FOOD and the FUTURE

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Labelling of foods produced using gene technology.

In August this year, the Australia New Zealand Food Standards Council voted to require mandatory labelling of all commercially available foods produced using gene technology. The implementation of this decision, expected to occur during 2000, will give Australia one of the strictest labelling policies in the world. There are fears that such an approach may be regarded as a barrier to trade, opening Australia to challenge in an international forum such as the World Trade Organisation. It is apparent however, that an international agreement about the extent to which foods produced using gene technology should be labelled is not going to be reached in the near future. In light of this lack of consensus, laws requiring mandatory labelling will at least protect consumers and give them the right to choose. Such an approach is not internationally anomalous and will see Australia well placed for the future.

Gene technology

Gene technology, or genetic engineering, is the scientific ability to manipulate genetic information within and between species. Genetic engineering has enormous potential and its application is already having an impact in many industries, including agriculture and food production. Its development however, has not been free from controversy. While gene technology promises enormous benefits for humanity, many potential risks have also been identified. The fact that genetic engineering involves the permanent manipulation of DNA, sometimes in ways that would not occur in nature, raises many complex questions. The long-term effects of genetic engineering have not been determined and there are concerns about the potential effect of interspecies DNA transfer on human health and the environment.

Advances in genetic engineering have always predated the development of accompanying regulation. Currently in Australia, the biosafety of genetic engineering research is regulated by the Genetic Manipulation Advisory Committee (GMAC), a non-statutory body.[1] While research is regulated centrally by GMAC, the commercialisation and release onto the market of the products of gene technology is regulated by other government bodies. Where food is concerned, the relevant body is the Australia New Zealand Food Authority (ANZFA).

The Australia New Zealand Food Authority

ANZFA is the statutory body with primary responsibility for the regulation of food production and food safety in Australia and New Zealand. Pursuant to s.7 of its enabling legislation, the *Australia New Zealand Food Authority Act 1991 (Cth)* (ANZFA Act), ANZFA is charged with developing food standards for incorporation into the *Food Standards Code.* Recommendations from ANZFA to amend or add a food standard are considered periodically by the Australia New Zealand Food Standards Council (ANZFSC). This body consists of Health Ministers from New Zealand, the Commonwealth and each

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Australian State and Territory. Proposals approved by ANZFSC are incorporated into the *Food Standards Code.* Uniform regulation results, as food must comply with the *Food Standards Code* to be sold legally in Australia.

ANZFA researches matters for proposed food standards, coordinates food safety initiatives and develops risk assessment policies for food. In developing and amending standards, ANZFA regulates the composition, storage, packaging and handling of food and the availability of information relating to food, including labelling and advertising. In doing so, ANZFA must have regard to its objectives, which are listed in descending order of priority in s.10 of the ANZFA Act:

> Objectives of the Authority in developing standards and variations of standards:
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> The Authority, in developing standards and variations of standards, must have regard to the following objectives in descending priority order:
>
> (a) the protection of public health and safety;
>
> (b) the provision of adequate information relating to food to enable consumers to make informed choices and to prevent fraud and deception;
>
> (c) the promotion of fair trading in food;
>
> (d) the promotion of trade and commerce in the food industry;
>
> (e) the promotion of consistency between domestic and international food standards where these are at variance.

Standard A18

In May 1999, a food standard regulating foods produced using gene technology came into force in Australia (Standard A18).[2] In its present form, Standard A18 bans from sale any food produced using gene technology until ANZFA assesses its safety for human consumption and decides whether any conditions should be attached to its availability.

The most controversial aspect of Standard A18 has been the provision made for the labelling of foods produced using gene technology. Presently under Standard A18, many of these foods do not have to be labelled, because they are not sufficiently different from conventional varieties to warrant labelling. Labelling is required only when genetic manipulation has changed the food to such an extent that it can no longer be considered 'substantially equivalent' to its conventional counterpart.

Substantial equivalence

The concept of 'substantial equivalence' was first advanced by the Organisation for Economic Co-operation and Development (OECD) in 1993 as a practical way to assess the safety of foods developed using gene technology.[3] The concept is based on the idea that existing foods can be used for comparison when assessing the safety of a new or modified food for human consumption. The principle makes use of the fact that known foods will generally have a long history of safe use. If, when compared, the characteristics of the modified food are sufficiently similar to those of the known food, the modified food is substantially equivalent to the conventional food and no additional safety or nutritional concerns result from its consumption by humans.

