive testing, the independence of the testing agencies, or just a ready acceptance that if the technology is used to save lives it should be accepted. However, the success of the technology in the medical field may not necessarily advance the argument in favour of permitting its use where the issue is not one of life and death.

Much emphasis was placed during the consultation process on the fact that the producers of genetically modified crops are primarily interested in profit and that claims to benefit mankind by producing better yields, less use of pesticides and herbicides, fuel and labour are really self-serving attempts to cover this primary motive. This view is understandable, but every large corporation exists for the same purpose. It is doubtful if many of the advances in medicine would have occurred had the pharmaceutical industry not perceived that they would profit from the considerable investment which they make in research and development. Also, profits depend on the ability to sell the new technology. If any of the perceived risks should occur, it would immediately impact on the products of the corporations concerned, with inevitable consequence for profits.

That the biotechnology industry has been of considerable economic benefit to Ireland is well established. The pharmaceutical companies who have established here have provided employment for many, particularly for graduates. Our national attitude to technology in general is an influencing factor for further inward investment in these and other high-tech sectors of the economy. Access to genetic modification technologies is also critical to the future competitiveness of Irish agriculture. In pure economic terms, if Ireland rejects or ignores biotechnology, it cannot expect to remain attractive to high-tech based investment nor can it remain competitive in arable farming and related food production if other countries are using the new technology. In our view, organic farming is a niche market sector of the economy, not a realistic alternative to safe conventional farming practices.

The calls for a general moratorium on the deliberate release of GMOs to the environment must be viewed in the light of our membership of the EU. At present, because of membership, we cannot ban the importation of genetically modified products which have been approved under the regulatory regime of the EU except in the one instance of some new safety issue coming to light after marketing approval has been granted. For example, Austria and Luxembourg have used this safety mechanism to provisionally prohibit a genetically modified maize product about which they have concerns. This is not a moratorium but a temporary expedient to deal with specific concerns.

Even if it was legally possible for Ireland to introduce a general moratorium, in our view a clear case for such a course of action does not exist. The deliberate release directive, inter alia, recognises potential risks from GMOs, and provides for the protection of human health and the environment through risk assessment and risk management. If an absolute assurance that GMOs would never cause any damage was possible, there would be no need for such legislation at EU or national level. In view of the fact that risk is acknowledged and addressed in EU law, and that current scientific evidence indicates that any potential risk is very small, a general moratorium would be disproportionate.

One point which emerged very clearly from the debate was the need for a far greater effort to inform the public on developments in biotechnology, such as the introduction of new varieties of genetically modified crop plants, which affect their day-to-day living. This must be addressed by the Government if it is to assure the public of the regulatory controls which are in place for the safe application of genetic engineering, as well as the benefits of embracing modern biotechnology and exploiting its economic and employment potential. On the specific issue of labelling genetically modified products, the rights of those consumers who do not wish to eat genetically modified products must be respected. On the broad question of segregation, we recognise that there are difficulties because of world trade agreements; the policy of mixing consignments in non-EU states is a reality which must be addressed on a practical basis.

The focus of national environmental policy in the area of deliberate release of products containing or consisting of GMOs should, in our view, be positive. It should reflect the potential economic benefits of genetic engineering and the importance of a strong, proactive biotechnology sector if Ireland is to maximise these benefits in terms of competitiveness, growth and employment. It should also reflect a fundamental national commitment to safety and environmental sustainability, based on scientific risk assessment and management. Environmental sustainability in this context should be interpreted as including the avoidance of:

- any impact which would undermine the overall viability of conventional or organic farming; and
- ill treatment of and suffering by genetically modified animals.

An important consideration for us is early agreement on a revised directive which takes account of experience of the Member States since the introduction of Directive 90/220/EEC. We are pleased to note that there was political agreement for this at the meeting of the European Council of Environment Ministers on 24 June 1999.

To support a positive but precautionary national policy position, based on scientific risk assessment and management, we recommend that the Minister should consider:

1. The identification, supervision and funding of a programme of independent generic research (i.e. not specific to any particular product) by the Environmental Protection Agency (EPA), specifically on safety issues related to the deliberate release of GMOs to the environment. We consider that the Agency's GMO Advisory Committee should be consulted on the objectives, administration and evaluation of such a programme.

This is necessary, in our view, to reassure the public, since they are likely to continue to be sceptical of assurances given by bodies perceived to have an association with the proponents of new technology. Notwithstanding any independent research undertaken at EU level, the specific climatic, geological and geographical position of Ireland underpins the need for a national programme.

2. A review of the functions and composition of the EPA's Advisory Committee on GMOs. In our view, the composition of the Committee should include direct representation of consumer interests.
3. The question of establishing an Information Agency, independent of the industry, was raised. We were particularly struck by the absence of independently validated information which would inform the public as consumers. We are satisfied that a greater effort must be made by the State to inform the general public about developments in modern biotechnology which involve risks, however small, for human health and/or the environment. Such information should be based on the needs of citizens and provided in language understandable to lay persons. However, we are not convinced of the need for a specific body to deal solely with information dissemination. Instead, we recommend that the EPA should take a more proactive role in disseminating information in relation to the environment. We also believe that the issue is much broader than the specific environmental focus of the consultation process on "GMOs & the Environment". We recommend, therefore, that the whole issue of information dissemination should be referred to the InterDepartmental Group on Genetic Engineering for consideration in the context of its broader remit.
4. A review and, if necessary, a strengthening of EPA resources to assure the public of its ability to fulfil the functions assigned to it under the GMO Regulations, 1994. We believe that the Agency's independence and competence are central to public confidence in the regulatory process, particularly in relation to its responsibility for

post release monitoring, which is likely to increase as new products are approved. In particular, the Minister should consider the resources available to the EPA for the purpose of undertaking research and disseminating information on the environmental impact of GMOs.

5. Two other issues which were raised in the course of the debate and which we believe require consideration in a wider context than environmental protection were liability and ethics.

(a) Liability is a complex legal matter which we could not possibly address definitively within our terms of reference. However, from an environmental protection point of view, there is substantial argument that responsibility for any damage to the natural environment arising from a genetic modification to a product released under Directive 90/220/EEC should rest with the body who sought and obtained consent for the release of that product. The complexity of the science and technology involved, as well as the level of commercial research which must be undertaken to develop genetically modified products, is such that it would be unreasonable to hold any body other than the notifier responsible for significant environmental damage which was unforeseen when consent to release was granted. There is also a strong argument that liability in this case should be strict, i.e. that negligence should not be required to be proved. The issue of liability should be considered primarily in the European context, and we think that the Minister should press for European acceptance of this principle.

