For discussion
on 20 March 2003

LegCo Panel on Food Safety and Environmental Hygiene

Food Labelling

PURPOSE

This paper seeks Members' views on the Government's proposals on nutrition labelling and the regulation of genetically modified (GM) food.

BACKGROUND

Nutrition information on food labels

2. Nutrients are vital to human for growth and maintenance of good health. As consumers' awareness of the association between diet and health increases, there is an increasing demand for information about nutrients contained in food intended for human consumption such that consumers can make healthy food choices, and hence reduce the risk of certain diseases and conditions, such as obesity. Our existing legislation does not provide for any specification on nutrition information on food labels. Although quite a large percentage of prepackaged foods sold in Hong Kong carry nutrition labels, the information presented and the formats used are not consistent. Hence, consumers may find the information provided on the food labels difficult to comprehend, and in some cases, misleading.

3. In 2001/02, the Food and Environmental Hygiene Department (FEHD) conducted a feasibility study on nutrition labelling and examined a range of options for implementation. The feasibility study also looked into the different international practices in overseas jurisdictions as well as the labelling guidelines issued by the Codex Alimentarius Commission[1] (Codex). A market

[1] The Codex Alimentarius Commission was created in 1963 by the United Nations Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work

survey was conducted at the same time to determine the prevalence of nutrition labels and related claims and to examine the contents of nutrition labels. Following the completion of the feasibility study, we have come to the conclusion that our policy objectives of protecting public health and ensuring food safety can best be achieved through the implementation of a mandatory nutrition labelling system by phases.

GM food

4. The Administration conducted a public consultation exercise on the labelling of GM food from February to May 2001. The results of the public consultation were presented to the Advisory Council on Food and Environmental Hygiene (ACFEH) in November 2001 and the LegCo Panel on Food Safety and Environmental Hygiene in December 2001. As there was concern about the possible price rise after the introduction of a mandatory positive GM food labelling system, the ACFEH recommended that a regulatory impact assessment (RIA) on the labelling of GM food in Hong Kong be conducted. A consultant was appointed to conduct a RIA in April 2002 to assess the economic impact of introducing a labelling scheme on packaged GM food. The RIA was completed in March 2003. A copy of the Executive Summary of the RIA prepared by the Consultant is at **Annex**. A copy of the full RIA report will be deposited at the LegCo Secretariat for Members' reference and information. The assessment indicates that there will be no increases in costs to the food trade under a voluntary labelling scheme. However, there will be some cost increases to the trade if a mandatory scheme is to be implemented. And the cost implications to the small and medium enterprises would be significant because they would have difficulties, among others, in securing contractual agreements with product manufacturers with regard to the product's GM status. The RIA also identified a number of barriers to implementation, which include the lack of international consensus of GM labelling and testing, and the lack of international standards on Identity Preservation and similar documentation systems for certifying the GM content of products.

5. Having considered the results of the RIA, the adverse impact on the small and medium enterprises and the need to proactively address the issue of the safety of GM foods in the future, we consider that it would be appropriate to introduce a pre-market safety assessment requirement for GM ingredients to be supplemented by a system of voluntary labelling.

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undertaken by international governmental and non-governmental organizations.

PROPOSALS

Proposal on nutrition labelling

6. To ensure that the declaration of nutrition information is consistent across all prepackaged food on sale in Hong Kong and to protect the consumers from false claims, it is necessary to implement a labelling scheme on nutrition information. This is also in line with Codex guidelines and the best international practice.

7. We propose to implement a mandatory labelling scheme on nutrition information by phases. In the initial stage, food suppliers who choose on a voluntary basis to carry nutrition information, nutrition claims and function claims on their products are required to follow a prescribed format. After a reasonable period of time of about five to ten years for food suppliers and consumers to familiarize with the new regulations, the requirements for nutrition labelling would be made mandatory and cover all prepackaged food products. The labelling scheme on nutrition information will be defined as the quantitative listing of nutrient values of a food. In accordance with international practice and local health considerations, we will require a nutrition label, if presented, to list out a set of core nutrients such as energy, protein, carbohydrate and fat. The level of nutrients should be expressed as absolute amount (in metric units) per 100g or 100ml of food.

8. As regards nutrition claims, both nutrient content and comparative claims would be allowed but these claims would be limited to those relating to the set of core nutrients to be prescribed by us. For nutrient content claims e.g. “high calcium”, “low fat”, they must contain a minimum or maximum level of that specific nutrient so that the claim is justified. For comparative claims e.g. “Reduced fat – 25% less than the regular product of the same brand”, they must specify on the label, among others, the minimum difference in nutrient content between the compared foods.

9. As regards nutrient function claims e.g. calcium aids in the development of strong bones and teeth, we propose that only those nutrients that are included in the list as laid down in the Codex guidelines can be the subjects of function claims. Health claims such as “regulate blood glucose of diabetic

patients" will be dealt with separately through the regulation of health claims.

Proposal on the regulation of GM food

Pre-market safety assessment of GM food

10. As a precautionary measure, many developed countries have established mechanisms to evaluate the safety of GM food. The World Health Organisation and Codex have recommended their Member States to set up regulatory framework for pre-market evaluation of GM food. Places like Canada, member countries of the European Union, Australia, Japan, Mainland China and Taiwan have already implemented similar safety assessment schemes.

11. Although GM foods currently available on the international market have passed risk assessments and are not likely to be harmful to human health, such situation may change and the current local regulatory framework may not suffice in ensuring future GM foods that will be available in the local market are also safe. Furthermore, as more varieties of GM food from different places of origin may appear in the market in future, it is appropriate to introduce a mandatory pre-market safety assessment to ensure the safety of new GM food intended for human consumption before they are allowed to be put on the market. Safety assessment of GM ingredients is based upon scientific principles and guidelines developed by Codex. It is the normal practice for overseas developers of GM ingredients (i.e. biotechnology companies) to conduct safety assessment of their GM ingredients according to the guidelines prior to marketing them. During the safety assessment process, they will identify whether a hazard, nutritional, toxic, allergenic or other safety concern is present. If a new or altered hazard is identified, the risk associated with it would be characterized to determine its relevance to human health.

12. We propose to introduce a requirement of pre-market safety assessment for food containing GM ingredients. Under the proposed scheme, importers or manufacturers of food containing GM ingredients will be required to submit documents and certificates to FEHD, prior to importing the food to Hong Kong, detailing the safety assessments that have been conducted by the developer of the GM ingredients (i.e. biotechnology companies). The assessment should be carried out in accordance with the guidelines prepared by Codex. The results of evaluations conducted on the ingredients by overseas regulatory authorities should also be submitted, which FEHD will take into

account in the pre-market safety assessment. Food containing GM ingredients that have passed the safety assessment can be sold in Hong Kong. Such safety assessments will enable the FEHD to determine whether the developers of GM ingredients have adequately addressed the safety issues. The same principles and evaluation regime are adopted by food regulatory authorities of developed economies worldwide. This will also prevent Hong Kong from becoming a dumping ground for GM food which may pose a risk to human health. To minimise the impact on the trade, a grace period would be granted to those GM products that are already in the market.

13. Over a period of time, FEHD will be able to build up a list of approved GM ingredients based on the applications made by the importers and manufacturers. The list will be publicised and updated regularly for public reference. It is the responsibility of the importers and manufacturers to find out if their products contain only approved GM ingredients, and if so, the food may be imported without any further safety assessment. For food containing GM ingredients not on the approved list, an application to FEHD for pre-market safety assessment will be required.

14. To ensure that food containing unapproved GM ingredients are not on sale in the local market, FEHD will take food samples from the market for testing of unapproved GM varieties from time to time. Unapproved GM products would be required to be removed from the market, and the importers will be prosecuted.

Voluntary labelling of GM food

15. At present, there is no international consensus on the labelling of GM food. There is also a lack of strong justification for the labelling of GM food on food safety grounds. That being the case, encouraging the trade to adopt a voluntary labelling system may be a practical alternative to address some consumers' demand of making informed choices. Since negative claims on GM food are common in the local market, with some of them misleading, standardizing the terminology of, and developing a set of general guidelines on GM labelling may help the trade in making truthful GM claims. We therefore propose to issue a set of guidelines on the labelling of GM food and encourage the trade to adopt voluntary labelling in accordance with the guidelines. The proposed guidelines would provide reference to the trade in making truthful positive and negative labels. Standardized terminologies and overarching

principles underlying the recommended labelling approaches would be included in the guidelines.

ADVICE SOUGHT

16. Members are invited to comment on our proposals as set out in paragraphs 6 to 15 above.

NEXT STEPS

17. Taking into account any views Members may have, we will proceed to consult the public, the food trade and other organizations on our nutrition labelling proposal in 2003. The Department of Health and FEHD will also launch a public education programme on nutrition and nutrition information on food labels.

18. Regarding the regulation of GM food, we will work out the details of the pre-market safety assessment requirement and consult the trade and related organizations on our proposal in due course. We will also draw up a set of voluntary labelling guidelines in consultation with the trade and relevant organizations.

