

AFRICAN CENTRE FOR BIOSAFETY

**CRITICAL ANALYSIS OF SOUTH AFRICA'S LABELLING REGULATIONS FOR
GENETICALLY MODIFIED FOOD, FEED AND PRODUCTS DERIVED FROM
GM-FED ANIMALS**

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October 2004**

TABLE OF CONTENTS

ACKNOWLEDGEMENTS	3
SCOPE OF ANALYSIS.....	3
SUMMARY	3
BACKGROUND	6
LABELLING REGULATIONS AND SOUTH AFRICAN GOVERNMENT POLICY ON LABELLING OF GM FOOD	8
DETAILED COMMENTS	10
SECTION 1, DEFINITIONS	10
SECTION 2, WHAT MUST BE LABELLED?	13
<i>Excluded: GM Food and Feed; Foodstuff derived from GM fed animals.</i>	<i>13</i>
<i>Voluntary Labelling</i>	<i>13</i>
<i>Included: Allergens</i>	<i>15</i>
<i>Included: Animal material containing genetic material derived from human or different taxonomic animal family.....</i>	<i>16</i>
SECTION 3, ENHANCED CHARACTERISTIC CLAIM.....	16
<i>Promotion of positive public perceptions of GM.....</i>	<i>16</i>
SECTION 4, GM FREE LABELLING	17
<i>Prohibition on GM free labelling.....</i>	<i>17</i>
CONCLUSION	17

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“Consumers can enquire from the seller of the food whether it is genetically modified or not and determine if they wish to consume it”

Thoko Didiza, Minister of Agriculture and Land Affairs¹

ACKNOWLEDGEMENTS

The writer is extremely grateful to Harmut Meyer, Sue Mayer, Arpad Pusztai and Susan Bardocz for the comments they made on the South African ‘Regulations Relating to the Labelling of Foodstuffs Obtained Through Certain Techniques of Genetic Modification.’ As always, the writer is indebted to Lim Li Ching from the Third World Network for her guidance, insight and unflagging commitment to biosafety.

SCOPE OF ANALYSIS

This analysis is confined principally to biosafety issues pertaining to the labelling of genetically modified organisms (GMOs) and genetically modified (GM) food, animal feed and foodstuffs derived from animals fed with GM feed. It does therefore not canvass the South African constitutional and statutory situation regarding consumer choice and access to information, as these are best left to those who have the requisite expertise.

SUMMARY

The labelling of genetically modified food serves an important function of providing the public with information. However, its value also lies in its biosafety function regarding the traceability of GMO from farm to plate, risk management and monitoring of the impacts of GM food and feed on animal and human health.

South Africans have been consuming GMOs and GM products, including maize, a staple food, without their consent and knowledge for several years. The South African government does not require that GM crops be segregated from non-GM crops during production, processing, and distribution. The government has furthermore, failed to establish an identity preservation system, whereby the unique identification of GMOs/GM varieties can be traced throughout the food chain, from farm to plate. Thus, in the event that a variety of GM maize causes adverse affects on animal and/or human

¹ *GM food concentrated in three provinces* Business Day. 19 December 2003.

health, it will be almost impossible for anyone to trace the offending GM variety, and hence, the offending biotechnology company.

On the 16th January 2004, seven years after South Africa began commercially growing GM crops and three years after it approved the commercial growing of GM white maize, the Department of Health published *Regulations Relating to the Labelling of Foodstuffs Obtained Through Certain Techniques of Genetic Modification*. The Regulations were made in terms of section 15(1) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act, No.54 of 1972). These Regulations not only seriously flout the South African consumer's right to choose, but place consumers at great risk.

According to the South African government, GM foods are safe and therefore, the need for labelling as a warning is unnecessary. The Department of Health has publicly stated that all genetically modified foods are carefully assessed by **independent laboratories** to ensure that they are equal or better in all ways to the conventional product, and will not increase allergenicity or toxicity. However, civil society organisations working on biosafety issues have never come across any food safety assessments that have been assessed by independent laboratories. Indeed, what has become patently evident is that only desk- top reviews are conducted of inadequate and highly questionable food safety information generated by the biotechnology industry.

The South African labelling regulations adopt the United States model where the use of GM techniques *per se* is not itself a trigger for labelling. The South African labelling Regulations do not apply to the GM foods currently imported, marketed and released in South Africa (or elsewhere in the world for that matter). It is only when there is a 'significant difference' in the final food that labelling is required. The circumstances where this is considered to be significantly different is if there are human/animal genes; allergens; requires different cooking; or has altered nutritional composition. There are no GM foods currently commercialised that would fall within this scope. Therefore, South African consumers will be given no choice over the current generation of GM foods.

GM animal feed have thus also been excluded from the scope of the Regulations. GM animal feed contain genes, which make them resistant to antibiotics used for the treatment of diseases in both humans and animals. The introduction of antibiotic resistant marker genes into animal feed could severely undermine the effective treatment of diseases if the antibiotic resistance is transferred to bacteria, which are harmful to human and animal health. The risks associated with antibiotic resistance are totally unacceptable, especially in South Africa where antibiotics are used to treat opportunistic HIV and AIDS infections. South Africa's Genetically Modified Organisms Act, 1995, does not require that the effects of antibiotic resistance genes in the digestive flora of animals eating the GM feed be monitored.