(b) Ethical issues which were raised in the debate were both complex and difficult. However, we did not find that genetic modification, assuming the satisfactory resolution of safety concerns and concerns regarding the alleviation of suffering in genetically modified animals, would be likely to conflict with the ethics of the vast majority of the population. We note that, during the debate, a proposal for the establishment of a national biotechnology ethical committee was raised. We would recommend that the establishment of a national expert bioethics committee should be considered by the InterDepartmental Group on Genetic Engineering.

6. The introduction of a programme for public education in biotechnology was also raised in the course of the debate but we were not convinced of the need for such an initiative. In our view, the most immediate public need is adequate information from regulatory authorities.

In addressing the whole issue of information and education, the question as to whether there was an adequate and appropriate focus on the teaching of science, particularly at secondary level was raised. While there was no substantial debate on this issue, we believe that it is a question which requires further examination, particularly in relation to the national capacity to exploit the full potential of biotechnology in the future. The issue has a direct and important relevance to the function of the InterDepartmental Group on Genetic Engineering and we recommend that it should be taken into account by that Group.

7. One of the concerns raised in the course of the debate related to the difficulty in understanding the provisions of the deliberate release directive - 90/220/EEC. We believe that guidelines readily understood by the general public would be both helpful and reassuring. We recommend that, in association with the proposed amendment of the Directive, Ireland should seek a commitment to EU guidelines on the interpretation of the amended provisions.

Part 1 *The Consultation Process*

1.1 The Charing Panel was established by the Minister for the Environment and Local Government with the following terms of reference:

to manage a two-part debate and to report to him our conclusions on -

- the identification and prioritisation of the key environmental issues which should inform the development of national policy on the deliberate release of genetically modified organisms (GMOs) to the environment, and
- the considerations raised in relation to each of the environmental issues examined in the substantive discussion in Part II of the debate.

1.2 This was part of a consultation process initiated by the Minister on 24 August 1998 when he issued a consultation paper entitled "Genetically Modified Organisms & the Environment". He identified a need for further dialogue on the issues raised in the responses to the consultation paper and decided to facilitate an oral debate in which all of the respondents would be invited to participate.

1.3 The potential environmental impact of genetic modification processes is regulated under two EU Directives for which the Minister for the Environment and Local Government has overall responsibility at national level - Directives 90/219/EEC on the contained use of genetically modified micro-organisms and 90/220/EEC on the deliberate release of genetically modified organisms to the environment. Under Directive 90/219/EEC, "contained use" relates to laboratory and industrial activities where the genetically modified micro-organisms involved are not released into the environment. Directive 90/220/EEC covers the open marketing of genetically modified products (i.e. products containing or consisting of GMOs) within the EU as well as limited trial releases at the development stage of new products.

1.4 Within the EU, related areas, such as the sale in the Union of genetically modified food products to final consumers and the sale of genetically modified seed varieties for cultivation, are covered under separate Community legislation for which other Ministers have responsibility at national level. In this connection, we understand that an InterDepartmental Group was recently set up to prepare a report for the Government on all areas of genetic engineering.

1.5 The debate was a two-part exercise assisted by an eight person Stakeholder Panel comprising two industry representatives, two academic representatives and four representatives of a group of participating non-Governmental organisations (NGOs). The first part of the debate was intended to focus on identifying and prioritising the key environmental issues for substantive discussion at the second

part. The function of the Panel was to assist us in structuring the proceedings by leading and responding to the debate. Its composition was decided by the Minister following consultation with the group of NGOs regarding their representation.

FIRST (AGENDA SETTING) DEBATE

1.6 The first debate, which was a full day debate, took place on 25 May 1999 and a copy of the draft agenda is provided at Annex I. It was adopted without amendment and was generally followed throughout the day.

1.7 The eight members of the Stakeholder Panel, the order in which they spoke and the groups or interests which they represented were as follows -

Industry

Mr. Matt Moran, Irish BioIndustry Association, and
Dr. Patrick O'Reilly, Monsanto Ireland.

Non-Governmental Organisations (NGOs)

Ms. Sadhbh O'Neill, Genetic Concern,
Dr. Paul Dowding, University of Dublin,
Mr. Quentin Gargan, Genetic Concern, and
Dr. Ruth McGrath, VOICE.

Academia

Professor Peter Whittaker, NUI, Maynooth, and
Professor Fergal O'Gara, University College Cork.

1.8 Following the presentations from the Stakeholder Panel, we had a wide ranging debate in which all interests present participated. Although the objective of the day was to identify and prioritise key issues, as opposed to discussing them in detail, many issues were discussed at some length for the purpose of emphasising particular points of view.

1.9 At the outset, we hoped that the exploratory debate would provide us with a reasonably clear agenda for more substantive debate on the second day. That did not happen. Accordingly, we drew up an agenda based on what we considered to be the main issues raised. These were summarised as -

- the science, including the ethical basis for it;
- the economic issues for Ireland in a sustainable development context;

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- risk assessment;
 - information and communication; and
 - consumer choice and the right of every person not to have to use genetically modified foods.

1.10 Overall, we are satisfied that the agenda and structure of the debate on the first day worked well, and that all interests had ample time and opportunity to identify issues of concern to them and to make a case for their inclusion on the agenda for the substantive debate. Notwithstanding the absence of a clear consensus on a final agenda for the second day, we believe that all of the critical issues in relation to the deliberate release of GMOs were raised.

1.11 The final item which we addressed on the first day was the structure for the substantive debate. We proposed to follow the same format in principle, the only change being that the members of the Stakeholder Panel were to make short presentations on individual issues as they arose during the day, rather than general presentations early in the day.

SECOND (SUBSTANTIVE) DEBATE

1.12 The second debate was held on 3 June 1999 and was also a full day debate. A copy of the agenda identified for the second day is provided at Annex II. It encompassed what we considered were the major issues raised in part one and was aimed at ensuring a balanced and well structured analysis of issues from all perspectives.

1.13 The theme for the morning of the substantive debate, balancing environmental and economic considerations, reflects the concept of sustainable development in that environmental and economic considerations must be balanced if we are not to deprive future generations of the social and economic benefits of a high quality natural environment. We consider sustainable development an essential focus in the light of a number of individual issues which emerged in the exploratory debate, e.g. safety, biodiversity and economic growth potential arising from the commercialisation of GMOs.

1.14 The objective of the afternoon session was to consider the direction which national policy should take. Against the background of the morning session on the sustainability of deliberately releasing GMOs to the environment, the question arose whether, notwithstanding legal constraints, Ireland should impose some form of moratorium on genetically modified products. For some, this was the only

substantive issue which should have been debated but such an approach would not have reflected the many concerns raised on the first day. A focus solely on the moratorium issue would not have been a balanced approach to the substantive debate.