Health, Welfare and Food Bureau
March 2003

FSEH Panel
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FINAL REPORT

Food and Environmental Hygiene Department

Regulatory Impact Assessment on Labelling of Genetically Modified (GM) Food

March 2003

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FINAL REPORT

Food and Environmental Hygiene Department

Regulatory Impact Assessment on Labelling of Genetically Modified (GM) Food

March 2003

Reference C2363

For and on behalf of
Environmental Resources Management

Approved by: Dr Andrew Jackson

Signed:

Position: Managing Director

Date: 6th March 2003

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ACRONYMS

ACPC	Alberta Canola Producers Association
ACPA	American Crop Protection Association
ANZFRMC	Australia New Zealand Food Regulation Ministerial Council (formerly Australian and New Zealand Food Standard Council (ANZFSC))
AQSIQ	Administration for Quality Supervision, Inspection, and Quarantine (China)
CEN	Comité Européen de Normalisation
CEO	Chief Executive Officer
CSD	Census and Statistics Department
DIN	Deutsches Institut für Normung (German Institute for Standardization)
DNA	Deoxyribonucleic Acid
EFB	Environment and Food Bureau (Hong Kong)
ELISA	Enzyme Linked Immunosorbent Assay
EU	European Union
FEHD	Food and Environmental Hygiene Department (Hong Kong)
FSANZ	Food Standard Australia and New Zealand (formerly the Australian and New Zealand Food Authority (ANZFA))
FSAI	Food Standards Authority Ireland
FTE	Full Time Equivalent
GAIN	Global Agricultural Information Network
GATT	General Agreement on Tariffs and Trade
GIPSA	Grain Inspection Packers and Stockyards Administration
GM	Genetically Modified
GMO	Genetically Modified Organism
GMP	Good Management Practice
HACCP	Hazard Analysis and Critical Control Point
HFCS	High Fructose Corn Syrup
HKSAR	Hong Kong Special Administrative Region
HWFB	Health, Welfare and Food Bureau (Hong Kong)
IP	Identity Preservation
ISO	The International Organization for Standardization
KFDA	Korean Food and Drug Administration
MAF	Ministry of Agriculture (Korea)
MFN	Most Favoured Nation
MHLW	Ministry of Health, Labour and Welfare (Japan)
MOFTEC	Ministry of Trade and Economic Cooperation (China)
NERA	National Economic Research Associates
NGO	Non-Governmental Organisation
QA	Quality Assurance
QM	Quality Management
PCR	Polymerase Chain Reaction
PPM	Production and Process Method
R&D	Research and Development
RIA	Regulatory Impact Assessment
rDNA	Recombinant DNA

SKU	Stock Keeping Unit
SMEs	Small and Medium Sized Enterprises
SPS	Sanitary and PhytoSanitary
TBT	Technical Barriers to Trade
USDA	United States Department of Agriculture
WTO	World Trade Organisation

1 REGULATORY IMPACT ASSESSMENT

1.1 INTRODUCTION

The Government is currently considering options for labelling GM food. To this end, ERM was commissioned to undertake a Regulatory Impact Assessment (RIA) and to advise the Government on the findings.

1.2 OBJECTIVES OF THE STUDY

The objective of the RIA was to assess the economic impact of introducing a labelling scheme on pre-packaged genetically modified (GM) food in the Hong Kong Special Administrative Region (HKSAR). The assessment provides policy makers with information on:

- the relative merits of each labelling scheme with respect to practicality, enforceability and overall impact on food cost;
- the impact on the trade and HKSAR's trading partners, identifying the kinds of food that may be affected;
- possible impact on food supply and source of food; and
- cost to the Government in enforcing the labelling scheme.

The costs to the Administration, the trade and the public at large for five GM labelling options were identified and compared against the status quo.

1.3 THIS REPORT

This document represents the *Final Report* for the *Regulatory Impact Assessment on Labelling of Genetically Modified (GM) Food.* The remainder of the Report is set out as follows:

Section 2 presents the options for analysis;

Section 3 presents the needs analysis;

Section 4 provides information on stakeholder consultation;

Section 5 provides the impact analysis and findings; and

Section 6 presents the findings and barriers to implementation.

The following Annexes have also been included to provide additional details on the Study:

Annex A presents a review of international labelling regimes;

Annex B	presents a list of approved GM crops worldwide;
Annex C	presents details of Codex testing methods;
Annex D	is an overview of the food sector in Hong Kong;
Annex E	are case studies illustrating the potential implications of the labelling scheme on different businesses;
Annex F	presents the economic costs for each option broken down by household expenditure category; and
Annex G	presents the economic and financial costs of each option over a ten-year time horizon.

2 BACKGROUND

2.1 DEFINITIONS AND WORDING

The Food and Environmental Hygiene Department (FEHD) has provided ERM with a list of definitions. These are presented below and have been used throughout in understanding the options.

2.1.1 *Definitions from FEHD*

GM Food

GM food is any food or food ingredient that is, or is derived from, an organism in which the genetic material has been modified using modern biotechnology.

Modern Biotechnology

Modern biotechnology refers to the application of the following techniques that overcome natural physiological reproductive or recombinant barriers and which are not used in traditional breeding and selection:

(i) *In vitro* nucleic acid techniques, including but not limited to recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or

(ii) Fusion of cells beyond the taxonomic family.

Please note that terms including 'genetic engineering' are not commonly used in Hong Kong.

Genetically Modified Organism (GMO)

"Genetically modified organism" means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

Food Additives

Food additive means any substance that is added to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results. It or its by-products will become a component of or affect the characteristics of such foods. It is not normally consumed as a food by itself and not normally used as a typical ingredient of the food. Examples: preservatives, colouring matter and emulsifier.

Highly Refined Food

No detectable levels of novel DNA. Examples: cooking oil and soya sauce.

Flavourings

Flavourings are products used to impart odour, taste or both to a food or beverage.

Not Significantly Different Characteristics

Include composition or nutritional value significantly different from that of its conventional counterpart; level of anti-nutritional factors or natural toxicants significantly different from that in its conventional counterpart; the presence of an allergen that is not found in its conventional counterpart; the intended use of food is significantly different, or an animal gene has been introduced into food of plant origin.

Prepackaged Food

Refer to any food packaged, whether completely or partially, in such a way that the contents cannot be altered without opening or changing the packaging; the food is ready for presentation to the ultimate consumer or a catering establishment as a single food item.

Processing Aids

Processing aid means any substance or material, which is intentionally used in the processing of raw materials, foods or its ingredients to fulfil a certain technological purpose and its residues or derivatives may be present in the final product unintentionally. Examples: extraction solvents and enzymes.

Threshold

Due to the unavoidable mixing of GM and non-GM crops during plantation, harvest, transportation and storage, a tolerance limit is set such that any food ingredient with a GM content above this level will require labelling.

2.2 DESCRIPTION OF THE OPTIONS

2.2.1 *Institutional and Legislative Arrangements*

The proposed mandatory options discussed below would be integrated with the existing food labelling legislation (the *Food and Drugs (Composition and labelling) Regulations* made under section 55 of the *Public Health and Municipal* Services Ordinance (Cap. 132)). FEHD would be responsible for subsequent enforcement.

2.2.2 *Option (I). Voluntary labelling of GM food.*

Under this option the trade can label GM food on a voluntary basis. Effectively this represents the status quo situation, where presently there are no specific regulations regarding GM-status of products. While there are currently a range of products making negative GM claims in Hong Kong only

one product has been identified as carrying a label identifying the GM content [1].

2.2.3 ***Option (II). Mandatory labelling of designated products by phases - at 5% threshold.***

This option requires designated food products as major ingredients to be labelled. A major ingredient would be defined as one that is amongst the top five constituents of the food product by weight and as well as comprising at least 5% of the end product by weight. A 5% threshold would be allowed for these GM food products. In addition, significantly different characteristics, such as the emergence of an allergen and changes in composition or nutritional value must also be labelled. The first phase would designate GM soya bean and corn (and processed food containing GM soya bean and corn) be labelled, while a second phase would add canola, potato and cotton seed to the list of designated products.

It is assumed that:

- the second phase will be introduced three years after the first phase;
- highly refined food will be exempted (based on the absence of detectable traces of novel DNA; and
- mandatory labelling will be required for altered heath or nutritional characteristics.

The phasing of labelling reflects the fact that sampling and testing protocols, as well as reference materials, for corn and soya bean are relatively well established while those for second phase products are not.

Screening tests, specific trait tests and quantitative tests are possible for several commercial varieties of corn and soya (see *Section 2.4.1* for details on testing possibilities). Further, the market for 'non-GM' soya and corn products and ingredients has grown since 1997. This option would allow industry and retailers to establish a strategy for the labelling regulations and find alternative sources of supply or implement identity preservation (IP) systems.

Example of food that might require labelling: soya flour with more than 50g / kg (5%) of permitted GM soya varieties.

2.2.4 ***Option (III). Mandatory labelling of designated products by phases – at 1% threshold.***

This option requires designated food products that include GM soya bean and corn as major ingredients, as well as processed products with these GM agricultural products as major ingredients, be labelled as GM food. A major

[1] A preliminary analysis conducted by FEHD on pre-packaged food identified one brand of canned food that voluntarily labelled its products as containing GM ingredients.

ingredient would be defined as one that is amongst the top five constituents of the food product by weight as well as comprising at least 5% of the end product by weight. In addition, significantly different characteristics, such as the emergence of an allergen and changes in composition or nutritional value must also be labelled. GM soya bean and corn would be introduced in the first phase while canola, potato and cotton seed would be labelled in the second phase. A threshold of 1% would be allowed for these GM products.