The Labelling Regulations have also excluded foodstuff derived from animals fed on GM feed, from its scope, such as the meat of animals as well as products such as milk and eggs. Recently, Greenpeace compiled an investigative report that showed parts of gene substance of GM Soya and maize present in the milk of animals fed on GM Soya and maize feed.

The Regulations thus contemplate voluntary labelling of GM food and feed. However, food producers who may wish to label GM products or products that may contain GMOs, may be severely impeded from doing so, especially if such producers wished to

provide the consumer with full details of the GMO in question, in particular, information of the GM construct; the GM event, the transgenic line and trait etc because South Africa does not have an identify preservation system in place. Thus, those who may wish to indicate on the label that GM foodstuff, feed and products are derived from animals fed on a particular GM variety that contains antibiotic resistance marker genes (for example Bt 176 maize which has recently been banned in Spain because it contains the *bla* marker gene that confers resistance to ampicillin), will not be able to do so.

Generally speaking, the regulations contain legally and scientifically untenable, imprecise, and inconsistent definitions.

The Regulations require the labelling of foodstuff containing an allergen from any of the products listed in an Annexure. The Annexure comes directly from the 1992 U.S Food and Drug Administration's (FDA) "Statement of Policy: Foods derived from new plant varieties, notice" which to date, sets the rules for the voluntary GM food review system in the US, including the provision that labelling should only apply to risky food containing allergens etc. The list is composed of those foodstuffs that cause the major allergies in the U.S. The 1:1 adoption of the U.S list in South Africa is not appropriate. The list should name the important food allergens in South Africa. The rather limited list of products in the Annexure does not take into account that the genetic modification process itself may cause unintended effects and could give rise to potential allergenic properties in crops and products derived from such crops. Those that claim GMOs are safe, often rely on **theoretical** conclusions that the protein in question is unlikely to exhibit allergenic properties. However, this argument and its underlying assumptions has come under criticism by the Austrian government and underscores the need for independent testing.

The Regulations allow claims on labels to be made that GM foods have been improved or have acquired enhanced characteristics. These provisions do not require that the label contain the words 'genetically modified organism obtain through ..' as they are designed to introduce a positive connotation to GM foods- 'improved or enhanced'. In so doing, the Regulations seek to promote positive public perception of the process that leads to the creation of GM foodstuff.

The Labelling Regulations are subject to the *Regulations Governing the Labelling and Advertising of Foodstuffs* published under Government Gazette No. R. 2034 of 29 October 1993. Regulation 9(d) of Notice R. 2034 of 1993 prohibits a labels or advertisements that claim a foodstuff to be free if all other foodstuffs in the same class or category are free from such substance for instance, GM carrots because GM carrots are not yet commercially produced.

Constructive engagement by pressure groups with the South African government has proved fruitless over these last few years. These groups should urgently test the constitutionality of the labelling regulations, and force the South African government to require the mandatory labelling of all GM food and feed, including the labelling of animal products derived from animals fed with GM feed-irrespective of whether transgenic DNA is detectable in such food, feed and products. The added costs of such labelling should not be borne by consumers who have not been consulted when decisions were first made, to market and commercially grow GMOs. These costs should be borne by those that profit from the sale and use of GMOs.

The South African government must also make available for public scrutiny the mysterious GM food safety assessments it claims have been assessed by independent laboratories.

It is incumbent upon the South African government to urgently establish a sound unique identification system in order to come in line with the Biosafety Protocol, particularly the provisions of Article 18 of the Protocol dealing identification and traceability of GMOs. As a Party to the Biosafety Protocol, South Africa is expected to fully comply with the provisions of the Protocol. It should start doing this sooner, rather than later, before it is taken to the Protocol's Compliance Committee, especially by its neighbours from the Southern African Development Community (SADC).

BACKGROUND

The labelling of genetically modified food serves a critically important function of providing the public with information and also functions as a mechanism to manage risks. As an information tool, labelling upholds the consumer's right to know what he or she is purchasing or using. As a risk management tool, the information that labels can provide to end-users refers to a GMO or GM product's toxicity, allergenicity or environmental safety. Consequently, with this information, the end user can take appropriate steps to minimise or avoid the risks specified, for example, by following the instructions on a label or refusing to purchase the product.

On the 16th January 2004, seven years after South Africa began commercially growing GM crops² and three years after it approved the commercial growing of GM white maize,³ the Department of Health published *Regulations Relating to the Labelling of Foodstuffs Obtained Through Certain Techniques of Genetic Modification*. These Regulations were made in terms of section 15(1) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act, No.54 of 1972). The objective of the Act No 54 of 1972 is to safeguard the consumer from foodstuffs that are harmful or injurious to human health.

White maize is South Africa's most important agricultural product because it is used as a staple food for millions of people not only in South Africa, but also in the Southern African region.⁴

2 The first crop to be granted approval by the National Department of Agriculture was Monsanto's GM maize (MON810) for commercial planting, and animal and human consumption. Agbios GM Database <http://www.agbios.com/dbase.php>. The GM maize is also referred to as 'yellow maize' and is used in South Africa as an important ingredient in feed rations for dairy, beef, poultry and egg production. Trends in the Agriculture Sector 2003 National Department of Agriculture www.nda.agric.za/doc/Trends2003.Field_husbandry.pdf. This maize is also a raw material for the production of starch used in turn, in the manufacture of sweeteners, syrups, and fermentation products. Maize oil is also extracted from the germ of the kernel. Thus maize products are present in a wide range of processed food products.