1.15 In our view, there were three possible policy options -

- (1) a total moratorium on deliberate releases of GMOs to the environment;
- (2) a combination of a limited moratorium and selected releases for certain products, subject to regulatory control; and
- (3) unlimited release, subject to regulatory control.

1.16 In order to address all three approaches, it was necessary to examine the moratorium issue in relation to the perceived risk, and the safety provisions of the regulatory regime already in place, as well as proposals to update and strengthen those provisions. The need for complementary measures in areas such as consumer information and education in any consideration of regulatory control clearly emerged in the first part of the debate.

1.17 It was a matter of regret to us that nineteen NGOs who participated in the consultation process chose to withdraw from the second day's proceedings. Their absence denied us an opportunity to question them on some of the issues they raised. Despite their absence, we were aware of their views from their written submissions and their presentations on day one of the debate. In addition, many contributions from the floor on day two gave voice to their concerns.

Part II Conclusions

2.1 SCOPE OF REPORT

2.1.1 Our terms of reference confined our examination to environmental issues. The effects on food or human health are not included, although some of the considerations raised in the course of the debate will apply in any examination of these issues. The remit of the Minister for the Environment and Local Government in the area of modern biotechnology includes both the contained use of GMOs and deliberate release of products containing or consisting of GMOs to the environment. Although there is considerable activity in Ireland involving the contained use of GMOs, mostly micro-organisms in laboratory situations, we found no evidence of public concern regarding this aspect of genetic engineering. Our report reflects the debate which we heard and focuses on the potential environmental impacts arising from the deliberate release of GMOs, e.g. genetically modified crop plants, for both research and marketing purposes. The EU legislation concerned with protecting the environment from the potential impacts of deliberate GMO releases, including related human health considerations, is Council Directive 90/220/EEC of 23 April 1990.

2.1.2 A question was raised during the course of the debate as to whether genetically modified animals were covered. While any release of genetically modified animals would be covered under the deliberate release directive, no specific proposals in this regard were identified and it is not known if any are planned. The predominant concerns raised in the written responses to the consultation paper and in the two days of debate related to the potential impact of genetically modified crops on the environment. In this regard, it is important to point out that the scope of the directive does not extend to cloning.

2.1.3 In any examination of the potential environmental impact arising from the deliberate release of GMOs, it is important to have regard to the provisions and objectives of existing legislation in this area, as well as the proposals to amend it. Council Directive 90/220/EEC on the deliberate release of GMOs to the environment was adopted in April 1990 and is part of a broad Community legal framework relating to modern biotechnology. It was transposed into Irish law under the Genetically Modified Organisms Regulations, 1994 and the Environmental Protection Agency is the competent authority in Ireland for the purposes of the Regulations and the Directive. A proposal from the European Commission to update the Directive (see chapter nine of the consultation paper) is currently at an advanced stage of consideration by the Council of Environment Ministers and the European Parliament.

2.1.4 The two main objectives of the Directive are –

- harmonisation of regulatory requirements at Community level; and
- protection of the environment, including human health considerations arising in an environmental context.

2.1.5 In terms of environmental protection, the Directive recognises the possibility of damage to human health and the environment from deliberate releases of GMOs, including the possibility that the effects of such releases on the environment may be irreversible. It addresses the safe development of products utilising GMOs by laying down harmonised provisions to control potential risks for both human health and the environment.

2.1.6 The safety provisions of the directive are based on a precautionary approach under which deliberate releases of GMOs to the environment must be undertaken in accordance with a "step-by-step" principle, i.e. containment is reduced and scale of release increased gradually, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken. Fundamental to this precautionary approach is a prior notification and consent requirement for all proposed releases, and case-by-case assessment and evaluation of potential environmental risks.

2.1.7 It is clear to us, therefore, that recognition of an environmental risk factor in the deliberate release of GMOs, to the extent that the possible effects of such releases may be irreversible, is not new and safety measures were included in the deliberate release directive adopted in 1990, and reflected in corresponding Irish legislation. The possibility of risk to the environment is recognised, and the key issues in this regard are the extent of the risks involved and the effectiveness of the safety measures in place. In regulatory terms, the issue with which we are faced is not the need for legislation but rather the adequacy of the current deliberate release directive and proposals to amend it.

2.1.8 In parallel with its safety objectives, the internal market objective of the directive is to harmonise the laws, regulations and administrative procedures of the individual Member States on GMO releases. In other words, any disparity in the rules which apply to the deliberate release of GMOs to the environment in different Member States could create unequal conditions of competition or barriers to trade in products containing GMOs and should be eliminated. Therefore, the provisions of the directive must be uniformly applied throughout the Community.

2.1.9 However, where a Member State has justifiable reasons to consider that a product approved under the directive constitutes a risk to human health or the environment, Article 16 provides that it may provisionally restrict or prohibit the use and/or sale of that product on its territory. This safeguard clause is intended to deal with emergency cases where new data or evidence concerning environmental safety becomes available after a product has received marketing approval. It does not cover field trial releases for research purposes. This type of emergency action was taken by Austria and Luxembourg on foot of their concerns regarding a Bt-maize product. The suggestion made by some NGOs that this was a moratorium is quite clearly a misunderstanding of the true position.

2.2 THE MORATORIUM QUESTION

2.2.1 For some, this was the main issue for debate. To address it, we believe that the State has to consider –

- whether a moratorium can in fact be introduced unilaterally under EU law and, if so, whether such a course is necessary; and
- if this is not feasible, whether the Government should propose an EU-wide moratorium ?

2.2.2 While any interpretation of Community law would ultimately be a matter for the European Court, we understand that Article 16 of the Directive is being administered by the Minister on the basis that the introduction of a unilateral moratorium on marketing releases by an individual Member State would not be consistent with its internal market basis under Article 100a of the EU Treaty. We understand that the position was clarified for Environment Ministers at the European Council meeting on 24 June 1999 and that a legal basis for an EU-wide moratorium does not exist.

2.2.3 Against this background, our conclusion is that unilateral action involving any form of general moratorium on marketing releases of genetically modified products is not an option open to Ireland or any individual Member State of the EU. It is worth repeating here that a general moratorium is completely different to the limited and provisional emergency action which may be taken by Member States, under Article 16 of the directive, in the case of products which are already on the EU market.

2.2.4 The directive is silent on moratorium action on controlled research field trial releases. If it were possible to have a unilateral ban on field trials, the question is whether such a step would be either wise or indeed necessary. We are not

convinced on the need or the wisdom of banning small-scale trial releases carried out with the consent and under the supervision of the EPA, and we have set out the basis for this view later in the report.