This option is the same as option (II), however, a threshold of 1% would be allowed for these GM products. We have therefore made the same assumptions:

- the second phase will be introduced three years after the first phase;
- that highly refined food will be exempted (based on the absence of detectable traces of novel DNA; and
- that mandatory labelling will be required for altered heath or nutritional characteristics.

It is understood that different grades and blends of oil vary in amount of detectable DNA. For example, salad oil grade will have few (if any) traces of DNA present, whilst less refined or cold pressed oils may have detectable traces. The same is true for corn and soya derivatives. International standards have not yet been established for individual products.

Example of foods to be labelled at the second phase: cold pressed/ unrefined canola oil or potato chips made from an approved potato variety.

2.2.5 ***Option (IV). Mandatory labelling of all GM foods at 5% threshold with the exemption of highly processed food.***

Under this option, GM ingredients exceeding 5% threshold in any food product would need to be labelled. In addition, significantly different characteristics, such as the emergence of an allergen and changes in composition or nutritional value must also be labelled. However, highly refined food items as well as food additives, flavourings and processing aids are exempted from labelling requirement.

Example of food product that might require labelling: corn snacks e.g tortilla chips.

2.2.6 ***Option (V). Mandatory labelling of all GM foods at 1% threshold with the exemption of highly processed food.***

This option is essentially the same as the preceding one except the threshold is set at 1 %. This 1% threshold level would apply to where unintended adventitious contamination has occurred.

Example: soya Lecithin when used as a food ingredient would require labelling.

However, it should be noted that, under FEHD definitions, lecithin when used as a food additive (as defined in *Section 2.1.1* – lecithin is often used as an emulsifier) would not require labelling. This suggests the need for FEHD to define 'food additive' more closely, perhaps as a proportion of the overall product or by traces of novel DNA (similar to the Australian and New Zealand scheme as outlined in *Annex A*).

2.2.7 *Summary of Options*

Table 2.1 presents a summary of the options described above.

Table 2.1 Summary of Options

Option	Threshold	Ingredients covered by threshold	Assumptions	Exemptions
Option I	Voluntary.	Voluntary	N/A	N/A
Option II	5% of top 5 ingredients.	In the first phase soya and corn, in the second phase canola, potato and cottonseed.	Mandatory labelling for altered characteristics & second phase after three years.	Highly refined food exempted from both phases
Option III	1% of top 5 ingredients.	In the first phase soya and corn, in the second phase canola, potato and cottonseed.	Mandatory labelling for altered characteristics & second phase after three years.	Highly refined food exempted from both phases.
Option IV	5% in any food ingredient.	All food items except the 4 categories of exemptions.	Mandatory labelling for altered characteristics.	Processing aids, flavourings, highly refined foods and additives.
Option V	1% in any food ingredient.	All food items except the 4 categories of exemptions.	Mandatory labelling for altered characteristics.	Processing aids, flavourings, highly refined foods and additives.

2.3 SCENARIOS

2.3.1 *GM-free sub option*

The Steering Committee of the RIA study stated that caution should be used in conjunction with the term "GM-free". The consultants were presented with an FEHD paper outlining international practice on "GM-free labelling". Several points from this paper are included below:

- During the Environmental and Food Bureau (EFB) public consultation (2001) there was overwhelming support that negative claims in a food label should be substantiated by documents certifying that an IP system was in place for the ingredients used.

- The EFB Consultation Paper (2001) stated that 'GM-free' and similar labels will give consumers the impression that the food products so labelled are totally free of GM content and they should be used with caution to avoid giving consumers misleading information. However, it was also noted that this issue was raised at the Codex meeting on labelling in 2001 and Hong Kong should monitor any developments closely and neither lag behind nor fall out of line with internationally adopted practices.

The GM-free category in its absolute definition covers all foods including those that no longer contain any novel DNA but were derived from biotech crops. Therefore ingredients that are exempted from other options, for example refined oils, starches, and sugars, would not be exempt from this category. In addition, no food ingredients, processing aids, or flavours derived using modern biotechnologies, should have been used anywhere in the production process. By most international standards this would exclude cheese produced with GM chymosin and in some countries this would also exclude meat finished on GM grains. In practice GM-free claims would require an IP system to assure the non-genetically modified status of ingredients.

Some stakeholders have noted that voluntary labelling with this additional GM-free option takes into consideration the need of interested consumers without imposing costs and restriction associated with labelling on the trade and consumers at large. One of the problems associated with negative labelling is that the costs of testing and IP in order to substantiate a GM-free claim as a 0% threshold does not permit any adventitious contamination. Further, if the food producer is found to be making a false claim (i.e. the food product does contain GM content, accidentally or not) this would be in breach of Hong Kong's regulations surrounding labelling. i.e. *labels should be truthful not misleading and conform to the relevant requirements regarding the composition of the food product.*

As described above, absolute GM-free claims are a sub option that few producers opt for as paying the associated costs to achieve zero tolerance are

so high. The exception to this has been where organic labelling schemes have been implemented, as most organic certification schemes involve assurances of GM-free as part of the overall production process. However, the cost implications of achieving GM-free status are likely to be less than those for organic foods as GM-free products would not have to meet the additional requirements required to qualify as organic.

2.4 *TESTING FOR GMOS*

Detection of GMOs typically requires laboratory analysis. The type of test involved will depend upon the levels of sensitivity required and type of the sample material.

Raw grains, seeds and lightly processed products can be tested for protein content using an immuno-assay analysis procedure called Enzyme Linked Immunosorbent Assay (ELISA). These tests allow quantification of specific proteins (in this case the proteins expressed as a result of the novel DNA) and are relatively cheap and easy to conduct.

However since proteins are denatured with heat and food processing, most processed food products tests rely on the detection of novel DNA. Typically this can be up to a three-stage process (the exact number of stages depends on detection needs) and involves using Polymerase Chain Reaction (PCR) testing procedures. PCR procedures involve the extraction and amplification of DNA and therefore can detect extremely small amounts of DNA. Typical PCR analyses to detect novel DNA include:

- **Screening:** The first stage involves screening by searching for genetic markers that indicate genetic modification. Common markers include '35S-promoter',the 'NOS-terminator' and 'nptII' [1], but details of crop type and origin of crop will also help determine the search for other common gene markers. Screening tests are usually used with raw materials or where little information about the composition of food products is available that will identify GM-status. While screening can identify common markers that indicate genetic modification it cannot, on its own, identify the actual GM ingredient.

- **Identification**: The second stage involves identifying specific traits. Again after consideration of information on origin and type of crop, 1-2 tests may be used to detect distinct genetically modified sequences allowing definite determination of the GMO. This qualitative method allows detection of particular crops (for example approved and unapproved crop varieties).

- **Quantification:** If a qualitative test result is positive, quantitative methods can be used to establish the level of novel DNA. Realtime PCR techniques determine the ratio between genetically modified DNA

[1] NptII marker is a kanamycin resistance gene

and non-modified DNA and thus allow determination of the proportion of genetically modification material within a sample. These tests can be used to determine levels of contamination within a food product or determine the level of DNA found in a food ingredient such as cornstarch. Quantification procedures using PCR technologies are relatively new and therefore more costly.

Table 2.2 ***Relative Amounts of DNA in Different Foods***

Product	Amount of DNA Isolated
Soya Beans	+++
Soya Meal	+++
Soya Drink	++
Soya Sauce	+
Lecithin	+
Refined Oil	(+)
Corn	+++
Corn Snacks	++
Corn Starch	+
HiFructose Corn Syrup (HFCS)	(+)
Tomato	++
Ketchup	++
Soya Flour	+++
Tofu	+++
Natto	++
Cookies	+
Crude Oil	+
Chocolate	++
Canned Corn	+++
Corn Grits	+++
Corn Flakes	+
Veggie Burgers	+++
Tomato Paste	++
Canola Honey	+
+++	> 100ng/µl
++	5 to 100ng/µl
+	< 5ng/µl
(+)	DNA not always detectable

Source: Spiegelhalter, Lauter and Russell, Journal of Food Science, Vol. 66, No. 5, 2001

2.4.1 *Limits of DNA detection*

Detection of DNA depends upon the total amount of extractible DNA. The more highly refined the finished food product the more difficult it is to detect and extract DNA. This is shown in *Table 2.2*, where DNA is only extractable from refined oil in some cases, whereas extractible DNA in tofu is found at levels over 100ng/µl.

In some cases, it is possible to detect GM material down to a level of 0.01%. However, the sensitivity of detecting DNA using PCR also depends on the quality of DNA extracted from the food products. Ingredients such as sugars and cocoa found in a typical cookie can act as inhibitors within the PCR procedure. Therefore, the DNA quality and hence the sensitivity depends upon elimination of sugar, cocoa, glycoproteins etc, prior to the isolation of DNA.

In addition, availability of certified reference materials also affect the limits of DNA detection.