³ *South Africa to produce first GMO white corn 2002-2003*

www.monsantoafrica.com/news/africashowlib.ph+ml?uid=6740

⁴ Trends in the Agriculture Sector 2003 National Department of Agriculture www.nda.agric.za/doc/Trends2003.Field_husbandry.pdf

Maize is mainly consumed as a staple food in its milled and not highly processed form. Over the last four years, the South African government has authorised the import of bulk shipments of hundreds of thousands of metric tonnes of GM maize from Argentina, containing several GM maize events, namely MON810, T25, Bt11 and Bt 176 mainly for animal feed.⁵ According to the Animal Feed Manufacturers Association, GM maize is being imported from Argentina by the animal feed industry in the Western Cape because imported GM maize is cheaper than maize on the South African market.⁶ South African pressure groups have objected to these cheap imports of GM maize from Argentina.⁷ The duty of the government of South Africa is to protect the public from the risks posed by GMOs, based on the precautionary principle and not to enable industry to source the cheapest maize on the global market.

In 1997, South Africa also approved Monsanto's GM cotton for commercial planting and for consumption as food and feed. About two thirds of the harvested cotton crop is seed. Cottonseeds are crushed to produce cottonseed oil, cottonseed cake (meal) and hulls. Cottonseed oil is used in cooking oil, in shortening and salad dressing, and is used extensively in the preparation of snack foods such as crackers, cookies and chips. The meal and hulls are an important protein concentrate for livestock.⁸

During 2001, the National Department of Agriculture approved Monsanto's GM Soya (MON 4032) for commercial planting, food and feed. In South Africa, soybeans are mainly used for animal consumption, but it is also used for human consumption. A major food use of soyabean is as purified oil used in margarines, shortenings, and cooking and salad oils. It is also a major ingredient in food products such as tofu, tempeh, soya sauce, simulated milk and meat products.

According to Willie Maree, director of business relations of Monsanto South Africa (Pty) Ltd, GMOs can be found in meat, milk, eggs and a variety of processed foods that contain soya. This includes foodstuff as varied as ice cream, burgers, fish paste and margarine.⁹

South Africans have thus been consuming GMOs and GM products without their consent and knowledge for several years. According to a survey conducted in South Africa by the National Consumer Forum during 2003, the overwhelming majority of people interviewed knew nothing about GM foods, and those that did, expressed concern about the health effects of GM foods and demanded the labelling of GM foods to be enforced through legislation.¹⁰

⁵ For a listing of the permits granted by the Executive Council in terms of the Genetically Modified Organisms Act, 1995, see www.nda.agric.za. See also, "Demand For A Ban On Imports Of Bt176 And For A Public Enquiry Into Safety Of Food Derived From Genetically Modified Crops" Protest Letter, 10 May 2004, African Centre for Biosafety, Biowatch South Africa, Safe Food Coalition and SAFeAge. <http://www.biosafetyafrica.net>.

⁶ Gregor Botha *GMOS and the Animal Feed Industry* http://www.afma.co.za/AFMA_Template/1,2491,7677_2412,00.html.

⁷ Open Letter From South African Civil Society Addressed To The South African Delegation Attending The First Meeting Of The Parties To The Cartagena Protocol On Biosafety, Kuala Lumpur, Malaysia, 23-27 February 2004. *Stop All Trade in GMOs Now! Implement The Biosafety Protocol NOW!* <http://www.earthlifeafrica-ct.org/za/ct/article.php?story=20040223141749217>

⁸ *Agbios GM Database* <http://www.agbios.com/dbase.php>

⁹ *We Have been eating GM food for five years* Melanie Gosling, Cape Times, September 2002.

¹⁰ *GM food: SA public still knows 'nothing'* SAPA, June 2003
<http://www.dailynews.co.za/index.php?fSectionId+500&ArticleId-162502>

The South African government does not require that GM maize be segregated from non-GM maize during production, processing, distribution etc. The risk of contamination by way of co-mingling of GM animal feed imported into South Africa with maize milled and distributed for human consumption is thus extremely likely, as has already occurred with Starlink maize.

The South African government has furthermore, failed to establish an identity preservation system, whereby the unique identification of GMOs/GM events can be traced throughout the food chain, from farm to plate. Thus, in the event that GM maize for instance, causing adverse affects on animal and/or human health, it will be almost impossible for anyone to trace the offending GM event, and hence, the offending biotechnology company. **There is no reason why the South African government should shield the biotechnology industry in this way.**

LABELLING REGULATIONS AND SOUTH AFRICAN GOVERNMENT POLICY ON LABELLING OF GM FOOD

The South African government has followed the United States model where the use of GM techniques *per se* is not itself a trigger for labelling. The South African labelling regulations do not apply to the GM foods currently imported, marketed and released in South Africa (or elsewhere in the world for that matter). It is only when there is a 'significant difference' in the final food that labelling is required. However, this will not include situations where there is novel DNA or protein, unless it is considered to be significantly different. The circumstances where this is considered to be significantly different is if there are human/animal genes; allergens; requires different cooking; or has altered nutritional composition. There are no GM foods currently commercialised that would fall within this scope. Therefore, South African consumers will be given no choice over the current generation of GM foods.

