Submission

Proposed National Regulatory System for Genetically Modified Organisms[1]

December 1999

Background

Consumers' Health Forum (CHF) welcomes the opportunity to provide preliminary input to the development of a national system for the regulation of Genetically Modified Organisms (GMOs).

While the nature of GMOs and their use are not well understood by many consumers, there is widespread concern that they could pose considerable risks to the environment and health risks to consumers. There is also concern that if these risks were realised, their impact on the community and our environment may be significant and difficult to control. People look at the experience of the release of many other non-genetically modified organisms into the Australian environment at earlier times and the difficulties these have caused. In the health area, people look at the development of antibiotic-resistant bacteria through the inappropriate use of antibiotics and ask for caution in relation to GMOs. A cautious approach to research on, use and release of GMOs is warranted, given these community concerns.

So far as the regulatory framework is concerned, CHF strongly supports the statement in the Overview of the Discussion Paper that:

> Over the past decade, consumers have become increasingly interested in the way in which businesses and services are regulated. Community expectations of transparency and fairness, as well as a desire to be involved in the development and review of regulatory systems, have increased across the board.
> ...
> With genetically modified food entering the food system, and with the number and range of genetically modified crops increasing, consumers are looking for an appropriate system to be put in place to protect them and the environment from any potential risks associated with GMOs.[2]

Given the strong consumer interest in all these issues, CHF looks forward to participation in consultations on the draft legislation and to receiving a detailed briefing from the Interim Office of the Gene Technology Regulator (IOGTR) about how they see any legislation being put into practice.

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[1] Commonwealth Interim Office of the Gene Technology Regulator (IOGTR) in collaboration with State and Territory Officials. *Discussion Paper - Proposed national regulatory system for genetically modified organisms - How should it work?* Draft for comment. October 1999. (the Discussion Paper).

[2] IOGTR in collaboration with State and Territory Officials. *Overview - Current regulatory and administrative arrangements for controlling genetically modified organisms in Australia*. October 1999 (the Overview): page 8

Current Regulatory Regimes

The Discussion Paper sets out the range of regulatory mechanisms at State/Territory and Commonwealth levels that deal with different aspects of the control of GMOs. It mentions an area of regulation that is of specific interest to health care consumers - that covering human gene therapy:

> Genetically modified products used in human gene therapy are regulated by the TGA [Therapeutic Goods Administration] both in clinical research, under the Clinical Trial Notification Scheme and the Clinical Trial Application Scheme; and in registration (for marketing) of such products. In research on GM products for human gene therapy, NHMRC also supervises such research through its Gene and Related Therapies Research Advisory Panel (GTRAP) which has no legislative powers but advises the TGA. GTRAP in turn receives advice from GMAC [the Genetic Manipulation Advisory Committee] via cross-membership of the Committees.[3]

The importance of research in gene therapy for some health consumers is acknowledged by CHF. The first successful gene therapy procedure occurred in 1990 and was used to treat an immune system defect called ADA deficiency in children. Blood cells with normal ADA genes were injected into the patients' bodies where they produced enough normal cells to improve their immune systems. Internationally, gene therapy experimentation is underway at the moment for such diverse diseases as malignant brain tumours, cystic fibrosis and HIV/AIDS.[4] There is a need to ensure that all of the processes used in the regulation of human gene therapy are equally as transparent and publicly accessible as those discussed below for GMO regulation.

What will the proposed legislation cover?

The specific purposes identified for the new legislation, as distinct from the other regulatory mechanisms which mostly relate to products, is that this legislation *will predominantly focus on living and viable GMOs rather than GM products.*[5]

For the purposes of the legislation, "organism" will be defined as *a biological identity capable of reproduction or of transferring genetic material and includes a microorganism*[6] *that is not a human being.*[7]

Genetic modification will be defined as *the altering of the genetic material in an organism by a way that does not occur naturally (for example, through processes such as mating or natural recombination or both).*[8]

Why consumers are particularly interested in this area of regulation

Compared to products containing genetically modified material, GMOs raise specific concerns for consumers. Because we are talking about a new living thing with the capacity to reproduce

[3] Discussion Paper: footnote 2, page 9.
[4] United States Mission to the European Union. *Genetically Modified Organisms.* Available at: http://www.useu.be/archive/food.html, viewed 9 December 1999.
[5] Discussion Paper: page 14.
[6] Discussion Paper: page 16.
[7] Discussion Paper: page 15.
[8] Discussion Paper: page 16.

and pass on genetic material, it raises fundamental questions about how much we can and do understand about the operation and behaviour of living things.