2.4.2 *Standard Setting in testing and detection methods*

International consensus on appropriate testing methodologies and standard procedures has not yet been reached. However, some progress has been made in the EU, where Comité Européen de Normalisation - European Committee for Standardisation (CEN) has produced draft European Standard on sampling procedures and are in the planning stages of producing stages of establishing detection protocols.

2.4.3 *Codex Alimentarius Commission - Consideration of Analytical Methods*

The Ad Hoc Working Group on Analytical Methods was established under the Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology in 2000. The terms of the Task Force will expire in 2003. The Ad Hoc Working Group on Analytical Methods has published a list of validated methods for further discussion and consideration in the meeting of the Codex Committee on Methods of Analysis and Sampling.

Most of these methods (which are found in *Annex C*) were based on polymerase chain reaction (PCR). Again the PCR tests fall into three categories, which enables the:

- screening for recombinant DNA (rDNA);
- detection of specific rDNA; and,
- quantification of the amount of rDNA.

2.4.4 *Draft European Standard: Detection of Genetically Modified Organisms and Derived Products*

The draft European Standard "Detection of Genetically Modified Organisms and Derived Products - Sampling" prepared by Working Group 11 within the Technical Committee CEN/TC275 "Food Analysis" will, when complete, outline best practice in the methodologies and apparatus to be used in the detection of genetically modified foods and derived products and later, as a European Standard, it will constitute a reference for national governments in Europe.

The draft standard describes general principles that emphasise that samples should be representative of the lots from which they have been taken and outline steps to avoid adventitious contamination of the samples. The draft standard recognises that many trade associations already have standard sampling procedures, which form part of contracts between their members, but in the absence of such agreed sampling procedures gives guidance for setting up valid sampling strategies. It aims to outline best practice in the sampling of raw materials (bags, moving goods, sampling from rail wagon,

lorry, barge and ship, sampling from silos, bins and warehouses) and of finished food products.

2.4.5 *US approach to testing protocols*

Currently there is no consensual agreement within the US on testing protocols, although the US governmental standardisation planning association has established their own procedures in conjunction with the American Association of Cereal Chemists.

The US Department of Agriculture's (USDA's) Grain Inspection Packers and Stockyards Administration (GIPSA) undertook a survey of testing laboratories in the US and in Europe with a view to certifying testing labs and improving overall performance of testing for biotechnology-derived grains and oilseeds. GIPSA published the findings of this survey as part of a proficiency program designed to identify areas of concern and improve testing capabilities and reliabilities. However the US maintain that the results obtained during this proficiency program cast doubt on some of the 3rd party testing laboratories and the testing procedures used. It is unlikely that the US will accept, in the near future, any international moves to reach consensual agreement on testing protocols and indeed this has become a sticking point at Codex committees.

2.5 *APPROVED CROP VARIETIES*

Globally different government and regulatory authorities have approved over 60 GM crop varieties from more than 15 crop types. These include food crops and flowers as outlined in *Table 2.3* below.

Table 2.3 ***Crop Approvals***

Crop	No of approvals
Papaya	1
Potato	4
Rice	1
Soya bean	4
Squash	2
Tomato	7
Tobacco	4
Beet	2
Rape seed	16
Carnation	2
Maize	14
Cotton	4
Flax	1
Chicory	1

Source: Compiled from various sources.

Crops grown in one country have not necessarily achieved approval in other countries and this has resulted in product withdrawals in some countries. For example the Food Safety Authority of Ireland (FSAI) identified two products that contained unapproved GM ingredients in a pilot survey in 1999 and subsequently required these products to be removed from sale.

The table below summarises some of the common crops approvals and their associated testing possibilities. Further details on crop approvals by different regulatory authorities and lists of crop approvals from various countries can be found in *Annex B*. Also in *Annex C* is a list of testing methods collated by the Codex Committee.

Table 2.4 ***Testing Possibilities for Approved GM Crops***

Crop/Manufacturer	Brand	Approval	Screening Test	Specific Test	Quanti -tative Test
Corn					
AgrEvo	LibertyLink	USA	+	+	+
Monsanto	YieldGard	USA, EU (GB)	+	+	+
DeKalb	B16	USA	+	(+)	+
PGS	Seed Link	USA	+	+	+
Novartis/Mycogen	Maximizer, Event 176	USA, EU, Can, Jap	+	+	+
Northup King/ Novartis	BT11	USA, EU (GB), Can, Jap	+	+	+
Cotton					
Monsanto	Bollgard	USA, Can, Mex	+	+	
Monsanto	Roundup Ready	USA, EU (GB)	+	+	
Papaya					
Maiselle U	Sunset	USA	+	-	
Potato					
Monsanto / Nature Mark	New Leaf Potato	USA, Can, Jap, Mex	+	+	
Monsanto	New Leaf Potato	USA, Can, Jap, Mex	+	+	
Avebe	Unknown	EU (NI)	+	-	
Pumpkin					
Asgrow	Freedom II	USA	+	+	
Upjohn / Asgrow Chicory	Freedom II	USA	+	-	
BejoZaden	Unknown	EU	+	-	
Rapeseed					
PGS	SeedLink, InVigor	EU, Can, Jap	+	(+)	
AgrEvo	Innovator	USA, Can, EU (GB), Jap	+	+	
Calgene	Laurical	USA, Can	+	(+)	
Monsanto	Roundup Ready	USA, Can, EU (GB), Jap, Mex	+	(+)	
Soya					
AgrEvo/Hoechst	Unknown	USA	+	+	
Monsanto	Roundup Ready	USA, Can, EU, Jap, Arg	+	+	+
DuPont	Unknown	USA	+	+	
Tobacco					
Rhone-P /Seita	Unknown	EU	+	+	
Tomato					
Monsanto	Unknown	USA	+	(+)	
Calgene	FlavrSavr	USA, Can, EU(GB), Mex	+	+	
Zeneca & Petoseed	Unknown	USA, EU(GB)	+	+	
DNA Plant Tech	Endless Summer	USA, Can	+	(+)	

Source: Information provided by various private sector testing laboratories. For detailed information on the testing possibilities for approved GM crops, please refer to *Annex C Codex Analytical Testing Methods.*

Notes: EU = Europe GB = Great British Can = Canada Mex = Mexico
NI = Netherlands Jap = Japan Arg = Argentina

3 NEEDS ANALYSIS

3.1 INTRODUCTION AND BACKGROUND INFORMATION

The debate surrounding GMOs has been an emotive and value laden one, with many dimensions and a wide range of participants. Conflicting arguments, miscommunications and partial truths have all left the consumer, farmer and the food producer confused.

Principally the debate has centred around four main areas: trade, environment, health & safety and ethical/ religious dimensions. Here we briefly outline some of the issues that have caused the GM dispute to become so contentious.

3.1.1 *International Trade Law Analysis of the EU Approach to GM Labelling*

Introduction

The evaluation of policies surrounding biosafety and labelling has, in part, been driven by the escalation of trade (1) conflicts between the United States and Europe on both GM labelling law and a moratorium on imports of GM food imposed by the European Community.

These jurisdictions provide an illustration of two contrasting labelling options. As a starting point for the trade law analysis, in summary, the EU position has been taken (reflected in Commission Regulation 49/2000/EC and the latest Commission Proposals placed before the European Parliament for First Reading by its Environment Committee on 16 April 2002) that all imports containing a threshold limit of 1% or more genetically modified ingredient must be subject to mandatory labelling and tracing based on origin unless appearing on a 'negative list' of food ingredients (2). As the EU mandatory labelling regime is subject to the most concerted discussion of international trade law implications it is analysed, in legal terms, according to applicable World Trade Organisation (WTO) legal rules. This is of particular importance as it provides an understanding of the likely outcome of such legislation in any WTO dispute settlement hearing.

A summary of the main WTO considerations is given below.

WTO Disciplines as they pertain to EU Mandatory Labelling

From the outset, it should be noted that any conclusions related to the WTO-status of GM labelling regimes are uncertain because there is no WTO case

(1) Related to the trade arguments are a number of other grounds for dispute including part of a wider argument that encompasses the relevance of intellectual property rights (IPR) and international agreements in the context of new and emerging biotechnologies.

(2) The 'negative list' would include food ingredients which Member States would agree do not require labelling as they contain no genetically modified material.

law on GM labelling. Consequently, we shall simply summarise the main points that may arise in considering the WTO-compatibility of EU mandatory labelling as follows:

- **Committees.** The WTO Sanitary and PhytoSanitary (SPS) Measures Committee and the Technical Barriers to Trade (TBT) Committee provide the institutional basis for initial WTO member discussion of GM labelling regimes. Both Committees have discussed the EU GM labelling regime.

- **Sound Science.** To the extent that GM labelling regimes impose restrictions on trade flows there must be a "scientific justification" for said trade measures (See for instance, the SPS Agreement and The Hormone Beef Decision – European Communities – Measures Concerning Meat and Meat Products, 16 January 1998, WT/DS26/AB/R).