Non-government organisations in South Africa reacted angrily to the Regulations upon its publication, calling them a 'sham.' According to these groups, "These Regulations do not require that GM foodstuff be labelled and effectively defeat the very purpose for labelling of any sort, namely to give the consumer the right to choose. They are totally unacceptable in that they don't require mandatory labelling of any of the major GM crops currently grown in South Africa. The Department of Health has cunningly provided industry with a way out of mandatory labelling by invoking the discredited and scientifically flawed concept of 'substantial equivalence'"¹¹

On the 12 February 2004, Member of Parliament, Kent Durr from the African Christian Democratic Party introduced a motion in the House of Parliament, National Council of Provinces, which sought to require that the government urgently review the Regulations. The African National Congress, the ruling party and former liberation movement, opposed the motion.

The rationale for the South African government's decision not to require the mandatory labelling of GM food and feed is contained in a two page document issued by the

¹¹ SAFEAGE Press Release 1 February 2004. *NGOs Slam Sham GM Labelling Regulations*. <http://www.safeage.org.za>.

Department of Health publication titled 'Explaining GMO Food Labelling'.¹² These include:

- Compulsory labelling of GM food would result in the increase in food prices and negatively impact on street vendors and the majority of the population who have limited purchasing power, especially those dependent on staple food;
- Systems to detect and identify GM-genetic material/protein by way of diagnostic techniques are subject to error, abuse and are expensive;
- Compulsory labelling of GM food is not practical since GMOs may increasingly appear in 30 000 products that contain maize and soybean ingredients;
- Segregation of GM food from non-GM foods is expensive.

However, pressure groups in South Africa find it ironical that increased costs should be proffered as an excuse to avoid guaranteeing consumer choice, when the proponents of GM technology argue that GMOs will provide cheaper and more plentiful food.¹³

According to the South African government, GM foods are safe and therefore, the need for labelling as a warning is unnecessary. "The label merely gives information. There are other ways of providing information."¹⁴ However, the claims made by the South African government must be more carefully scrutinised. The Department of Health has publicly stated that all genetically modified foods are carefully assessed by **independent laboratories** to ensure that they are equal or better in all ways to the conventional product, and will not increase allergenicity or toxicity.¹⁵ (own emphasis). The African Centre for Biosafety and Biowatch South Africa have been engaging with the National Department of Agriculture (NDA) and the Executive Council regarding applications for import and market approvals. In the course of their work, they have never come across any food safety assessments that have been assessed by independent laboratories.¹⁶ Indeed, what has become patently evident is that only desk- top reviews are conducted of the inadequate and highly questionable food safety information generated by the biotechnology industry, such as Monsanto, Syngenta, Dow Agrosiences and so forth.

Additionally, the Department of Health also contends that there is no evidence, to date, that shows GM foods have an adverse effect on human health.¹⁷ However, neither the Department of Health nor any other government agency has to date conducted any reliable and proper post commercialisation testing and monitoring for the effects of GMOs on animal and human health. This failure has arisen because the Genetically Modified Organisms Act does not address the issue of post commercialisation testing and monitoring adequately or at all. Hence, the South African government is not in any position to make the assumption that GMOs are safe for human consumption, "because no one has become ill or died as a result of consuming GM food" as is so frequently

¹² <http://www.doh.gov.za/department/foodcontrol/docs/explain.html>.

¹³ SAFEAGE Press Release 1 February 2004. NGOs Slam Sham GM Labelling Regulations. <http://www.safeage.org.za>.

¹⁴ Understanding GMOs. Department of Health. <http://www.doh.gov.za/department/foodcontrol/gmo/brochure.html>.

¹⁵ Understanding GMOs. Department of Health. <http://www.doh.gov.za/department/foodcontrol/gmo/brochure.html>

¹⁶ See www.biosafetyafrica.net for the objections filed by the African Centre for Biosafety to a number of applications for the import, marketing and environmental release of GMOs.

¹⁷ Understanding GMOs. Department of Health. <http://www.doh.gov.za/department/foodcontrol/gmo/brochure.html>

stated. This is particularly pertinent that the South African government has no way of monitoring what and how much of GM food and feed has been consumed by people and animals over any given period of time.

According to the South African government, the South African Bureau of Standards is in the process of developing an identity preservation system for non-GM grains/foods. The effectiveness of such a system is debateable, taking into account that the South African government has to date, made no attempt to safeguard non-GM food from contamination through co-mingling on farms, silos and along the food chain. Although voluntary identity preservation systems are currently in use by several major agricultural producers^{18 1920}, neither the Department of Agriculture nor any other government agency has conducted any reliable or proper post commercialisation testing and monitoring to determine the extent of the contamination of non-GM crops in the fields.²¹

DETAILED COMMENTS

SECTION 1, DEFINITIONS

“certain techniques of genetic modification”

This concept is identical to the definition of ‘modern biotechnology’ of the *Cartagena Protocol on Biosafety* (Biosafety Protocol) as well as *Codex Guidelines on Risk Assessment for foodstuff derived from genetically modified plants* (Codex). It is recommended that the concept be renamed to modern biotechnology. South Africa is a Party to the Biosafety Protocol and is also a signatory of the Codex Alimentarius, established by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO), which sets international food safety standards.