The principle of substantial equivalence is not universally accepted as a valid assessment of the safety of modified foods. The concept is controversial. Some believe that the principle is based firmly on scientific principles, in that characteristics of the conventional and modified foods can be accurately measured and compared. Others consider the principle to be flawed because of its indefinite terms. The extent of the equivalence required is often questioned. There are also concerns raised about its reliance on information from existing conventional foods for comparison, because in some cases there may be a lack of appropriate data from the conventional food.

Development

The initial version of Standard A18 recommended by ANZFA to ANZFSC required only non-substantially equivalent foods to be labelled. In July 1998, ANZFSC accepted the recommendation, but recognised that there was a lack of consensus, both in Australia and internationally, about the extent to which foods derived from gene technology should be labelled. As such, on 17 December 1998, ANZFSC voted to extend the labelling provision.

In August 1999, ANZFSC agreed to further extend the labelling provision contained in Standard A18 to all foods produced using gene technology, to require clear labelling of all genetically modified food ingredients. This decision was affirmed by ANZFSC at its most recent meeting on 20 October 1999. In the near future, proposed amendments to Standard A18 will be released for public discussion. The results of this further consultation will be considered by ANZFSC at its next meeting in early 2000, when a decision as to the final format of Standard A18 is expected.

The decision to extend the labelling provisions contained in Standard A18 occurred in response to concerns about gene technology that have been expressed both domestically and internationally.

Influences

In submissions received by ANZFA during the development of Standard A18, several arguments were apparent. Consumer groups stated that food produced using gene technology should be labelled, to protect consumers' fundamental freedom to choose the foods they wished to consume.[4] Industry groups argued that mandatory labelling was unnecessary and would inhibit industry development.[5]

The initial adoption by ANZFA of a limited labelling provision in Standard A18 can be traced to concerns about the possible international implications of a decision to impose mandatory labelling. The Department of Foreign Affairs and Trade (DFAT) argued against mandatory labelling on the basis that such a requirement could be viewed as an indirect trade barrier. In its 1998 Reasons Statement, ANZFA stated that mandatory labelling had been rejected because 'mandatory labelling of food that is substantially equivalent to existing conventional foods is ... unlikely to be consistent with Australia's ... obligations as a signatory to World Trade Organisation agreements and therefore difficult to sustain in the likely event of a challenge in that forum ...'

DFAT argued that future access to export markets would be dependant on an ability to utilise the efficiency benefits of gene technology. As such, any regulatory policy implemented in Australia had to provide producers with certainty and consumers with sufficient confidence in the industry to ensure Australia remained competitive. DFAT did not support mandatory labelling, because it was a stricter requirement than that imposed by other nations. DFAT stated

that as Australia's major food trading partners consisted of Asia-Pacific Economic Co-operation (APEC) countries such as the United States, Japan and Canada, from a trade perspective it would be beneficial for Australia to harmonise its food standards with those of APEC members.[6] Significantly, it was also argued that the application of the guidelines would result in Australia being held to be in breach of its World Trade Organisation (WTO) membership obligations.

The World Trade Organisation

Formed in 1994, the WTO is a relatively new international body.[7] It has assumed responsibility for the administration of long-established trade agreements, including the 1947 *General Agreement on Tariffs and Trade* (GATT).[8] The GATT is the primary agreement governing multilateral trade, providing a structure facilitating fair and non-discriminatory trade between member nations, including Australia.

As a member of the WTO, Australia is a party to all agreements annexed to the WTO Agreement, including the GATT, the *Agreement on Technical Barriers to Trade* (TBT)[9] and the *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS).[10] These agreements establish minimum standards to ensure trade regulations in member nations facilitate free trade and are harmonised as far as possible with international standards. They do not prevent the adoption of measures to achieve legitimate objectives such as the protection of life and health, but such measures should not be more restrictive of trade than is necessary to achieve the legitimate objectives.

Agreement on the Application of Sanitary and Phytosanitary Measures

The SPS relates to domestic standards established to protect the health of humans, plants or animals. In relation to food, an SPS measure is defined to be one that operates to 'protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-carrying organisms in food, beverages or foodstuffs'.

The SPS operates to remove the right to arbitrarily restrict access to markets on health and safety grounds. Members must harmonise SPS measures on a global basis by adopting international standards where they exist, and be able to scientifically justify regulations that impose higher requirements than an agreed international standard. An international agreement relating to the subject matter of Standard A18 has yet to be reached. It is, therefore, arguable that the SPS has only limited relevance to the formulation of labelling provisions to regulate food produced using gene technology. However, in light of a recent decision of the WTO, the application of the SPS to procedures governing the approval of genetically modified crops has been identified by WTO members as an issue requiring clarification.[11] Any clarification may have implications for the application of the SPS to labelling regimes.