- **International Standards.** National legislators should consider the work of WTO-recognised international standardising bodies. For example, if the Codex Alimentarius Commission (a WTO-recognised international standard-setting body) were to evolve standards on labelling and traceability (using a "substantial equivalence" test as is currently being attempted) then these standards would be an important reference point for judging "sound science", and therefore the WTO compatibility of national measures. This conclusion arises because Article 3 of the SPS Agreement mandates (international) harmonisation of health and plant health standards. As well, Article 5(4) of the SPS Agreement requires WTO Members to minimise negative trade effects in determining SPS measures.

- **SPS Exemptions.** As a practical matter, exemptions from these rules will generally be allowed if, according to Article 4(3), there is a scientific justification for more trade restrictive standards or there is provisional application of said measures pursuant to Article 5(7) of the SPS Agreement.

- **Legitimate Objectives.** Further to this point, Article 2 of the TBT Agreement allows trade-restrictive regulations where "legitimate objectives" (i.e. health and safety) can be achieved in a "least trade restrictive" manner. The US claims that the safety of GM products is well established. It argues that countries that restrict GMO imports on the grounds that they pose a threat to human or plant life may be breaching the WTO SPS Agreement as GMOs have not yet been proven 'dangerous' (1). Of course, the European Union would take the alternative position that scientific evidence and/or the application of the precautionary principle would dictate that threats of

(1) World Development Movement Briefing Paper on GMOs: GMOs and the WTO, November 1999. http://www.wdm.org.uk/cambriefs/GMOs/GMOs_WTO.htm

environmental harm or harm to human health are the justification for mandatory GM labelling.

- **"Technical Regulation".** Although there is a definition of "technical regulation" in the TBT Agreement, it has not been subject to much jurisprudential scrutiny. This is an important point because it is indeed possible that the EU challenged measures could be defined as a "technical regulations". On the other hand they may not be "technical regulations" in which case the EU may argue that the TBT Agreement should not be applied to the challenged measures. As such, it is not clear how and whether the TBT Agreement should be applied.

- **Article III.** Article III of General Agreement on Tariffs and Trade (GATT) 1947 (in force under WTO law) articulates the non-discrimination principle of "national treatment" which disciplines a WTO Member's use of internal taxation and regulation. National treatment requires that imported goods be accorded the same treatment as domestic "like products". It is the domestic/foreign product counterpart to the Most Favoured Nation (MFN) rule. As such, the United States would take the position that mandatory labelling requirements for products containing a GM component would be discriminatory by reference to their non-GM counterparts. The EU would counter-argue that GM and non-GM products are "unalike" because their compositions are physically dissimilar.

- **Production and Process Methods.** It may also be the case that a mandatory tracing and labelling scheme, of the kind prescribed by the EU model, contravenes Article III and TBT Agreement, "production and process method (PPM)" restrictions. However, specific case law under the TBT Agreement has not clarified whether the TBT Agreement PPM language re-interprets the Article III PPM test.

- **Article XI.** Article XI is the major GATT provision prohibiting the use of non-tariff barriers, proscribing quantitative restrictions such as quotas "instituted or maintained by any contracting party on the importation .... or on the exportation or sale for export of another contracting party's product". A GM content labelling requirement applied as a condition of importation into the EU single market may be subject to this provision, but Article XX/WTO Agreement relief may be available.

- **Article XX (b).** Article XX (b) can provide a "human, animal and plant life or health" protection exemption to a WTO Member whose measures have been challenged and found to be in breach of one of the GATT/WTO obligations including all of the Articles discussed above. On this point, the EU would make reference to any environmental or medical science attesting to the threat posed to domestic markets/consumers/the national domestic environment by GM-based products subject to the mandatory labelling measures.

- **Precautionary Principle.** It would also argue these points on the basis of the internationally recognised precautionary principle which would seek to place a burden of proof on the United States to show with 100% certainty that agricultural biotechnology causes no adverse environmental or human health effects. Invocation of the principle effectively shifts the burden of proof of GM safety onto the United States and away from the EU.

While the key legal issues to be argued are now clear, the results of any formal WTO trade law evaluation of the above-mentioned EU GM labelling measures is relatively uncertain.

3.1.2 *Environment*

Principal environmental objections centre around the fact that once GMOs are released into the environment there is no way of recalling them and the effects could be irreversible. Concerns include:

Possible Negative Environmental Impacts

- ***Potential changes in the level and nature of biodiversity.*** (1) GMOs can affect the environment through direct ecological effects (e.g. impacts on biodiversity through the widespread use of commercial strains) or through indirect environmental effects (e.g. changes in agricultural management practices).

- ***Genetic pollution, super weeds and super pests.*** (2) Intensification of agriculture conflicts with alternative organic ideologies and sustainable agriculture. There are also concerns that GM strains could become superweeds, wiping out local species and becoming 'pest plants' in their own right.

However, proponents assert that there are environmental gains associated with GM crops that include:

Potential Environmental Benefits

- Crops grown with lower level of chemical pesticides and use of low tillage farming practices (leading to related reductions in soil erosion and water usage)

(1) GM varieties have been found to be growing in the wild in Mexico, an important in situ conservation area for wild land race or criollo maize varieties. The possible introgression of transgenes is of particular concern because Mexico is the centre of origin for the domestication of corn. Farmers in India were found to be selling unapproved Bacilius thuringiensis (Bt) cotton in India - marketing the strains as hybrid strains. An English Nature study in Canada recently found "superweeds" - the result of gene-stacking in GM oilseed rape, where the seeds produced had accumulated resistance to more than one herbicide.

(2) Long term efficacy of Bt crops may lead to Bt-resistant insects and redundancy of Bt-biological pesticide used in organic farming. Crop plants with virus resistance (from genes derived from viruses) could lead to viruses with the potential to kill native plant varieties.

- In addition, biotechnology could provide some of the future solutions to meeting global food needs in environmentally friendly ways.

3.1.3 *Food Safety and Public Health*

Another area that attracts considerable debate is that of health and safety, again much of the debate focussed on the 'unknown' effects. Principal arguments include:

Perceived Risks to Human Health

- possible long term adverse effects on human health
- potential allergenicity (1)
- antibiotic resistance (2)
- higher herbicide residues in vegetables

Potential Health Gains

- reduced toxic compounds in foods (lower mycotoxins in maize etc)
- improved nutritional content - either by addition of micro-nutrients or improved digestibility and palatability
- GM foods and production methods are subject to more rigorous scrutiny than conventional crops

Future Possibilities

There are also a number of future possibilities that biotechnology could apply to. Development and commercialisation of these products, would, of course, be dependent upon the receipt of sufficient research priorities, relevant safety assessment and so on.

- Quality traits - crops grown with improved nutritional qualities, low phytate, high stearate
- Neutraceuticals or functional foods
- Novel plants with pharmaceutical trait, e.g. edible vaccines
- Agronomic traits, e.g. plants grown for marginal areas (arid resistant, saline tolerant, heat tolerant)

(1) Much of the public controversy surrounding allergenicity arose when Pioneer Hibred transferred a protein gene from a Brazil nut to soya beans. The allergenic properties of the nut were also transferred so the soya bean was never commercialised; however, this is often cited as an example. Many allergic reactions are a response to proteins; therefore, testing for the allergenicity of novel recombinant proteins forms part of all safety assessments.

(2) Initial GM crops included antibiotic resistance marker genes used to identify successful incorporations by target DNA. This practice is being phased out.

- Changes in levels of agro chemical inputs required, e.g. plants that can fix nitrogen
- Industrial uses (especially in micro organisms)
- Plants that detect landmines
- Coloured cotton plants
- Bio fuels – e.g. rapeseed and corn are used as feed stock for bio-diesel
- Phytoremediation - biological remediation of environmental problems using plants

3.1.4 *Other Objections – Ethical, Personal, Cultural or Religious Objections*

There is a range of other objections to biotechnology which are not covered here in detail but include:

- ***Cultural or Religious Concerns***: Food has cultural or religious significance to many groups of people. (1) To some religious groups, interference with what they see as the sanctity of life, (2) or "playing God", is not acceptable. Major religions have not rejected GM technologies out of hand. The scope to use these techniques for the advancement of humanitarian causes is recognized, but the bio-ethics of what is acceptable is still a matter for heated debate.
- ***Personal and ethical concerns***: Certain consumers object to food production methods or company policies. For example, some would choose to eat food that has been subject to specific production methods, e.g. organic, halal, vegetarian, cruelty free, bovine - growth hormone free, environmentally sound, etc. In the past this has led to the boycotting of foods and food companies (e.g. over the sale of powdered milk in Africa, or tuna capture methods that are not dolphin friendly). Much of the initial EU debate was fuelled by consumer interest groups demanding the 'right-to-know' and clear mandatory labelling that would facilitate informed choice.

3.2 *LABELLING FOR FOOD*

Why label food?

"Labelling", as defined in the Food and Drugs (Composition and Labelling) Regulations, includes any words, particulars, trade mark, brand name, pictorial matter or symbol relating to the food and appearing on the packaging of the food or on any document, notice, label, ring or collar

(1) Halal and kosher foods are obvious examples.