Human beings have, for centuries, managed reproduction of crops and animals to develop "strains" which have characteristics which are seen as useful to human beings. The difference with this new technology is that:

it involves the transfer of genetic material between organisms that would never be able to breed in any natural or laboratory setting. Vast evolutionary boundaries can be crossed ... Human beings have the ability to mix the genetic composition of organisms that have been on separate, distinct evolutionary paths for thousands or millions of years. For example, we have placed genetic information from humans into mice, and scorpion genes into corn. This genetic mixing is possible because the genetic information of all organisms is carried in the same DNA codes.[9]

Why consumer participation in risk assessment and monitoring is so important

The fact that GMOs are living things with the capacity to breed and presumably possibly "interbreed" with existing non-GMO organisms means that, once released into the environment either deliberately following authorisation or accidentally, it may be very difficult to "fix" a mistake. Scientific understanding of the effect of introducing DNA into another organism on its other characteristics is incomplete.

The process of genetic engineering creates risk and uncertainty in a number of ways. By transferring new "regulatory" genetic information into the recipient organism, genetic engineering can destabilise the way DNA replicates, transcribes and recombines. Our understanding about the role of such regulatory information is incomplete, and so the alteration of the DNA sequence may have unintended and unexpected effects on the cellular processes of the recipient organism. This uncertainty is compounded by the imprecise techniques used for inserting DNA. Although genetic engineering techniques are generally precise in isolating the desired DNA string in the original organism, they are imprecise when inserting it in the recipient organism. The random nature of the insertion prevents scientists from knowing which of the organism's regulatory function might be affected. Uncertainty and risk associated with the process of engineering are also reflected in the resulting genetically modified organism. As a result of altered regulatory functions, GMOs may exhibit increased allergenic tendencies, toxicity, or altered nutritional value. They may also exhibit mutations, which are errors that can occur in the sequence or reading of the DNA within a cell. Altering regulatory functions may create new components or alter levels of existing components of an organism.[10]

It is not that consumers fail to recognise that there may be positive effects from the genetic modification of organisms. For example, it is understood that human DNA sequences were transplanted into mice and these special mice are now used to produce certain components for human blood needed in medicine.

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[9] Stilwell M. Van Dyke B. *An Activist's Handbook on Genetically Modified Organisms and the WTO.* July 1999: under section headed "Background on GMO product labelling - Scientific Background" Available on the US based Consumer's Choice Council website : http://www.consumerscouncil.org/policy/handbk799.htm, viewed 9 December 1999. The Consumer's Choice Council is an association of environmental, corporate and human rights organisations from 25 different countries, dedicated to protecting the environment and promoting human rights and basic labour standards.

[10] Stilwell M et al. *An Activist's Handbook on Genetically Modified Organisms and the WTO.* July 1999: "Risks and Uncertainty Associated with Biotechnology" (see footnote 9).

However, when general release of a GMO into the environment is contemplated, there are serious issues to be weighed up. The limits of our current knowledge require us to proceed very cautiously:

...risks are compounded when a GMO product is released into an uncontrolled environment. The interaction of GMOs with other complex biological systems such as the human body or natural ecosystems, cannot, in many cases, be anticipated or fully tested before commercial release. The incredible complexity of even the simplest organism prevents scientists from knowing many important short- and long-term effects of genetic modification. While it is impossible to predict the long-term implications of releasing genetically manipulated plants or animals into the wild, grounds exist for proceeding with caution.[11]

Principles underpinning any GMO regulatory framework

The Commonwealth's National Strategy for Ecologically Sustainable Development (NSESD) set out a number of principles relating to protection of the environment, one of which is known as "the precautionary principle".[12] Applying this principle to GMOs, Government needs to ensure that reasonable efforts are made to protect society from risks posed by GMOs, even while scientific evidence about such risks is incomplete.

In the view of CHF, the prime objective of the proposed regulatory system must be the protection of public health and safety and the protection of the environment in relation to the use and release of GMOs.

The importance of good information for the community

To allow the community to actively participate in policy development around these important issues, there must be open, transparent processes to ensure consumer education, awareness and confidence. There is a need for good quality publicly available information without the hyperbole of some press reports on these issues and which is not filled with jargon. As the issues are new and may have implications at all levels of society, a range of educational strategies will need to be considered over time, to generate informed community discussion and debate. Consumers need to be involved in developing this education process, and consideration should be given to resourcing of consumer organisations to enable their effective contribution.