2.2.5 If a unilateral moratorium on marketing releases is not an option at this time, and we believe that is the case, the obvious question is whether Ireland should propose an EU-wide moratorium. We believe that it could only consider such a course if an appropriate legal basis existed and well founded environmental grounds to warrant spearheading such a proposal at EU level had been identified. We will address the question of environmental grounds for proposing a European moratorium later in the report.

2.3 ECONOMIC BENEFITS

2.3.1 We accept that the biotechnology industry is an important contributor in Ireland to economic growth and the provision of jobs, especially high-quality graduate employment.

2.3.2 A recent Forfas report¹ states that "virtually all analysts predict that biotechnology will be the basis for major economic growth". Seven major sectors are important to the Irish economy - pharmaceutical and healthcare; food and drink; agriculture, forestry and fisheries; environment; regulatory affairs and law enforcement (through forensic science); information technology; and medical devices. The report warns that, if Ireland fails to invest in the development of a biotechnology infrastructure, we "will not only fail to benefit from the new biotechnology in terms of a large number of new, high quality, high added value jobs, but many existing jobs in the pharmaceutical and chemical industries, the food and drink industries and in agriculture will be jeopardised".

2.3.3 In terms of global competitiveness, industry presented the view at the debate that Europe tended to be at a disadvantage and in danger of falling behind in the exploitation of biotechnology. We were told that the 1997 study by EuropaBio² (The European Association for Bioindustries) predicted that in Europe alone, the biotechnology sector will be valued at 250 billion ECU and affect 3 million jobs by the year 2005, subject to the right conditions for investment. For this potential to be realised, industry pointed out that there must be a willingness to embrace the science and technology concerned, with due precaution.

¹ Technology Foresight Ireland, Report of the Health and Life Sciences Panel.

² Benchmarking the Competitiveness of Biotechnology in Europe.

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- 2.3.4 Much of the Irish economy is biologically based, particularly in the food, chemical and pharmaceutical sectors. Valued at £13 billion, these sectors support 65,500 jobs. Against this background, the possibility that 70% of forecasted growth in biotechnology will be in the agrifood sector underpins the potential impact of this technology in maintaining economic competitiveness. BioResearch Ireland emphasised the importance of access to genetically modified crops because of their increasing strategic benefit for farmers, particularly access to crops which can deliver specific characteristics.
- 2.3.5 Apart from the area of genetically modified plants for the agriculture sector, development areas which are industrially and economically important, and which can benefit from biotechnology, include the exploitation of organisms for starter cultures for cheese, yoghurt and fermented products. The use of genetically modified rennet to replace an animal sourced product, thereby protecting consumers against the possible risk of CJD disease, was presented as an example of how technology can be used positively to overcome a difficulty and protect the food chain.
- 2.3.6 An emerging and beneficial area involves the use of probiotic bacteria, i.e. bacteria which have protective effects on human and animal health. It was stressed to us that potential also existed to create a strong environmental sector using industrial ecology applications to, for example, minimise the impact of industry and agriculture on the environment through the use of environmentally friendly micro-organisms to replace the use of pesticides and fungicides based on chemicals, and to maximise fertiliser use. Other areas include the protection of the environment through the removal of pollutants from contaminated soils. Also the use of chemicals and antibiotics which may end up as residues in the food chain causing potential pollution can be avoided by the use of genetically engineered vaccines.
- 2.3.7 In view of the importance of the agriculture and agrifood sector to the Irish economy, we concluded that potential benefits of adopting biotechnology could not be ignored. This position was reinforced by the response from industry to our questions on the likely economic consequences of adopting a stand-still policy, i.e. maintaining existing practices irrespective of trends elsewhere in the world. Such a policy, we heard, would erode competitiveness and bring about a slow death for the Irish industries affected. We take this to imply successful application, including public acceptability, of biotechnology by our competitors.
- 2.3.8 The increasing importance of organic farming for both producers and consumers was raised by a number of organisations and individuals opposed either in principle or in part to genetic engineering. Their concern regarding any negative impact from

genetically modified crops on further growth in the organic sector was understandable. However, the environmental sustainability of organic farming practices, particularly in relation to their impact on biodiversity was strongly challenged by the Academic Group. They claimed that the lower productivity of commercial organic farming, compared to conventional farming, resulted in a higher impact on ecosystems and wildlife habitats because more land was needed to achieve the same output. Interests who support genetic engineering based crop farming claim that because of its high yield on a lower land take there was a lower impact on biodiversity. Economic value and environmental sustainability were issues on which both sides of the debate held strongly opposing views and where little, if any, ground for consensus appeared to exist.

2.3.9 Overall, it seemed to us that the opportunity exists for organic, conventional and genetic engineering based farming to co-exist, with due recognition and respect for one another, and to compete fairly for available markets. In economic terms, however, we could not ignore the fact that the organic sector in this country is currently operating from a very low base in terms of market share and could not be regarded at present as a realistic alternative to high volume output of food produce and products by the mainstream agriculture and agrifood sectors, using conventional means. In our view, the organic sector did not make a convincing case for refusing or limiting access by conventional Irish farmers to safe genetic modification technologies which are already available to their competitors or in presenting the organic sector as a real alternative to crop farming based on conventional practices or genetic engineering. We recognise that the possibility of genetically engineered crops undermining organic farming practices is a real concern for the organic farming sector as well as consumers of organic foods. In our view, responsibility for addressing this concern, and providing reasonable assurance to the organic food sector and the regulatory authorities on the issue of viable co-existence rests with the biotechnology sector.

2.3.10 The prospects for growth in biotechnology seem good. However, we had to consider whether the prospect of a large number of high quality jobs was a sufficient justification for embracing genetic engineering and endorsing the deliberate release of GMO to the environment or whether the price in terms of other considerations such as safety and overall acceptability was too high. To satisfy ourselves on the balance between safety and economic considerations, particularly in relation to views expressed by participants at both parts of the debate, we examined two specific questions –

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- how safe are GMOs, including their potential impact on biodiversity; and
 - if they are safe, is commercial exploitation ethical ?

We propose to discuss these in the following paragraphs.