(2) The non-renewable status of GM 'terminator' seeds did not sit well with Hindu farmers, who believe in reincarnation of all living beings.

accompanying the food; (L.N. 222 of 1985). Typically, manufacturers or distributors design labels to provide the consumer with information about a food product and are intended to serve 3 main objectives:

1) to ensure adequate and accurate information relative to health, safety and economic concerns;

2) to protect consumers and industry from fraudulent and deceptive packaging and advertising practices

3) to promote fair competition and product marketability (Einsiedel, 2000)

Hong Kong Food labelling requirements for pre-packaged food require the following information to be clearly printed on the labels:

- Name of food
- List of ingredients
- Indication of "use by" or "best before" date
- Statement of special conditions for storage or instruction for use
- Name and address of manufacturer or packer
- Count, weight and volume of Food (metric units)

These labelling requirements are specified in detail as part of the *Food and Drugs (Composition and labelling) Regulations* made under section 55 of the *Public Health and Municipal Services Ordinance* (Cap. 132). Essentially, the regulations require that food labels are comprehensible, not misleading or deceptive and conform to the relevant requirements regarding composition of the food product.

Currently there are no regulations covering labelling of GM food. But the general provisions regarding the truthfulness of food labels apply to all labels and all the information provided in the labels, including any information about the GM content of the food item concerned.

3.3 CURRENT STATUS OF GM FOOD AND LABELLING IN HONG KONG

3.3.1 *Current status of GM food in Hong Kong*

Although there are no regulations in Hong Kong covering the labelling of genetically modified food, some food producers have adopted labelling policies that are used in the EU and in Japan.

Tests to detect GM food in the market place in Hong Kong have been carried out by Greenpeace and the Consumer Council. Of 105 products tested by the

Consumer Council in 2000, GM residues were detected in 21 samples of food products.

3.3.2 *Products likely to contain GM content*

GM foods found in the global marketplace largely originate in the first instance from crops grown in three countries (US, Argentina and Canada) and are dominated by products derived from soya and maize with lesser amounts derived from canola and cotton seed. Together the combined acreage of these three countries accounts for 98% of the global GM crop area, in total some 45 million hectares. The rest of the world grows mostly GM cotton crops and together total only 2% of the world GM area. China accounted for 1% of the area cultivated in 2000, whilst a further 9 countries grew the remaining 1%.

Table 3.1 provides a breakdown of the area harvested for GM crops in 2000.

Table 3.1 ***Genetically Modified Crops in 2000***

Country	Million Hectares	Percentage of Global
Argentina	10	22.6%
Australia	0.2	0.5%
Canada	3	6.8%
China	0.5	1.1%
France	<0.1	<1
Mexico	<0.1	<1
Spain	<0.1	<1
USA	30.3	68.6%

Sources: James, C (1997-2000) "Global Review of Transgenic Crops", ISAAA Briefs, 2000

Currently the two most widely adopted GM crops are soya and maize. Both of these crops are widely used in the food industry, both as wholefood agricultural products (e.g sweetcorn and green soya beans), but more extensively as processed derivatives such as flour, starch, oil, emulsifiers and sweeteners.

Tests in other countries such as those undertaken by the Food Safety Authority in Ireland on soya products (1), found that in the initial screening 18 of 37 samples screened for positive GM ingredients. Of the 18 positive samples, further qualitative traits identified that 15 of these samples contained genes from the herbicide tolerant soya variety Roundup Ready (a Monsanto variety). The survey of soy products followed a survey undertaken in May 2001 investigating the GM-status of corn and maize products.

3.3.3 *Types of GM trait in the global market place*

The largest proportion (95%) of all GM crops presently grown around the world have been modified for two traits, namely herbicide tolerance (HT) and insect resistance (IR). GM crops grown in the various countries are subject to approval by the appropriate regulatory authority. Lists of crops that have

(1) Survey of Foodstuffs for the Presence of Genetically Modified (GM) Soy. Food Safety Authority of Ireland, January 2002

met with approval can be found in the *Annex B*. Food products in Hong Kong with GM content are likely to be those ingredients are likely to be derived from HT soya, HT canola, HT &/ or IR corn and HT &/ or IR cotton.

Figure 3.1 ***Trait modifications in food crops available on the global market***

Herbicide Tolerant. Plants can be genetically engineered to be tolerant to a selected herbicide (usually glyphosate). This enables weeds to be controlled by a single application of a broad-spectrum herbicide as all other plants & weeds that are not GM modified will be eliminated. Advantages to the farmer are late application of the herbicide thus producing fewer demands on farm management, reduced applications and reductions in associated labour and fuel costs.

Insect Resistant. Insertion of insect-resistance genes from, for example *Bacilius thuringiensis* (*Bt*) provides the plant with an inbuilt pesticide thus reducing the amount of chemicals needed to control natural pests such as the Boll worm (a pest in cotton crops). Further, due to the reduced insect damage, undamaged grains have a reduced susceptibility to mycotoxins and therefore are more stable in storage.

Stacked Traits. This is a term used where a combination of the above traits or resistances are engineered into a single plant variety (e.g. Bt and herbicide tolerant cotton).

Quality and Other traits. At present few GM crops with other traits are being grown commercially. Crops grown with improved nutritional qualities (e.g., 'golden rice' a Vitamin-A enhanced rice strain) as well as other properties are currently in development. It is likely that these types of crops will undergo additional scrutiny before they are approved for food use.

3.3.4 Soya

Soya is imported into Hong Kong either as a raw material or as a component of a processed food product. Agricultural products consumed directly include green soya beans and soya bean sprouts. Soya beans are processed locally into a variety of soya products including soya milk, tofu and soya sauce. Soya products derived from soya flour and soya oil are found in a wide range of processed products including bakery goods, processed meat products, salad sauces and chocolate products. The Food Standards Authority Ireland (FSAI) estimated that two-thirds of all manufactured food products contain derivatives or ingredients from soya. Lecithin derived from soya is widely used as an emulsifier and a bulking agent.

Globally, soya is the dominant GM crop accounting for 58% of the transgenic area under cultivation in 2000.

- Global plantings of soya amounted to 72 million hectares (ha) in 2000. 36% of this global area, some 25.8 million ha was planted to GM varieties, namely herbicide tolerant varieties.
- The majority of GM soya was planted in the US.
- 54% of all of US soya is transgenic.

3.3.5 *Maize/Corn*

GM maize enters Hong Kong as either processed food or as raw materials. Of the 30,000 tonnes of maize that is imported into Hong Kong, nearly 40% originates from Australia (who do not yet grow commercial GM maize varieties), 15% from China (likewise do not yet grow commercial maize).

- In 2000, some 10.3 million hectares, (7% of all corn plantings) were planted to transgenic corn varieties globally.
- Again the US accounted for the bulk of GM maize (78%).
- 25% of all US maize is estimated to be GM.
- 20% of Argentinean maize is estimated to be GM.
- 20% of the maize imported into Hong Kong originates from the US and Canada.

Production of maize globally is in excess of 560 million tonnes. Much of this production goes into animal feed with the remaining entering the human food chain. There are many different types of maize grown for the food chain, sweetcorn varieties are grown for the corn-on-the-cob, frozen and canned vegetable market; whilst soft (dent) maize grown mainly in Europe and hard (flint) maize grown in South America are used in the food processing industry. Typical corn products produced from soft maize include snack food, cooking oil, margarine and salad dressings, whilst products derived from hard maize include bakery products and cereal products.

Maize entering the food processing chain generally undergoes either dry milling to produce corn flakes, corn grits and cornmeal for use in the cereals, brewing, feed and snack food industries. 15% of maize corn is used by corn refiners and converted through a wet milling process into cornstarch, corn sweeteners, corn oil, and many other processed ingredients. Corn-derived ingredients for food applications include corn oils, starch, maltodextrins, and three major classes of sweeteners: corn syrups, dextrose, high fructose corn syrups (HFCSs) and crystalline fructose. These ingredients are used in a large number of processed food applications, including beverage, baking, confectionery, dairy, jams and jellies and condiments. Other corn derived products such as gluten meal, gluten feed, corn germ meal and condensed corn extractives are used extensively in animal and poultry feed production.

In a 1999 survey of 30,000 products in US grocery stores, 13 percent were found to contain refined corn ingredients from the wet milling process.

3.3.6 *Soya and Corn derivatives found in processed foods*

Estimates made by US trade associations suggest that up to 70% [1] of processed food (in the US) may contain corn or soya-derived ingredients. For example a typical cake mix may contain hydrogenated soya bean oil, modified corn starch, mono and di-glyercides, dextrose and soya lecithin. Soya and corn-derived ingredients may act as carriers for secondary ingredients such as flavourings, colourings or vitamins. However, it cannot be ascertained as to how many percent of the processed food (in the US) that certain corn or soya-derived ingredients have used GM corn or soya.

3.3.7 *Canola/ Oilseed Rape*

Oilseed rape or canola is an oilseed grown for both industrial and food uses. End products of the refined and crushed rapeseed are the production of vegetable oil. The meal is used for animal feed.

- Globally only 7% of the canola crop is transgenic, with most of this found in the US and Canada, where 35% of the combined crop is estimated to be transgenic.
- 75% of Canadian production is estimated to be from GM varieties.
- Hong Kong imports crude and refined oil from Canada, however the majority of the crude rape oil is then re-exported, with only a residual amount remaining in Hong Kong.