“**corresponding existing foodstuff**” does not appear to make much sense because it refers to food that existed before ANY changes have been introduced by example, plant breeding.

¹⁸ There are several major Agricultural co-operatives in South Africa that segregate their maize from GM maize-these are AFRIGRI, (old OTK) KOLK and VKB. Personal Communication, representative of African Products, 6 April 2004.

¹⁹ Personal Communication, Mr Brink, GRAIN SA, 6 April 2004.

²⁰ Personal Communication, Mr Anton Lubbe, SENWES, 8 April 2004.

²¹ It must be noted that according to Cotton South Africa, and contrary claims by Monsanto, Syngenta and indeed the South African government, cotton does have a wild relative, *Gossypium herbaceum* subsp. *Africanum*, found in South Africa. The possibility for gene transfer in locations within the United States where wild or feral cotton relatives exist (Hawaii and Florida) has led the Biopesticides & Pollution Prevention Division (BPPD) proposing containment provisions for these states. EPA Pesticide fact sheet for Bollgard Cotton. Monsanto Biotech Basics. http://www.biotechknowledge.com/biotech/bbasics.nsf/product_information_bollgard_cotton_pest.htm?OpenPage. The USEPA has reviewed the potential for gene capture and expression Cry endotoxins in cotton by wild or weedy relatives of cotton in the United States, its possessions or territories. The possibility for gene transfer in locations in Hawaii and Florida, where wild or feral cotton relatives exist has led to the EPA imposing stringent sales and distribution restrictions on Bt crops within these states. These containment measures are intended to prevent the movement of Cry1Ac from Bt cotton to wild or feral cotton relatives that exist in Hawaii and Florida. Cotton Relatives. <http://www2b.abc.net.au/rural/grow/newposts/0/post38.htm>.

“**food additive**” this definition is quite complicated, but reflects the Codex definition.²²

“**food ingredient**” this definition not only reflects the ‘food’ definition of Codex,²³ but also includes ‘food additive’ which gives rise to inconsistencies since the food additive definition means ‘any substance ...not normally used as a typical ingredient in foodstuff.’ It would have made more sense, had the definition of food ingredient referred to **unapproved** food additives.

“**foodstuff obtained through certain techniques of genetic modification**” This definition excludes foodstuff derived from an animal which is not itself a genetically modified organism but has been fed on feed in the production of which genetic modification is used. This definition should be revised in the light of the publication of an investigative report revealing parts of gene substance of GM Soya and maize being present in milk of animals fed on GM Soya and maize feed. The research report points out several possibilities as to how the gene segments may have found their way into the milk: via the GM feed fed to the animals, or as a result of the animals having breathed in the dust from the feed.²⁴ At a public hearing in Britain concerning Chardon LL, a herbicide tolerant maize variety produced by Aventis, Professor Bob Orskov, Director of the International Feed Resource Unit in Aberdeen, Scotland, one of the country’s leading experts on ruminant nutrition, stated that the scientific case put forward for the GM maize was inadequate. He said, ‘As a scientist, I wouldn’t drink milk from cows fed GM maize with the present state of knowledge.’²⁵

”**genetically modified organism**” and “**organism**” it is unknown why the drafters have chosen not to use the corresponding definitions of the Biosafety Protocol.

“**significantly different**” This definition is reproduced here, because of its central importance to the regulations. Significantly different means, in respect of a foodstuff obtained through certain techniques of genetic modification, that characteristics scientifically assessed through an appropriate analysis of data are different from those of corresponding foodstuff, taking into account accepted limits of natural variation in that foodstuff.’

The words ‘analysis of data’ means that the foodstuff does not need to be analysed itself but only the existing data. The word ‘appropriate’ before the word ‘analysis’ should be replaced with the words ‘state of the art’. ‘Analysis of data’ should specifically include biological testing which is aimed at identifying new components giving rise to toxicity, allergenicity and so forth.

The terminology ‘taking into account accepted limits of natural variation’ is too imprecise to make any legal or scientific sense. This allows for the taking into account of any published data for example, wheat, be it 2 or 20 years old. The objectives of the Foodstuff Cosmetics and Disinfectants Act in terms of which these labelling regulations

²² <http://www.fao.org/DOCREP/005/Y2200E/y2200e07.htm>.

²³ <http://www.fao.org/DOCREP/005/Y2200E/y2200e07.htm>.

²⁴ Greenpeace Press Release 22 June 2004. *Traces of Genetic Engineering detected in milk* <http://weblog.greenpeace.org/ge/archives/001471.htm>.

²⁵ The Independent (London), October 19, 2000. Pg.8. “Inquiry Warned Over Milk From GM-Fed Cows.”

have been promulgated, are to safeguard the consumer from foodstuffs that are harmful or injurious to human health. It stands to reason therefore, the data gained from analysis of the new foodstuff must be compared with the data concerning **existing** corresponding foodstuff.

For the labelling regulations to apply to GM foodstuff, then this definition would have to change to expressly include all foodstuff containing new proteins coded for foreign DNA should clearly and unequivocally be included.