2.4 SAFETY, BIODIVERSITY AND ETHICAL CONSIDERATIONS

Safety

- 2.4.1 From the first day of the debate, safety emerged as one of the most important issues for all interests, hence its prominent position on the agenda for the substantive discussion. In our view, the major issues in relation to safety were not whether its importance was recognised and accepted by industry and regulators, but rather what risks were involved, what constituted an acceptable level of protection for human health and the environment, and whether that protection was adequately provided for in current legislation and current practice.
- 2.4.2 Industry's commitment to safety assessments for products derived from modern biotechnology is based on the concept of substantial equivalence as developed by internationally recognised bodies such as OECD and the World Health Organisation, as well as a strong safety record to date. The concept of substantial equivalence involves establishing the safety of introduced changes and comparing genetically modified products to their conventional counterparts. This safety testing procedure is already in place, and no adverse risk for human health and the environment has been found following the commercial growing of 56 genetically modified crops, involving 70 million acres in 30 countries.
- 2.4.3 Industry's safety record is supported by the view of the representatives of the academic world at the debate that, in 25 years, genetic engineering has caused no injury or death to humans, or harm to the environment. For the purpose of underpinning their independence, it was pointed out by representatives of the Academic Group that most of the 500 scientists actively working on GMOs in this country are not funded by industry.
- 2.4.4 We raised specific questions regarding the means of checking that there have been no adverse effects on human health or the environment, e.g. increase in diseases or a weakening of resistance to diseases. The academic view was that it was extremely difficult, if not impossible, to prove a negative, and criteria had to be adopted in deciding on the basis of balance of probability. The absence of evidence of adverse effects related to genetic modification technology at present suggests that on the balance of probability there will be no adverse effects in the future. However, this

was qualified by the general caveat that it was impossible to say for certain that there might not be an adverse effect at some time in the future and it was important to remain alert.

Biodiversity considerations

- 2.4.5 In environmental terms, the potential impact on biodiversity emerged as one of the major issues of concern in relation to the deliberate release of GMOs to the environment, particularly from organisations and individuals opposed to such releases. Specific technical issues of concern ranged from potential horizontal gene transfer and possible emergence of super-weeds due to the insertion of herbicide tolerant genes, to possible unforeseen effects arising from the combination of promoters, such as that derived from the Cauliflower Mosaic Virus, with viruses and other genes, and the impact, direct or indirect, of inserted genes such as Bt on non-target populations of insects, including beneficial insects.
- 2.4.6 In more general terms, it seemed to be generally accepted that all types of agriculture (organic, conventional and genetic engineering based) impact on wildlife habitats. However, two academic speakers (one on behalf of the NGO Group and one on behalf of the Academic Group) presented completely opposing views on the level of impact of different types of farming on biodiversity. On behalf of the NGO Group, we heard that low input/low output farming supported more species than undisturbed wilderness or intensive farming methods. The contrary view from the Academic Group was that commercial organic farming was the greatest threat to biodiversity because of its lower level of output and that high yield levels from genetic engineering based agriculture provided the potential for the restoration of wildlife habitats. In theory, high-tech, high-yield farming may have the potential to benefit biodiversity but we heard no practical evidence to support this contention.
- 2.4.7 The interests on both sides of the debate (i.e. those in favour and those against) strongly defended their respective positions, both in their submissions and their presentations. Industry and academia maintained that their positions were supported by the general findings of a range of independent research projects which showed no negative impacts on biodiversity. They emphasised their belief in the precision of the science and technology involved, as well as the proven safety record of modern biotechnology over the last twenty five years or so. Those opposed to the deliberate release of GMOs to the environment contended strongly that there was a lack of independent research to verify claims made by the biotechnology companies, that environmental risk assessment requirements and field trials were inadequate in terms of addressing the potential risks of releases on a commercial

scale, and that there was no evidence to demonstrate that there would be no long term negative impact on human health and/or the environment.

2.4.8 Genetic engineering is a technology which attracts clearly conflicting, but science based, views. This was borne out in the debate when highly technical and complex issues such as risk assessment, antibiotic resistant markers, pollen dispersal, gene flow and virus pathogenicity were discussed. The principle of substantial equivalence was one of the cornerstones of the case made by industry for genetically modified products to be subjected to the same regulatory requirements as their conventional counterparts. This argument was questioned by the NGO Group on the ground that assumptions in relation to the behaviour of inserted genes in chromosomes and in relation to the question of those genes evolving should they escape were not borne out by independent research.

2.4.9 On these detailed technical issues, we could not conclude beyond reasonable doubt that one point of view is right. However, we recognise that they raise a range of considerations which are critically important in defining the parameters of safety procedures such as risk assessment and monitoring.

2.4.10 The concerns regarding the long term potential impact of GMOs on biodiversity, which are held by those opposed to the deliberate release of genetically modified products, do not, in our view, justify a moratorium. They underpin the need for effective and precautionary legislation in this area. In addition to environmental risk assessment, regulatory control requirements should include provisions in which a strong emphasis is placed on post-release monitoring. This is the only real basis on which to assess the ongoing and potential long-term impact of commercial-scale crops on biodiversity. Responsibility for post release monitoring (including the full cost of administration and supervision by the appropriate competent authorities) should be borne by the biotechnology sector and rigorously enforced by the regulatory authorities. At EU level, the results of post release monitoring should be co-ordinated and made available to the public in a format that is both easy to access and understand.

Ethical considerations

2.4.11 Ethics is not an exact science which comes up with exact answers. It looks at all sides of issues and presents the whole picture, and leaves it up to individuals to decide on the correct response.

2.4.12 Those opposed to genetic modification for ethical reasons have deeply held views. These are based on the belief that life in its broadest sense, encompassing all plant

and animal lifeforms, is sacred and should not be the subject of interference by humankind. For example, some reject anthropocentric Western values and ethical norms as not being capable of addressing contemporary moral issues in any comprehensive or effective way. Their view is influenced by the ecological ethic that the earth is a single ethical system and that the ethical norm is the well-being of the comprehensive community as opposed to the well-being of the human community. On this basis, contemporary ethics must focus on the large community of the living.

2.4.13 Industry pointed out that their representative body EuropaBio, has developed a voluntary code of Core Ethical Values which includes a commitment to promote efficient and sustainable agriculture. This proactive step in relation to ethics, industry claimed, demonstrated that it has not focused solely on science. Its code was supported by independent reports, such as the May 1999 report from the Nuffield Council on Bioethics. The Nuffield report focused specifically on genetically modified plant technology in world agriculture, and on the main ethical principles of general human welfare, maintenance of people's rights, and justice. It concluded that -

- genetic modification of plants does not differ to such an extent from conventional breeding that it is in itself morally objectionable,
- a moral obligation exists for the world's scientific community to develop genetically modified crops, and
- no basis exists for a ban on genetically modified foodstuffs or a moratorium on commercial plantings.