Currently refined oils and downstream products, and products from animals fed on GM canola are not required to be labelled GM in the EU, Japan, Australia and New Zealand and a result canola as a GM ingredient is not considered to be as difficult as soya or corn in meeting with labelling regulations as there are no detectable traces of novel DNA. In a few instances however canola pollen has been detected in honey.

3.3.8 *Cotton seed*

Cottonseed oil, extracted from cottonseeds is used in animal feedstuff (40% of crop) whilst the remainder is used in processed goods and as a food ingredient. Within the US the greatest proportion of oil is used in salad and cooking oil (73%) baking and frying (21%) and margarines (2%). Hydrogenated cottonseed oil is used to make stearine, which has applications in chewing gum, emulsifiers. Stearine is also used as an encapsulating agent and as a stabilizer in peanut butter.

- Refined cottonseed oil imports from the US totalled 7,400 tonnes. The majority of the oil is re-exported and only 7% remains within Hong Kong.

(1) IFT Expert Report on Biotechnology and Foods, Food Technology, vol.54, no.9, September 2000

- 72% of the US cotton crop is estimated to be from GM varieties.

3.3.9 *Potatoes*

The global area planted to GM potatoes was less that 1% of the 2000 harvest. Again GM potatoes originate in North America. The majority of potatoes imported into Hong Kong originate from the US (47%) whilst Australia (32%) and China (9%) provide the other main contributions. The latter two countries do not yet grow GM potatoes commercially. Therefore at the moment the amount of GM potatoes entering Hong Kong is likely to be very small.

Potato products imported into Hong Kong include:

- potatoes, fresh or chilled;
- potatoes, cut or sliced but not further prepared;
- potato starch;
- flour and meal of potatoes;
- flakes, granules and pellets of potatoes;
- prepared or preserved potatoes, other than by vinegar or acetic acid, frozen;
- prepared or preserved potatoes, other than by vinegar or acetic acid, not frozen; and
- those potatoes products included in the snack food categories.

Table 3.2 ***Other GM products***

Biotech products already approved	Papaya Peppers Peanuts Cantaloupe Potatoes Sugar Beets Squash Raddichio Sunflowers Tomatoes
Other GM Products	
Milk Production	A biotechnology - produced version of chymosin (an enzyme derived from calf rennet used to coagulate milk). It is used in 60% of all hard cheese products made today.
Milk Production	Recombinant Bovine Somatotrophin (rBST) - used to induce extra milk production in 30% of US dairy cows.
Food Processing aids and minor ingredients	GM yeasts are used in the brewing and baking industries. Additionally other GM microorganisms are in use in other industrial and food industries.

4 CONSULTATION AND BUSINESS STAKEHOLDER CONCERNS

4.1 INTRODUCTION

While the role of this Study is not to undertake a formal consultation on the proposed labelling options, the Consultant has contacted and sought the views of a large number of business stakeholders and other interested parties to ensure that the likely financial impacts on their businesses and their concerns are understood.

This has been done through a variety of means, including meetings, interviews (face-to-face and telephone) and written communications (fax, email and letters). The contacts made, the views received and the key issues raised are summarised below. It should be stressed that we have not attempted to repeat all the many and diverse views expressed but have summarised the key issues and concerns raised. Further, it should be noted that this section does not present views received from other stakeholders in Hong Kong such as the general public and other concerned parties, but only includes those views received from businesses consulted during the course of the study. Lastly, the subject of GM Food remains a sensitive subject for agro-food processors and therefore it is important to note the confidential nature of some of the replies.

Table 4.1 Summary of Stakeholder Consultations

	Number Contacted	No of Responses
Importers, Wholesalers & Distributors	15	7
Manufacturers	20	13
Retailers	8	3
International Retailers	4	2
Consumer and Political Groups	2	2
Consulates and Other Departments	12	8
Trade Associations	6	4
Laboratories	6	5
Government Departments	3	3
Others Contacted	3	3
TOTAL	**79**	**50**

The above table illustrates the extent of the consultation undertaken during the course of the study. Different stakeholders were identified to try and provide representative views from different parts of the local food trade. However, it should be noted that the views presented here are unlikely to fully representative of the entire local food sector due to the limited sample size and lack of response of certain sectors. Further descriptive accounts of selected stakeholder consultations can be found in *Annex E*.

4.2 KEY ISSUES RAISED BY STAKEHOLDERS

Amongst others, ERM has consulted with the representatives from the following business groups:

- Importers and wholesalers
- Manufacturers
- Retailers
- Consulates and other foreign Government representatives
- Trade associations
- Commercial laboratories
- Interest groups

The results of these consultations are described in more detail below.

4.2.1 *Importers and Wholesalers*

ERM had face-to-face interviews with importers and wholesalers. Key issues raised by this group are summarised in *Table 4.2* below.

Table 4.2 ***Key Issues Raised by Importers and Wholesalers***

	Key Issues Raised
1.	• Due diligence: A key concern raised was where does the responsibility for labelling lie? Who would be responsible in the event of a false claim - importers or retailers?
2.	• Importers and wholesalers act as middlemen, and as such expect any costs resulting from a labelling requirement to be passed on to the retailers.
3.	• Many of their clients have already demanded non-GM soya beans. Non-GM forms part of the quality criteria of their contracts with clients.
4.	• They consider relabelling costs to be one off costs that would be relatively small compared to overall sales.
5.	• Although they are generally in favour of GM labelling, it was felt that levels of awareness of many consumers and even those in the food trade was not that high.
6	• Importers sourcing products from Japan, Korea and Australia reported no increases in the wholesale price that was attributable to the introduction of GM regulations in these countries.

4.2.2 *Manufacturers*

ERM met with various members of the manufacturing industry, these included local manufacturers and multi-nationals who operate manufacturing facilities both here in Hong Kong and also elsewhere in Asia and then export those products to Hong Kong. Key issues raised by this group are summarised in *Table 4.3* below.

Table 4.3 ***Key Issues Raised by Manufacturers***

	Key Issues Raised
1.	• Many companies do not wish to publish a public policy on GM. They feel that with the regulatory environment and the marketplace for non-GM ingredients evolving the future is uncertain and therefore they do not wish to publicly make claims that they would be held to in unforeseen circumstances. • Some felt that labelling only packaged foods discriminated towards manufacturers who produced at high quality standards, rather than those who sold unpackaged products through the wet markets.
2.	• Manufacturers will meet the regulations of the market country. • Manufacturers will meet the demands of the consumers even if this involves a demand for non-GM; major manufacturers are reluctant to lose market share and therefore will reformulate. • Overseas experience with Japanese and Korean regimes would indicate that consumers have not rejected GMO presence where not labelled (i.e. GMO containing products that are exempted from labelling in Japan and Korea have not been impacted by consumer purchasing changes).
3	Regarding reformulation and IP • Product reformulation in Australia has resulted in extensive Research and Development (R&D) costs to ensure acceptability of all aspects of the reformulated product, such as shelf life, texture, flavour and colour. • Extensive time, effort and documentation are required to make changes and maintain strict compliance requirements in Australia. This involves audit trails and/or DNA analysis to ensure ongoing compliance. • Larger manufacturers can integrate IP testing into their QM systems. • The sources available for some IP ingredients can be limited and expensive. • It is considered that most local suppliers do not know what IP systems entail in practice. • Definitions of IP have not yet been agreed on. • Minor ingredients are imported from many countries, and it is these ingredients that contribute to the difficulties in maintaining a non-GM labelling requirement. For example, annatto colouring is generally soya based and GM enzymes are often used to clarify sugar during production. • Manufacturers in China have limited knowledge as to whether their ingredients use GM or not, and have limited means of testing. • Many suppliers who claim to offer non-GM products have no means of verifying the claims, and upon testing the claims may turn out to be false. • Cost of reformulation will vary between product categories. Simple replacement will be cheaper than recipe redesign and associated testing.
4	Regarding the impact on retailers and retail prices • Where false positives occur (false positives are the incorrect identification of GM content. Due to the sensitivity and complexity of testing techniques false positives are relatively common in testing for the GM content), products may wait in the dock and potentially result in distribution delays. In Hong Kong, retail outlets impose penalties of up to HK$ 10,000 per Stock Keeping Unit (SKU) per day for empty shelf space. Supermarkets and the high shelf slotting fees that they charge heavily affect prices of food products. • Retail prices are rarely determined by raw ingredient costs (cost plus approach) - they are determined by pricing strategies and the marketplace.