The provision of information written in plain language for consumers should be a requirement under the system. For example, if an organisation wanted to seek the release of an organism, they should be obliged to actually produce a plain language explanation which would be presented to the Regulator along with the required scientific evidence. The Regulator could then check the accuracy of the Plain English version of the information for consistency and accuracy with the full document, and if it is not adequate, this could be grounds for rejecting the

[11] Stilwell M et al. *An Activist's Handbook on Genetically Modified Organisms and the WTO.* July 1999: "Risks and Uncertainty Associated with Biotechnology" (see footnote 9).

[12] In the NSESD, the relevant guiding principle says : "where there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation". The NSESD is set out in full at: http://www.environemnt.gov.au/epcg/esd/nsesd/intro.htl#GoalsEtc, viewed 9 December 1999. For an examination of the applicability of this concept to health matters, see Brown V. "Cross-referencing sustainability and equity - linking environmental and public health law" in Australian Institute of Health, Law and Ethics (ed) *Public health law in Australia - new perspectives.* 1998 : pages 233 and following - see especially page 234.

application. Once again, consumers need to be involved in the development of these explanations to ensure that their information needs are met.

Consumer participation in the regulatory processes

Equally, any regulatory processes established to deal with questions about risk assessment and safety need to ensure the recognition of community values and expectations and also to be open and transparent, as has already been identified by the European Commission.[13] Such processes are not purely scientific, nor should they be seen as such, given the current level of knowledge about complex ecosystem and human physiological reactions.

All assessments need to be based upon the precautionary principle and to include consumer representatives on the decision-making body. The commercial interests of those seeking the release of GMOs must never be traded off against the prime objective of the protection of public safety and environmental integrity. Rather, when looking at the risks, there is a need to look at the *public* benefits and the risks together, in determining whether it is appropriate to release a GMO.

Community interests in cautious approaches to risk assessment and release practices

Concerns about safety are not simply a knee-jerk reaction to the technology or an automatic fear-based response. There is already evidence that some GMOs released have acted in a different manner than expected. The United Nations Industrial Development Organisation (UNIDO) has released research that looks at the risks of escape and spread of GMO genes into related weed populations. This is considered an important issue, as some of the GMOs already released are herbicide-resistant crop plants. This research concludes that:

> Suggestions that crop traits will escape into wild populations are not exaggerated: escapes can and do occur. Also, it is important to reiterate that these crop traits from traditionally improved crops can and do persist in wild populations. Caution is warranted with the proposed wide-scale commercial release of transgenic plants given the unpredictable nature of pollen exchange and the generally unknown consequences of transgene establishment in wild populations ... It is recommended that transgenic crops have wide isolation barriers coupled with active and aggressive weed management, both in and around the field. These recommendations are intended to provide a framework for the continued development and eventual wide-scale release of transgenic plants, while at the same time, minimising the risk of ecological and economic disasters.[14]

These potential catastrophic consequences of inappropriate release accounts for the importance placed by consumers on effective government regulation.

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[13] The European Commission. Background Briefing No 34. Genetically Modified Organisms. 26 July 1999. This states that the Commission has proposed "increased transparency, with publication of summaries of the notifications, assessment reports and the EU Committee's opinions". See : http://www.cec.org.uk/pubs/bbrief/bb3498.htm, viewed 9 December 1999.

[14] Arriola P. "Risks of escape and spread of engineered genes from transgenic crops to wild relatives" - Biosafety Review on the UNIDO Biosafety Information Network and Advisory Service website : http://binas.unido.org/binas/Library/cabi/arriola.html, viewed 9 December 1999.

Processes of Risk Assessment

The complex information that needs to be assessed as part of the regulatory process presents a dilemma for consumers, and in fact, for the wider community. It is likely in many cases that both the potential benefits and the hazards will be unclear. Consumers are therefore seeking greater access to *both the knowledge and basis* upon which approval and release decisions might be made.

In order to be credible in the eyes of consumer stakeholders the necessary risk assessment procedures must demonstrate consideration of issues and values relevant to the community. Consumer input into the processes and consumer participation on the decision-making bodies are crucial issues for this. Existing research clearly demonstrates that to be effective, consumer participation needs to be appropriately resourced and supported. It is clear however that community and consumer participation in risk assessment processes is crucial to the rigour and credibility of the system overall.

Experience suggests that it can be difficult to reconcile the highly complex and evolving scientific knowledge required to properly assess safety issues, with the range of other considerations likely to be important for consumers. An ethics assessment based approach is not sufficient to ensure proper consideration of "the public interest" - something may be quite "ethical" in the technical sense used in medical research, but may not be in the public interest.