2.4.14 The academic view was based on the application of two principles from medical ethics, beneficence and non-malficence, to the impact of genetic modification of biodiversity. Beneficence exhorts us to do good and non-malficence to do no harm. In view of the fact that the greatest loss of biodiversity is caused by the loss of wildlife habitats to agriculture, the ethical principle of "do no harm" demands that the least possible area of land be used for agriculture and that farming should be as efficient as possible. It was argued that genetic engineering based agriculture was already shown to be more productive than conventional agriculture and commercial organic farming. It was also stressed that those who claim an ethical right to organic food must not forget the ethical right of the vast majority of people to the benefits of cheap, safe and wholesome food.

2.4.15 In response to our questioning regarding the relationship between human beings and other species of animals, whether it was ethically right to modify an animal if

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- (a) such modification was harmful to the animal, and
 - (b) the genetic modification impacted on the unique character of its species,

the general academic view was that there should be no unnecessary or unwarranted suffering for any animal. An anti-vivisection argument was raised in this context and, while we understand and respect this point of view, it fell outside of our terms of reference.

2.4.16 With regard to the specialness of species, we heard from the academic group that this can be overstated. Species are dynamic concepts. Lateral transfer of genes is a natural process and species are changing all the time. Changes brought about by natural lateral transfer would be a slow process; genetic engineering allows such change to happen much more quickly. We note that an ethical question may arise in relation to the transfer of genes in ways that cannot occur naturally.

2.4.17 While the ethical issues which were raised in the debate were both complex and difficult, we did not find that genetic modification, assuming the satisfactory resolution of safety concerns and concerns regarding the alleviation of suffering in genetically modified animals, would be likely to conflict with the ethics of the vast majority of the population. We note that, during the debate, a proposal for the establishment of a national biotechnology ethical committee was raised. We would recommend that the establishment of a national expert bioethics committee should be considered by the InterDepartmental Group on Genetic Engineering.

2.5 GMO RELEASES TO DATE

2.5.1 The science and technology involved in the development of genetically modified products are highly complex, and the case presented by those who claim GMOs are harmless is difficult to assess by non-specialists. However, as a Panel, we found it convincing in general terms in relation to releases up to this. Releases are widely accepted in the United States and Canada. They have been broadly accepted up to this in the EU, subject to strict regulation on a precautionary, step by step basis, and case-by-case evaluation.

2.5.2 Notwithstanding the concerns of those opposed to the deliberate release of GMOs into the environment and their total rejection of claims by industry and the academic world regarding the safety record of genetic engineering over the last 25 years or so, the fact remains that the marketing of genetically modified products is highly regulated. Also, while particular instances of alleged damage arising from genetically modified products are strongly contested by both sides of the broad genetic

engineering debate, there is no general recognition or acceptance of a link, or the probability of a link, between a genetically modified product and particular damage to human health and/or the environment. This, in our view, does not absolve regulatory bodies and industry from adopting a strict precautionary approach to a technology which is relatively new and rapidly expanding.

2.6 BALANCING RISKS AND BENEFIT

2.6.1 To assess what environmental policy course Ireland should pursue requires a balancing of -

- (a) the perceived dangers likely to arise from continuing to introduce GMOs into the environment, against
- (b) the likely damage of an anti-release policy position to the Irish economy and employment prospects.

2.6.2 Here, proportionality must be a consideration. If the risks of damage to the environment are small, the adoption of an anti-release position would be out of proportion to the likely damage and it would have serious effects of the competitiveness of key sectors of the economy. It would also give a false impression of Ireland's general attitude to technology based industry.

2.6.3 We are not convinced, on the basis of available knowledge and the precautionary legislation already in place or in prospect at EU and national level, that the deliberate release of GMOs to the environment will give rise to any significant danger for human health or the environment. However, the risk factor may change as future generations of products are developed and proposed for release, and the importance of maintaining a strong precautionary policy and a properly resourced regulatory regime cannot be ignored.

2.6.4 Against the current background of a low-level of risk, an absence of any scientific evidence of damage to human health and/or the environment resulting from the deliberate release of products containing or consisting of GMOs, and a precautionary regulatory regime, we believe that an anti-release policy (including any form of moratorium) would have a very negative impact on economic competitiveness. It would undermine inward investment, growth and employment in high-tech industries to which Ireland is well suited, as well as damaging the competitiveness of the arable farming sector of Irish agriculture. On balance, it is our view that the current risk factor does not justify stopping regulated releases at this time or suggest a need for such action in the future.

2.6.5 On the question of Ireland proposing an EU-wide moratorium on marketing releases, our view is that sustainable grounds for such a course were not evident in the written submissions, the presentations from the Stakeholder Panel or the open floor debate. A point was made regarding the importance of human intuition and instinct, and we recognise this but decisions have to be taken on the basis of existing evidence as assessed by human reason.

2.6.6 As we have indicated, at present there is no real evidence of any risk to the environment or to health from genetically modified products released under Directive 90/220/EEC. However, we have also indicated that rigorous testing is one of the ways in which the risk of any possible mishap, if not eliminated, can be at least substantially lessened. If field trials are abandoned in this country, how can such tests be carried out? To abandon field trials would expose us to the risk of some company obtaining consent to a general release of GMOs without our testing it in those areas which could be peculiar to Ireland. It would also mean that we would have no control or supervision over the testing and would be reliant on the expertise of others. In our view, that would be an unsatisfactory situation. It is important, in our opinion, that our national competent authority should have the opportunity to assess field trials of genetically modified crops in our own climate, and with regard to our own geographical and ecological situation prior to Community wide marketing consent being sought or given at EU level.

2.7 RESEARCH

2.7.1 Concerns, however, have surfaced recently in certain EU Member States relating to the thoroughness of scientific research in this area. Also, there are concerns among the general public here, across the EU, and to some extent more recently in the United States, about -

- (i) the lack of adequate information for consumers; and
- (ii) lack of convincing proof that scientific research is totally independent of vested interests, including the career prospects of genetic scientists. In particular, there is a view that much of the research is carried out and funded by the commercial operators which stand to profit from the development of such products.

2.7.2 It seems that consumers in Europe are less accepting than others of the assurances of scientists and regulatory bodies, particularly when compared to an apparently high level of acceptance of regulatory authority decisions in the United States. However,

we note that cultivation of genetically modified crops and releases of bulk genetically modified products in the EU are recent and coincided with major public concern about BSE. It is understandable that consumers could view with some scepticism scientific evidence adduced by industry itself, and seek assurances on the safety of any scientifically based development with potential to have a profound and long-term effect on their lives. Our view is that the future of genetic engineering depends on continuous endorsement of safety, product by product. We consider that the onus is on industry to continue to produce scientific evidence in support of individual notifications to release genetically modified products and, moreover, to do so in a manner that is easily understandable by and meaningful to consumers. Responsibility for providing, including funding, the information necessary to inform consumers and to gain their confidence rests entirely with industry.