This definition of ‘substantially different’ is a rather clever way of formally inviting the scientifically discredited concept of ‘substantial equivalence’ into South African regulation. The genesis of the concept of ‘substantial equivalence’ can be traced to the international meeting in 1990 of the United Nations Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO)²⁶ when GM foods were debated as being marginal extensions of traditional techniques. The FAO/WHO committee recommended that GM foods should be treated similarly to their non-GM counter-parts and that they be evaluated primarily by comparing their **compositional data** with those from their non GM-counter-parts. This would therefore lead to the presumption that GM foods would be accepted as being similar to the non-GM counterparts. (own emphasis) During 1993, the OECD formerly introduced the concept of ‘substantial equivalence’ as follows:

“For foods and food components from organisms developed by the application of modern biotechnology, the most practical approach to the determination is to consider whether they are substantially equivalent to analogous food product(s) if such exist...The concept of substantial equivalence embodies the idea that existing organisms used as foods, or as a source of food, can be used as the basis for comparison when assessing the safety of human consumption of a food or food component that has been modified or is new”²⁷

Hence, whenever official approval for the introduction of GM foods is sought and given in industrialised countries, and indeed in developing countries like South Africa, the concept of substantial equivalence is invoked. All that the biotechnology companies are required to do is refrain from introducing GM foods that do not have grossly different **chemical compositions** from those of foods already on the market (own emphasis).

‘Substantial equivalence’ absolves biotechnology companies from carrying out necessary nutritional and toxicological animal tests to establish whether the biological effect of GM crop-foodstuff is substantially equivalent to that of its non-GM counterpart.

It has long since been pointed out by scientists from the Dutch government that “compositional analysis...as a screening method for unintended effects...of the genetic modification has its limitations. particular regarding unknown anti-nutrients and natural toxins”.²⁸

‘Substantial equivalence’ has been severely criticised as being a pseudo-scientific concept, because it is seen as a commercial and political judgement masquerading as it if were scientific. It is also viewed as a barrier to further research into possible risks of eating

²⁶ Strategies for assessing the safety of foods produced by biotechnology, WHO, Geneva, 1991.

²⁷ Safety Evaluation of Foods Derived by modern biotechnology OECD, Paris, 1993.

²⁸ Kuiper, H.A. et al Food Safety Evaluation of Genetically Modified Foods as a Basis for Market Introduction (Ministry of Economic Affairs, The Hague, 1998).

GM foods.²⁹ A recent major literature review of food safety issues has shown a dearth of actual published scientific papers on which a reliable database of safety could be established.³⁰

“**taxonomic family**” this definition should be amended to include the following ‘or on the basis of its DNA’

SECTION 2, WHAT MUST BE LABELLED?

Excluded: GM Food and Feed; Foodstuff derived from GM fed animals

Section 2 of the South African labelling regulations require the labelling of a foodstuff if it is significantly different in respect of:

- the composition
- nutritional value
- mode of storage, preparation or cooking
- allergenicity
- human or animal origin.

There are no GM foods currently being commercially produced that in fact fall within the scope of this section! South African consumers are thus given no choice whatsoever, over the current generation of GM foods. These regulations contradict an earlier South African government’s position regarding the labelling of GM food. The Department of Health is on record as publicly stating, “consumers should be empowered to make informed choices about the purchase of GM products.”³¹ However, these Regulations also place consumers at great risk because they are unable to avoid risky GM foodstuff.

The Regulations do not also require that animal feed be labelled. GM animal feed contain genes, which make them resistant to antibiotics used for the treatment of diseases in both humans and animals. The introduction of antibiotic resistant marker genes into animal feed could severely undermine the effective treatment of diseases if the antibiotic resistance is transferred to bacteria, which are harmful to human and animal health.

As discussed above, the Regulations do not require the labelling of foodstuff derived from animals fed with GM feed, such as the meat, milk and eggs derived from such animals.

Voluntary Labelling

The Regulations thus contemplates the voluntary labelling of GM food and feed. However, food producers who may wish to label GM products or products that may contain GMOs, may be severely impeded from doing so, especially if such producers wished to provide the consumer with full details of the GMO in question, in particular,

²⁹ Millstone, E. et al Beyond ‘substantial equivalence’ Nature, Vol. 401, 7 October 1999, pp 525-526.

³⁰ Domingo, J.L. (2000) Health risks of genetically modified foods: many opinions but few data. *Science* 288, 1748-1749.

³¹ Understanding GMOs. Department of Health.

<http://www.doh.gov.za/department/foodcontrol/gmo/brochure.html>

information of the GM construct; the GM variety, the transgenic line and trait etc because South Africa does not have an identify preservation system in place.

The South African government grants approval to importers in a single application for the import of several GM varieties for use in South Africa as food, feed and/or processing.