Agreement on Technical Barriers to Trade

The TBT regulates the practical measures required to enforce standards relating to animal and plant health or food safety within a country. It states that technical regulations should be applied only to the extent necessary to fulfil a legitimate objective and should not create an unnecessary barrier to trade. Legitimate objectives include the prevention of deceptive conduct and the protection of human, animal or plant life. Article 1.5 of the TBT requires that 'technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to International trade'. Article 2.7 requires members to '[give] positive consideration to accepting as equivalent other members' technical regulations ...'

Examples of measures covered by the TBT include regulations relating to packaging and labelling of products. As such, the TBT is relevant to the formulation of Standard A18. The TBT encourages members to harmonise their regulations with international standards where they exist, but recognises the right of countries to adopt measures considered necessary to achieve legitimate objectives.

The submission presented to ANZFA by DFAT argued that the imposition of mandatory labelling in light of the US system would be an unnecessary barrier to trade, because mandatory labelling was more restrictive than necessary to achieve the aim of consumer protection. As such, Australia would be open to challenge in the WTO for breaching the TBT. Based on this submission, in July 1998 ANZFA recommended labelling requirements in line with those in place in the US.

In relation to foods produced using gene technology, the TBT would operate to ensure that labelling was imposed only to the extent necessary to achieve legitimate objectives. It is arguable, however, that the imposition of mandatory labelling is justified as a necessary measure for the achievement of several such objectives. For example, an objective relating to the protection of health and safety legitimises a regulation requiring labelling of genetically engineered foods containing potential allergens. In the same way, it could be argued that any failure to label these foods, in depriving consumers of the right to make an informed choice about their food, is deceptive. In these circumstances, it is reasonable to impose mandatory labelling to prevent such deceptive conduct.

On a broader level, a mandatory labelling requirement is an effective response to the high level of general consumer concern over genetically modified foods. Arguably, mandatory labelling of foods produced using gene technology is a proportionate way to achieve a consumer protection objective and would not constitute an unnecessary barrier to trade under the TBT.

The international perspective

The above debate is academic at this stage. Although it has been identified as a priority, the WTO has not yet adjudicated on disparate food labelling regulations. Consideration by the Committee on Trade and the Environment of options for 'eco-labelling' for environmental protection has been the closest the WTO has come to considering the issues raised by gene technology in food production and their implications for trade.[12]

Until recently, conventional wisdom stated that the WTO would not approve a measure imposing a trade barrier that was based on labelling requirements for food produced using gene technology where substantial equivalence could be demonstrated. However, the failure of the international food standards body, the Codex Alimentarius Committee on Food Labelling (Codex), to agree on an international labelling standard for food produced using gene technology has made this more debatable.

Codex is responsible for setting international food standards. These standards are highly regarded, with bodies including the WTO suggesting that their members adopt standards set by Codex. Codex has been considering an international standard for labelling of food produced using gene technology for several years. A stalemate has developed between countries that favour mandatory labelling and those that favour labelling only when substantial equivalence cannot be shown. During its meeting in April 1999, Codex again failed to reach agreement on the extent to which labelling should be required.[13] An international standard is unlikely to be put in place for at least another two years.

Internationally, controversy over the commercialisation of genetically engineered food has been far greater than that experienced in Australia to date. The increasing number of genetically engineered foods reaching the market has prompted the development of regulations in many jurisdictions. Of significance to this discussion is the relatively recent acceptance by the European Parliament of a Directive to regulate novel foods and novel food ingredients.[14] The reason for its significance is the fundamental difference in the approach of the Directive to the labelling of foods produced using gene technology compared to that of the United States (US).

United States approach

In the US, the Food and Drug Administration (FDA) has primary responsibility for ensuring food safety pursuant to the *Food, Drug and Cosmetic Act* 21 USC 321. The Act imposes a duty of care on food producers to ensure that all food presented to consumers is safe and complies with all legal requirements. This approach places regulatory emphasis on the safety of end products rather than the method of production.

In May 1992, the FDA published a policy statement relating to the regulation of plant-based genetically modified foods, which remains in force.[15] The policy details the appropriate standard of care for foods produced using gene technology and identifies where pre-market approval from the FDA will be necessary.[16]

In the US, foods produced using gene technology are subject to the same labelling requirements as conventionally produced food and food ingredients. Labelling is not required simply because genetic manipulation has formed part of the production process. On the contrary, the policy states that labelling will be required only where genetic manipulation has altered the composition of the food to such an extent that it is significantly different to its traditional counterpart. Thus, labelling of foods produced using gene technology is required only when the modified food is not substantially equivalent to its conventionally produced counterpart.