2.7.3 When notifications for consent under the deliberate release directive to place products on the EU market are submitted to competent authorities (EPA in the case of Ireland), they must be supported by research findings. During the debate, this was criticised on the ground that the processing and determination of deliberate release notifications on the basis of reviewing industry research was not an acceptable way of administering a regulatory system aimed at protecting human health and the environment. Product specific research is the responsibility of companies involved in developing and marketing genetically modified products. The role of competent authorities is to process and determine deliberate release notifications in accordance with the provisions of the directive, an integral part of which is to review supporting research presented by the notifiers.

2.7.4 However, it is a matter for the Governments of the individual Member States of the EU to ensure that their respective competent authorities are properly resourced to discharge their functions. An essential resource requirement for reviewing product data provided by biotechnology companies in the context of deliberate release notifications is access to relevant independent research. In our view, a programme of generic research, specific to Ireland's natural environment but not linked to any particular genetically modified product, should be implemented through the EPA as the national competent authority under the deliberate release directive. The functions of the Agency's Advisory Committee on GMOs could be amended, if necessary, to enable it to assist in identifying such a programme, supervising its implementation and evaluating the outcome. Arising from the consultation debate, examples of areas where independent research might be appropriate include rates of horizontal gene flow, rates at which viral genes reacquire the capacity to be pathogenic and escape, baseline studies of natural populations, the ecological impact of GMOs deliberately released into the environment, and the possibility of a

systematic difference between genetically modified and non-modified plants. Such a programme of research should not be confused with specific product research which biotechnology companies undertake for the purpose of developing new products. Regulatory authorities should not have any role in undertaking commercial research of this kind.

2.7.5 A more general question was raised in the course of the debate regarding the adequacy of EPA resources in terms of fulfilling its functions as national competent authority under the deliberate release directive. This matter is outside our specific remit but it is our view that the Agency's resources should be examined and, if necessary, strengthened to ensure public confidence in its capacity and competence to assess and determine the safety of proposed releases of genetically modified products under the Directive.

2.8 CONSUMER CHOICE

2.8.1 We strongly emphasise the importance of consumer choice, one of the few points on which there was agreement in principle among the various interests participating in the consultation process. In our view, labelling is the key issue and all labelling should be clear, easily understood by the lay person and sufficiently comprehensive to inform consumers on the contents of final products.

2.8.2 While there was consensus among the interests on the principle of clear labelling and consumer choice, it was not apparent to us how this might be achieved in practice. The NGO Group proposed segregation at source as the only real basis for clear labelling and consumer choice. We accept that two totally separate supply streams for conventional and genetically modified crops would guarantee this choice. However, it is a solution which ignores global trade considerations, as well as the economic realities of mass producing agricultural and agrifood products at a reasonable price. The policy of mixing conventional and genetically modified produce in non-EU nations, particularly countries with whom Ireland and the EU have important trade relations, such as the United States and Canada, is a reality which must be faced and which requires a more practical policy approach than segregation.

2.8.3 It is also important to put safety considerations into context in terms of labelling. Our view is that the overall acceptability of a genetically modified product on safety grounds is not a labelling matter. If a genetically modified product is regarded by a regulatory authority as generally unsafe for human health and/or the environment, as opposed, for example, to being unsuitable for persons with certain allergies, it would

be appropriate to ban that product from the market altogether. It would not make sense, nor would it be acceptable to the general public, to grant marketing consent for a fundamentally unsound product subject to it being labelled as unsafe. In cases where products may not be suitable for a percentage of consumers, the provision of adequate and appropriate information is of the utmost importance.

2.8.4 We have already referred to the need for a practical approach to the labelling provisions of the deliberate release directive and we have examined this need with a view to assisting the Minister in formulating policy on this specific issue. The scope of the directive only extends to products containing or consisting of viable GMOs and every product which receives marketing approval under its provisions should, in our view, be clearly labelled as containing GMOs. Where conventional and genetically modified produce is mixed, e.g. in bulk consignments for export to the EU, it is the presence of any significant amount of viable genetically modified material that is the key issue for those opposed to consuming GMOs and mixed consignments should therefore comply with the same labelling requirements as pure genetically modified consignments.

2.9 OVERALL CONCLUSION AND RECOMMENDATIONS

2.9.1 The precautionary principle on which Directive 90/220/EEC is founded, based on a step-by-step approach to releases and case-by-case risk assessment, ensures a high level of environmental protection. Against this background, it is our view that a case for a general moratorium or any variation on such action could not be justified.

2.9.2 The focus of national environmental policy in the area of deliberate release of products containing or consisting of GMOs should, in our view, be positive. It should reflect the potential economic benefits of genetic engineering and the importance of a strong, proactive biotechnology sector if Ireland is to maximise these benefits in terms of competitiveness, growth and employment. It should also reflect a fundamental national commitment to safety and environmental sustainability, based on scientific risk assessment and management. Environmental sustainability in this context should be interpreted as including the avoidance of:

- any impact which would undermine the overall viability of conventional or organic farming; and
- ill treatment of and suffering by genetically modified animals.

2.9.3 An important consideration for us is early agreement on a revised directive which takes account of experience of the Member States since the introduction of

Directive 90/220/EEC. We are pleased to note that there was political agreement for this at the meeting of the European Council of Environment Ministers on 24 June 1999.

2.9.4 To support a positive but precautionary national policy position, based on scientific risk assessment and management, we recommend that the Minister should consider:

- 1 The identification, supervision and funding of a programme of independent generic research (i.e. not specific to any particular product) by the EPA, specifically on safety issues related to the deliberate release of GMOs to the environment. We consider that the Agency's GMO Advisory Committee should be consulted on the objectives, administration and evaluation of such a programme.

This is necessary, in our view, to reassure the public, since they are likely to continue to be sceptical of assurances given by bodies perceived to have an association with the proponents of new technology. Notwithstanding any independent research undertaken at EU level, the specific climatic, geological and geographical position of Ireland underpins the need for a national programme.

- 2 A review of the functions and composition of the EPA's Advisory Committee on GMOs. In our view, the composition of the Committee should include direct representation of consumer interests.
- 3 The question of establishing an Information Agency, independent of the industry, was raised. We were particularly struck by the absence of independently validated information which would inform the public as consumers. We are satisfied that a greater effort must be made by the State to inform the general public about developments in modern biotechnology which involve risks, however small, for human health and/or the environment. Such information should be based on the needs of citizens and provided in language understandable to lay persons. However, we are not convinced of the need for a specific body to deal solely with information dissemination. Instead, we recommend that the EPA should take a more proactive role in disseminating information in relation to the environment. We also believe that the issue is much broader than the specific environmental focus of the consultation process on "GMOs & the Environment". We recommend, therefore, that the whole issue of information dissemination should be referred to the InterDepartmental

Group on Genetic Engineering for consideration in the context of its broader remit.