Hence the issue of developing and designing frameworks for risk and benefit assessment in conjunction with consumers must include consideration of what is unknown, which is critical to the rigour of the system overall and to ensuring the development of processes which satisfy public interest requirements.

Balancing risks and benefits

Prior CHF research on related issues[15] indicates that consumers recognise and are willing to support processes that involve trading known and unknown risks for identifiable benefits, provided they have access to balanced, quality information. While there is understanding among consumers of the need to provide for both economic and scientific development, there is appropriate resistance to any suggestion that scientific or economic benefits can be traded off against public health or environmental safety objectives.

Consumers want access to information and transparency of decision making, including the recognition that sometimes stakeholders involved in the process will have competing interests. CHF welcomes the Government's stated commitments to public safety but wants to see this adequately reflected in the legislation and resourcing of the regulatory framework. Consumers must be actively involved in both the development and implementation of the framework. For example, it unlikely that consumers would find the 30 day public comment period sufficient, on its own, to allow the public to have a voice. Given the general lack of public awareness of the issue and the complexity, it is likely to simply reinforce the lack of a "consumer voice" while allowing Governments to argue we "had our chance".

[15] Consumers' Health Forum. *Choosing Your Medicine. Making An Informed Decision About Complementary And Non Prescription Therapies*, CHF, Canberra. May 1999

If Government and industry expect such a short turn around for public input, there should be funding available for a consumer "watchdog" function. This could then look at proposals as they arose and alert consumers where there were issues about which consumers may have a view or an interest in making a submission. These are time consuming processes, and it is not feasible to expect voluntary organisations to be able to comply or assist in a meaningful and consistent way, without adequate resourcing.

Public Interest

Consumers are concerned that the potential benefits to industry stakeholders in the short term and the disproportionate access of these stakeholders to significant data, may, unless rigorously managed, produce unacceptable influence over risk and benefit assessment processes. The concept of "public interest" requires much more than that, and CHF would expect to see this reflected in the legislation.

It is noted that the Discussion Paper supports public access to information, except where it is "commercial-in-confidence". The experience of consumer organisations and others is that this exception can be used to actively preclude the dissemination of relevant consumer information. To address this issue, CHF considers that "commercial-in-confidence" exceptions to access to information should be as narrow as is possible, and certainly not be able to be asserted over any documents which are necessary to make the risk assessment, except in exceptional circumstances. Consumer representatives have been effectively involved in "commercial-in-confidence" decision-making in some other areas and must be involved in the design, specification and decision-making on such exceptions. Consumers also need to be involved in setting the broader agenda, as research interests and commercial interests are separate from the public interest.

Maintenance of safety and quality over time

CHF welcomes the proposed regulatory reporting and monitoring suggested in the Discussion Paper and its public accessibility. Given the outstanding concerns related to the basis of risk assessment (ie. whether it will be based on an overall assessment of the "public interest") and the range of competing interests, CHF wishes to emphasise the importance of independent compliance processes such as audit and reporting to ensuring public confidence in the rigour of the monitoring system.

Equally, there is a need to be clear about the interrelationships between the various proposed enforcement and compliance mechanisms, and to ensure that they will actually work. For example, it is often difficult in cases that involve protection of a broader "public interest" to obtain legal standing before the courts whose normal business in civil cases is the protection of private rights. Often some of the proposed processes are very time consuming and not suitable at all if there were an emergency requiring swift containment action. It is also unclear in the Discussion Paper about who would be liable for paying compensation when an authorised release gave rise to unexpected damage to either people or property. As a first principle, it would seem that the body which seeks to gain commercially from the release should, given the degree of uncertainty, be obliged to remedy unintended harmful consequences, even if there was no

negligence involved. However, such issues are given only passing attention in the Discussion Paper.

CHF looks forward to seeing the draft Bill to determine whether or not there is, in fact, adequate monitoring and enforcement provisions. There will also need to be sufficient resources allocated by Government to ensure the proposed operation of the regulatory framework.

Conclusions and Recommendations

CHF appreciates the clear intentions set out in the Discussion Paper to have an open and transparent regulatory regime to cover the use and release of living GMOs in Australia. However, given the complexity of the issues and the size of many of the commercial interests who may be seeking to use these technologies, CHF sees the protection of public health and safety and environmental integrity as fundamental principles which must apply to the regulator. Even where these tests are, to all current knowledge, satisfied, the Regulator needs to look at an overall assessment of what is in the public interest, given the great degree of uncertainty associated with the release of new organisms into the biosphere. CHF looks forward to the opportunity to be involved in both the further development of the regulatory framework and to participation in its implementation.