This policy has had an impact on trade. The US gene technology industry is the most advanced in the world. More crops have reached the stage of commercialisation than in any other country. So far, the imposition of the 1992 policy has meant that, in a majority of cases, foods produced using gene technology have not required labelling. In the US, genetically engineered produce is mixed with conventionally produced varieties and traded, without any notification of the genetic modification required. The US maintains that to segregate crops is unnecessary and uneconomical. This approach has caused a lot of controversy, particularly in Europe, where the regulation is very different.

The European Union approach

The European Union (EU) developed a Directive, *Regulation 258/97 Concerning Novel Foods and Novel Food Ingredients* in response to the increasing commercialisation of food produced using gene technology.[17] Food items that originate from genetically modified organisms fall within the definition of 'novel food'. The Directive imposes mandatory labelling on products that result from processes of gene technology. The labelling requirements are designed to ensure that there is science-based labelling of all genetically modified products. The practical effect of the Directive is that consumers in the EU have to be informed of any genetic differences between a new product and existing equivalent products.

In adopting the Directive, the EU has shown more caution than the US in accepting the commercialisation of genetically modified food. In Europe, consumers are more wary of the safety of the food supply and much more vocal with their labelling demands. The labelling requirements in place in the EU provide consumers with an ability to choose whether or not to purchase food produced using gene technology.

Implications for Australia

The enforcement of the Directive and its accompanying guidelines by the EU, which is also an economic trading power, is significant for Australia's adoption of what are likely to be similar labelling requirements in the near future.

The present lack of international consensus on the issue of labelling means that individual nations are free to establish their own system of regulation for foods produced using gene technology, unaffected by the requirements of the SPS. Applying the TBT, it is arguable that mandatory labelling is not an unnecessary barrier to international trade, but rather a reasonable way to achieve a legitimate consumer protection objective. In amending the labelling provision contained in Standard A18, ANZFSC should not be

concerned that the imposition of mandatory labelling will open Australia to a WTO challenge from a country with lesser labelling requirements.

The EU and the US are both WTO members. As such, there are two legitimate approaches that Australia can adopt with regard to labelling. The first would be to maintain the current requirements of Standard A18. This would be an adoption of the US labelling position. While the US approach is well defined, it is also inadequate from a consumer perspective. The alternative, extending the labelling provisions of Standard A18 to require mandatory labelling, is a more satisfactory approach from the point of view of satisfying ANZFA's s.10 objectives, where responding to the concerns of consumers is considered second only to the maintenance of health and safety. Internationally, acceptance of this approach by the EU opens the way for Australia to adopt similar requirements without fear of reproach from the WTO.

Conclusion

The level of regulation imposed currently by Standard A18 is designed to ensure that foods produced using gene technology and released onto the market are safe. However, it does not adequately address concerns about the effect of gene technology on health and the environment, or recognise the validity of the consumer desire to be informed about processes that have been utilised in the production of their food. ANZFSC has recognised this and will move to address the problem when it implements mandatory labelling requirements for all foods produced using gene technology in 2000. In moving to require mandatory labelling, ANZFSC will be adopting a form of regulation that responds to the needs of Australian consumers and balances the opinions of stakeholders at least until international disagreement is resolved.

References

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4. Australian Consumers' Association, *Submission to the Australia New Zealand Food Authority, Proposal P97 — Food Derived from Gene Technology*, 1997, p.4.
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6. APEC is the primary regional vehicle for promotion of open trade among member nations. Although it has no specific application to foods produced using gene technology, APEC has a voluntary agreement to facilitate trade in food between member nations: Asia-Pacific Economic Co-operation, *APEC Mutual Recognition Arrangement on Conformity Assessment of Foods and Food Products*, 1998 <http://www.apecsec.org.sg/scsc/scsc-food.html>.
7. Marrakesh Agreement Establishing the World Trade Organisation (opened for signature 15.4.94, entered into force 1 January 1995).
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12. Eco-labelling programs use criteria based on production methods to determine labelling requirements. Further discussion is needed on how the use of this criteria should be treated under the WTO TBT rules: WTO, 1997 *Eco-labelling* <http://www.wto.org/wto/environ/eco.htm>.
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16. Pre-market approval is necessary when a product has been genetically engineered to contain a known allergen, contains material from a source not currently in the food supply, or has changed nutritional characteristics compared to its traditionally produced counterpart. International Food Information Council (1992) *Food Biotechnology: Federal Regulations and Labelling* <http://ificinfo.health.org/brochure/bioregs.html>.
17. Regulation 258/97 applies to all newly available novel foods. Labelling also applies to foods already available: see Council Regulation (EC) No 1139/98 (26.5.98) *Official Journal of the European Communities*, No L 159, 3 June 1998, pp.4–7.