Such single approvals have three adverse consequences:

- (1) It reduces the liability by those responsible, in the event of a mix-up occurring as it did in the Starlink case. There is no reason why the South African government should protect the biotechnology industry in this way;
- (2) It does not allow food producers to indicate on their labels, that foodstuff of feed is derived from a particular GM event, that contains antibiotic resistance marker genes for example, Bt 176 maize which has recently been banned in Spain because it contains the *bla* marker gene that confers resistance to ampicillin.³² The introduction of GMOs containing antibiotic resistance genes into the food chain enhances the risk of worsening the problem as DNA can survive in animal and human gastro intestinal tract. There is scientific evidence that GM food can transfer its antibiotic resistance genes to bacteria in the gastro intestinal tract or to bacteria in the environment.³³ According to the British Medical Association “*There should be a ban on the use of antibiotic resistance marker genes in GM food, as the risk to human health from antibiotic resistance developing in micro-organisms is one of the major public health threats that will be faced in the 21st Century. The risk that antibiotic resistance may be passed on to bacteria affecting human beings, through marker genes in the food chain, is one that cannot at present be ruled out.*”³⁴ The risks associated with antibiotic resistance are totally unacceptable, especially in South Africa where ampicillin and related antibiotics are used to treat opportunistic HIV and AIDS infections. South Africa’s GMO Act does not require that the effects of antibiotic resistance genes on the digestive flora of animals eating the GM feed be monitored. South African NGOs have written to the South African government on the 10 May 2004, demanding a ban on Bt176 and calling for a public enquiry into the food safety of GMOs. To date, no proper response has been received.³⁵
- (3) It makes it extremely difficult for South Africa to fully comply with the outcome of negotiations under Article 18 of the Cartagena Protocol on Biosafety. The First Meeting of the Parties (MOP), Kuala Lumpur, Malaysia 23-27 February

³² 29th April 2004, Spain banned Syngenta’s genetically modified (GM) Bt176 maize for commercial cultivation on the grounds that it may confer resistance to ampicillin. (*El Estado español retirara un OGM a instancias de la UE. El maiz Bt 176 Podrian provoca resistencias a los antibioticos, GARA*). According to Richard Lopez de Haro, Spain’s Office of Crop Varieties, Spain’s food safety authority banned Bt 176 after the European Food Safety Authority (EFSA) published its report on the utilisation of antibiotic resistance marker genes in GM plants.

http://www.efsa.eu/int/press_room/press_release/386_en.html

³³ *Evaluating the risks associated with using GMOs in human foods*. New Scientist: January 30, 1999.

³⁴ British Medical Association. *The impact of genetic modification on agriculture, food and health. Recommendations*. May 1999.

³⁵ “Demand For A Ban On Imports Of Bt176 And For A Public Enquiry Into Safety Of Food Derived From Genetically Modified Crops” Protest Letter, 10 May 2004, African Centre for Biosafety, Biowatch South Africa, Safe Food Coalition and SAFeAge. <http://www.biosafetyafrica.net>.

2004, adopted an important decision on the documentation that accompanies bulk shipments of GMOs imported for food, feed and processing. In this regard, the MOP decided that in regard to GMOs imported for direct use as food, feed and processing, the documents should clearly identify that the shipment **may contain LMOs for direct use as food, feed or for processing and not intended for direct introduction into the environment.** The documents should include the **common, scientific and commercial names of the LMOs, the transformation event code or its unique identifier code to establish clearly the identify of the LMO and any unique identification.**

Included: Allergens

Genetic modification confers new allergic potential to crops. A famous example is a soybean genetically modified with a gene from a Brazil nut. Tests on blood taken from individuals allergic to Brazil nuts unexpectedly revealed that they had a similar allergic reaction to the GM soybean.³⁶ The US Environmental Protection Agency did not approve a GM maize variety “Starlink” of Aventis for human consumption because of concerns of the allergic potential of a toxin it produces (*Bacillus thuringiensis* Cry9c). There is evidence that Cry9c is heat stable and resistant to degradation in gastric juice, two important indicators of potential allergenicity.

The Regulations address the issue of allergens, but require the labelling of a foodstuff that contains an allergen from only those products listed in an “Annexure.” The products listed in the Annexure include only the following: Crustaceans, Egg, Fish, Groundnuts, Milk, Molluscs, Soya beans, Tree nuts, *and Triticum* cultivars. What this means is that in the future, GMOs that contain allergens from any one of these products, would have to be labelled. However, GM foodstuff containing allergens from other products would thus be excluded from labelling requirements. The Department of Health says no new allergens would be permitted to enter the food chain and that new techniques are being developed to prevent this situation, but does say how this is to be achieved.³⁷

The rather limited list of products in the Annexure do not take into account that the genetic modification process itself may cause unintended effects and could give rise to potential allergenic properties in crops and products derived from such crops. Those that claim GMOs are safe, often rely on **theoretical** conclusions that the protein in question is unlikely to exhibit allergenic properties because: (a) the newly introduced protein originates from a non-allergenic source; (b) there is no significant sequence homology to known allergens; (c) the protein will be rapidly digested in the intestine; (d) the protein is not glycosylated; (e) the protein is not new to the human diet. However, every one of these arguments and their underlying assumptions have been questioned by the Austrian government³⁸, and thereby unscoring the need for independent testing to be conducted

³⁶ Nordlee, J.D., Taylor S.L., Townsend, L.X, Thomas, L.A., & Bush, R.K. (1996) Identification of a Brazil nut Allergen in Transgenic Soybeans, *New England Journal of Medicine*, Vol. 334 (11) p. 688.

³⁷ Explaining GMO Food Labelling. Department of Health. <http://www.doh.gov.za/department/foodcontrol/docs/explain.html>.