- 4 A review and, if necessary, a strengthening of EPA resources to assure the public of its ability to fulfil the functions assigned to it under the GMO Regulations, 1994. We believe that the Agency's independence and competence are central to public confidence in the regulatory process, particularly in relation to its responsibility for post release monitoring, which is likely to increase as new products are approved. In particular, the Minister should consider the resources available to the EPA for the purpose of undertaking research and disseminating information on the environmental impact of GMOs.

- 5 Two other issues which were raised in the course of the debate and which we believe require consideration in a wider context than environmental protection were liability and ethics.
 - (a) Liability is a complex legal matter which we could not possibly address definitively within our terms of reference. However, from an environmental protection point of view, there is substantial argument that responsibility for any damage to the natural environment arising from a genetic modification to a product released under Directive 90/220/EEC should rest with the body who sought and obtained consent for the release of that product. The complexity of the science and technology involved, as well as the level of commercial research which must be undertaken to develop genetically modified products, is such that it would be unreasonable to hold any body other than the notifier responsible for significant environmental damage which was unforeseen when consent to release was granted. There is also a strong argument that liability in this case should be strict, i.e. that negligence should not be required to be proved. The issue of liability should be considered primarily in the European context, and we think that the Minister should press for European acceptance of this principle.

 - (b) Ethical issues which were raised in the debate were both complex and difficult. However, we did not find that genetic modification, assuming the satisfactory resolution of safety concerns and concerns regarding the alleviation of suffering in genetically modified animals, would be likely to conflict with the ethics of the

vast majority of the population. We note that, during the debate, a proposal for the establishment of a national biotechnology ethical committee was raised. We would recommend that the establishment of a national expert bioethics committee should be considered by the InterDepartmental Group on Genetic Engineering.

- 6 The introduction of a programme for public education in biotechnology was also raised in the course of the debate but we were not convinced of the need for such an initiative. In our view, the most immediate public need is adequate information from regulatory authorities.

In addressing the whole issue of information and education, the question as to whether there was an adequate and appropriate focus on the teaching of science, particularly at secondary level was raised. While there was no substantial debate on this issue, we believe that it is a question which requires further examination, particularly in relation to the national capacity to exploit the full potential of biotechnology in the future. The issue has a direct and important relevance to the function of the InterDepartmental Group on Genetic Engineering and we recommend that it should be taken into account by that Group.

- 7 One of the concerns raised in the course of the debate related to the difficulty in understanding the provisions of the deliberate release directive - 90/220/EEC. We believe that guidelines readily understood by the general public would be both helpful and reassuring. We recommend that, in association with the proposed amendment of the Directive, Ireland should seek a commitment to EU guidelines on the interpretation of the amended provisions.

Part I of consultation debate - Thursday 25 May 1999

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| 9.00 - 9.30 | Registration. |
| 9.30 - 9.45 | Opening address by Minister for the Environment and Local Government, Mr. Noel Dempsey, T.D. |

PROPOSED AGENDA

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| 9.45 - 10.00 | Background/contextual presentation by Department of the Environment and Local Government. |
| 10.00 - 11.00 | Presentations by Stakeholder Panel. |
| 11.00 - 11.15 | Coffee. |
| 11.15 - 12.15 | Continuation of presentations by Stakeholder Panel. |
| 12.15 - 13.15 | Open-floor debate on the identification and prioritisation of key environmental issues. |
| 13.15 - 14.30 | Lunch. |
| 14.30 - 16.30 | Continuation of open-floor debate on key environmental issues. |
| 16.30 - 17.00 | Coffee. |
| 17.00 - 18.00 | Chairing Panel conclusions on key environmental issues and arrangements for Part II of the debate. |
| 18.00 | Conclusion. |

Agenda for Part II of consultation debate - Thursday 3 June 1999

Balancing environmental and economic concerns

9.30am Environment

- safety
- ethical issues
- impacts on biodiversity

11.00am Coffee

11.30am Economy

- commercialisation of science and technology
- economic growth potential

1.00pm Lunch

Management and Regulation

2.30am Procedures and Processes

- risk assessment
- proportionality, including moratorium issue
- EU and national regulation

4.00pm Coffee

4.30pm Information and Education

- consumer choice
- transparency & labelling
- advice and consultation

6.00pm Conclusion

Moratorium issue

The case for a unilateral moratorium on GMO releases in Ireland was strongly pressed by those opposed to the type of releases covered by Directive 90/220/EEC. Having regard to the legal basis of Directive 90/220/EEC,

- we accept that there is no apparent scope for a Member State to impose such a general, unilateral moratorium;
- we are not convinced that a sustainable case exists for Ireland to propose a Community wide moratorium at EU level; and
- we take the view that a temporary EU wide moratorium (such as that being proposed by Greece), pending the coming into effect of the amended Directive, should only be supported by Ireland as part of a general consensus.

Proposed amendment of Directive 90/220/EEC

Safety for human health and the environment is paramount, and thus the regulatory regime for deliberate releases should be as robust and comprehensive as possible. For that reason we see considerable merit in updating and strengthening the safety and other regulatory provisions embodied in Directive 90/220/EEC, particularly the introduction of common criteria for environmental risk assessment, and stronger monitoring requirements linked to time limits for marketing consents. We therefore recommend that the Minister for the Environment and Local Government should support the completion of the amending process and the early implementation of the resulting Directive.

Consumer Choice

We strongly emphasise the importance of consumer choice. In our view, all labelling should be clear, easily understood by the lay person and sufficiently comprehensive to inform consumers on the contents of final products.

Research

Because of the potential increase in activity in biotechnology and its increasing importance, we consider that the State should sponsor additional independent scientific research, specifically on safety issues related to the deliberate release of GMOs to the environment.

Information

Both in the context of the consultation debate and media coverage of genetic modification generally, we are particularly struck by the absence of independently validated information which would inform the public as consumers. In consequence of this situation, we feel that relevant State agencies must take a more proactive role in providing full information in language understandable to lay persons. In particular, in the course of completing his review of national policy in this area the Minister should consider the resources available to the EPA

for the purpose of disseminating information on the environmental impact of GMOs. In a wider context, we would urge that the InterDepartmental Group on Genetic Engineering should address the broader information needs of citizens, including human health concerns.

23 June 1999