³⁸ Spök A, Hofer H, Lehner P, Valenta R, Stirn S, Gaugitsch H. Risk assessment of GMO products in the European Union: Toxicity assessment, allergenicity assessment and substantial equivalence in practice and proposals for improvement and standardization, July 2004, Austrian Federal Environment Agency Monograph.

with the real proteins from the GMO and not the bacterial surrogates, as is currently the case.

The Annexure comes directly from the 1992 U.S Food and Drug Administration's (FDA) "Statement of Policy: Foods derived from new plant varieties, notice" which to date, sets the rules for the voluntary GM food review system in the US, including the provision that labelling should only apply to risky food containing allergens etc. The list is composed of:

- (a) those foodstuff that causes the major allergies in the U.S; and
- (b) only contains those allergens, which can easily be determined by conventional laboratory studies.

In regard to (a), because it is known that food allergies are caused by different foods in different countries/societies, the 1:1 adoption of the U.S list in South Africa is not appropriate. The list should name the important food allergens in South Africa.

In regard to (b), the list does not contain major allergenic foods where allergens cannot be detected by established methods, for example in kiwi fruit, apples etc. A state-of-the-art approach to the regulations is thus recommended.

Included: Animal material containing genetic material derived from human or different taxonomic animal family

Animal material containing animal nucleic acid(s) or proteins(s) derived from a human or form a different taxonomic animal family must be labelled. According to the Department of Health, this labelling requirement addresses religious or ethical considerations.³⁹ 'Different taxonomic animal family' appears to exclude genes from species within the same taxonomic family. This threshold at the family level does not appear to be justifiable, but appears to have been inserted in order to ensure consistency with the substantial equivalence principle.

SECTION 3, ENHANCED CHARACTERISTIC CLAIM

Promotion of positive public perceptions of GM

This section allows claims on labels in respect of GM foods, that such food has been improved or has enhanced characteristics. However, such a claim would have to be validated and the claim must indicate that such improvement or enhanced characteristic has been achieved by certain techniques of genetic modification and that the wording is limited to 'genetically-enhanced foodstuff' or 'genetically improved foodstuff.' These provisions are not mandatory, and can be invoked at the discretion of food producers etc. Most importantly, it does not require that the label contain the words 'genetically modified organism obtain through ..' but introduces a positive connotation, 'improved or enhanced' and in so doing, promotes a positive public perception of the process that leads to the creation of the foodstuff.

³⁹ Explaining GMO Food Labelling. Department of Health. <http://www.doh.gov.za/department/foodcontrol/docs/explain.html>.

SECTION 4, GM FREE LABELLING

Prohibition on GM free labelling

The labelling of a foodstuff obtained through certain techniques of genetic modification is also subject to the Regulations Governing the Labelling and Advertising of Foodstuffs published under Government Gazette No. R. 2034 of 29 October 1993. The reason why specific reference is made to Notice R. 2034 of 1993 pertains to GM free labels.

Regulation 9(d) of Notice R. 2034 of 1993 prohibits a label or in an advertisement of a foodstuff a claim that a foodstuff is free from a particular substance if all other foodstuffs in the same class or category are free from such substance.⁴⁰ According to the Department of Health, a claim such as GM-free carrots implies that all other carrots contain GM-ingredients, which is not correct since no GM carrots are commercially grown.⁴¹

CONCLUSION

The Regulations on the labelling of GM food not only seriously flout the South African consumer's right to choose, but places consumers at great risk. Constructive engagement by pressure groups with the South African government has proved fruitless over these last few years. Environmental and food safety pressure groups should urgently test the constitutionality of the labelling regulations, and force the South African government to require the mandatory labelling of all GM food and feed, including the labelling of animal products derived from animals fed with GM feed-irrespective of whether transgenic DNA is detectable in such food, feed and products. The added costs of such labelling should not be borne by consumers who have not been consulted when decisions were first made, to market and commercially grow GMOs. These costs should be borne by those that profit from the sale and use of GMOs.

The South African government must also make available for public scrutiny the mysterious GM food safety assessments it claims have been assessed by independent laboratories.

It is incumbent upon the South African government to urgently establish a sound unique identification system in order to come in line with the imperatives of the Biosafety Protocol. A good unique identification system will greatly facilitate access to full biosafety information and risk assessments; can help enable traceability, surveillance, post-market monitoring, risk management, remedial actions and assignment of liabilities in cases of contamination or damage.

The current method of approval by the National Department of Agriculture, namely, the issue of one import permit for several GM varieties to be imported in one shipment, will not make it possible for South Africa, a Party to the Biosafety Protocol to comply with the provisions of Article 18 of the Protocol, as well as the outcome of either MOP 1 and

⁴⁰ <http://www.doh.gov.za/docs/regulations/1993/reg2034.pdf>.

⁴¹ Explaining GMO Food Labelling. Department of Health. <http://www.doh.gov.za/department/foodcontrol/docs/explain.html>.

the ongoing negotiations under Article 18 of the Biosafety Protocol. As a Party to the Biosafety Protocol, South Africa is expected to fully comply with the provisions of the Protocol. It should start doing this sooner, rather than later before it is taken to the Compliance Committee established by MOP1 especially by its neighbours from the Southern African Development Community (SADC).