	Key Issues Raised
5	Views on options • Support for Option II was expressed as this presented the least burden on the manufacturing sector. However, there are concerns as to if this product list would be reviewed at specified intervals. Support for a EU type of scheme was also expressed, but it was felt essential that this scheme should be fairly and appropriately enforced. • Some manufacturers thought that since 5% is an established trigger point in the food industry, it would be accepted as a GM threshold. For example, "above 5%" of fruit in a product allows it to be labelled as "containing fruit". • Other manufacturers were of the opinion that 5% was meaningless as it did not in practice give the consumer more choice and questioned what the threshold might mean to the consumer. • More restrictive options would effectively put an end to use of GM technologies in the food industry. • Some companies found the wording of the options to be unclear. They wanted clarifications on what the exemptions would be (especially under Options II and III).
6	• There were strong views on what should be allowed under the terms GM-free - the general opinion was that this was a term that was open to misuse and misinterpretation and therefore should not be allowed. • They did not consider that the voluntary option was effective as it left room for unfair practice in labelling claims. They claimed that a voluntary scheme has not been shown to be effective anywhere in the world.
7	On enforcement • Manufactures wondered what legal muscle would be used to verify claims made by manufacturers, and what would be the government's enforcement strategy. • They felt that a paper trail might be possible, but felt that regulations requiring testing would be expensive and prohibitive.
8	Regarding a role for government • Whilst the Government has outwardly expressed a neutral role stating that GM-products pose no risk to human health, by introducing mandatory labelling the Administration would inadvertently imply that there may be risks and therefore the consumer needs to know about GM content. • They would like to see strict codes of conduct for certification of testing laboratories. • It was felt that the Government's position on presenting a balanced view on labelling and providing education on GM food had not been heard widely. • Some companies felt that the HK SAR Government did not do that much to promote Hong Kong's manufacturing base. They would like to see more industry targeted initiatives and wider consumer information campaigns.
9	Due diligence • The manufacturers wanted to know where the due diligence for labelling would lie. In the event of a false claim being made who would be held responsible (the retailer, importer or manufacturer)? What would happen in the case of parallel imports?

4.2.3 *Retailers and Retail Associations*

ERM held ongoing discussions with the retail trade and the Hong Kong Retail Management Association. Key issues raised by this group are summarised in *Table* 4.4 below.

Table 4.4 ***Key Issues Raised by the Retail Trade***

	Key Issues Raised
1.	• Retailers stated that the margins are very thin and packing or repacking a product would be costly.
2.	• The main retail outlets in Hong Kong are served by many different suppliers (over 1000). • Even products from the EU and other countries where labelling is enforced cannot be guaranteed to be free of GM ingredients.
3.	• IP ingredients can be expensive - 30-50% price premium.
4	• Retailers importing from Japan, Korea and Australia stated that they had not seen any price change since new labelling regimes were introduced in those countries.

4.2.4 *Consulates and other foreign Government Representatives*

The Consultant met with representatives of foreign governments. These included meeting with agricultural and food trade representatives and biotechnology policy advisors.

Table 4.5 ***Key Issues Raised by Consultees***

	Key Issues Raised
1.	• All food products potentially may contain 'biotech soya or corn derivatives' regardless of where they are manufactured as 'biotech' soya and corn products are sold to food manufacturing plants across the world, including those in Asia.
2.	• It cannot be assumed that export products meet the same standards as domestic products.
3.	• They did not consider that product price on the shelf would differ by much and that the impact on the market was not easily testable as companies would tend to reformulate rather than carry a 'GM label'.
4.	• Any labelling legislation enacted should be robust in terms of meeting WTO commitments. • It is considered that harmonised Codex testing procedures and standards were a long way off. • It is foreseen that there may be disputes arising from the validity of testing procedures.
5.	• With regard to testing these costs escalate at the 1% level. • Technology only exists to test for known genetic markers and it is easier to test for known hazards than unknown hazards. • Future testing could involve wheat, papaya and palm oil.
6	• Other consulates presented us with additional options and suggested that consumer safety should be placed before costs. • It was suggested that by offering the consumer stricter labelling options this would help work within a framework towards consumer acceptance.

4.2.5 *Laboratories*

ERM visited commercial analytical testing laboratories situated within Hong Kong and consulted with the Government Laboratory. ERM also contacted international laboratories with experience in GM regulated countries. Key issues raised by this group are summarised in *Table 4.6* below.

Table 4.6 ***Key Issues Raised by Consultees***

	Key Issues Raised
1	• The role of FEHD was seen as providing clearly defined regulations, testing procedures, approved crop lists and clearly outlined enforcement strategies. • Consultees favoured a clear and simple policy framework, which when in place would allow the industry to get on with implementation. The consultees stated that some of their clients with manufacturing plants in other Asian countries (e.g. Thailand and China) would like to see a timely decision by Hong Kong to allow them to decide on their regional strategy.
2.	• Consultees saw the EU and Australian approach of no GM with an allowable adventitious contamination level to be a clearer approach than a threshold level, which permits GM content up to a certain level. They thought that with a 5% threshold level companies may work towards this level rather than towards omitting GM products. As such, they foresee there being difficulties in enforcing this (5%) level as well as there being potential for disputes between suppliers. • They foresee difficulties with Option II as occasionally it would be difficult to determine from which ingredient the GM content originated, especially since companies are reluctant to give compositional analysis or disclose the sources for all their ingredients. • They suspected that Option II would cover very few ingredients - perhaps only soya milk, bean curd and cornflakes - and as such would do little to address the demands of the consumer.
3.	• Whilst initial IP costs may be high, ongoing running costs can be integrated in Good Management Practices (GMP) or Quality Assurances (QA). However, it is likely that smaller food business in HK do not currently have these systems in place. • It was suggested that controlling for GM in an manufacturing environment may be given low priority in those smaller establishments, where primary considerations of GMP and consistent food hygiene levels were where initial priorities lay. • It was felt that the exemptions should not be made according to product ingredients (e.g. starch) as this was likely to be complicated and would involve extensive and detailed definitions. Instead they suggested that exemptions should be based on detectable levels of novel DNA. • It was suggested that it still might be 5 years before IP minor ingredients are widely available. • Some difficulties arise with the supply of reference material for the tests.

4.2.6 *Interest Groups*

ERM contacted representatives of environmental and consumer interest groups and some of the key issues raised are summarised in the table below.

Table 4.7 ***Key Issues Raised by Consultees***

	Key Issues Raised
1.	• The 5% threshold is not acceptable to the Non-Governmental Organisation (NGO) community.
2.	• Japanese type regimes do not give consumers any more choice, as there are so many loopholes and exemptions. It was felt that the Japanese government responded to considerable lobbying pressure from the US in adopting these regulations.
3.	• Consultees support a system that is based on detectable limits of novel DNA for exemptions rather than ingredient types (e.g. starches).
4.	• It was felt that by adopting a phased approach Hong Kong would have to visit the same ground twice.
5.	• Enforcement: it was felt that a 1% or a 5% level would in practice require identical enforcement strategies.
6.	• It was felt that in the absence of agreements on Codex agreements, industry would adopt a set of standards that meet global export markets, and these would likely centre on the EU regulations. As a consequence, Codex will likely be obligated to follow these de facto standards. • It was suggested that most European food manufacturers are operating at a 0.1% threshold, and that this is achievable.
7.	• Price premiums: grains markets have now fallen by 10%, and initial claims of high non-GM prices were overstated. • Further, many of the non-GM ingredients are used at less than 1% of product weight and contribute a similar amount to product cost.
8	• Results of a survey carried out by an interest group, found that 98% of HK people interviewed strongly supported labelling. • In a survey of local manufacturers, 73% of respondents suggested that there would be no or minimal impact to production cost if labelling is implemented. • 91% of local manufacturers suggested that there would be no impact on food price.

5 IMPACT ANALYSIS

5.1 APPROACH TO ANALYSIS, DATA AVAILABILITY AND COST ASSUMPTIONS

5.1.1 Introduction

Predicting the Future and Data Availability

This RIA seeks to predict the future impacts of various regulatory options on businesses and the economy as a whole. The approach adopted in this study is to:

- as far as possible base predictions on accepted facts, previous studies, or actual experiences of the trade in meeting similar requirements either in Hong Kong or overseas.
- where quantitative information does not exist, the study relies on expert opinion and/or information from the relevant stakeholders in developing appropriate assumptions.
- where assumptions have been made the impacts of altering these assumptions are examined through sensitivity analysis.

Therefore it should be stressed that the predictions that follow are not intended to be exact predictions of the future, but rather to illustrate the range and extent of possible future impacts of the proposed measures identified, and to inform decision makers

Determining the number of products that may be affected by the various thresholds and options.

In order to establish the total number of products and product units that might be impacted by GM labelling requirements (under the various options), ERM undertook a detailed survey of food products and food ingredients in Hong Kong. We verified our findings from trade data and considered market share data (by type of product, brand, retail outlet, country of origin and packaging status) to establish proportions of products within each product category that might potentially be impacted under the various options. The product categories were based on those groups (and sub groups) used by the Census and Statistics Department (CSD) in their Household Expenditure Survey.

Thus the number of product impacted was identified by survey, discussions with the trade and with reference to the known GM-status of products on the market (identified from public statements of food manufacturers and/or product labels). Information from the trade on whether products have already been reformulated (due to consumer concerns) has been taken into account in the analysis.

In differentiating between the number of products impacted at different thresholds (e.g. 1% and 5%), reference has been made to analysis of data obtained from a local laboratory. This analysis revealed that 66% of products impacted at the 1% threshold would also be impacted at the 5% threshold. A similar breakdown has thus been assumed in the analysis.

Re-labelling and Repackaging Costs

The costs associated with changing the packaging and labelling will fall on the trade. The redesign costs of labels/artwork are considered to be one-off costs. Given sufficient lead time and warning these can be worked into any periodic/routine changes that might occur or at the very least allow existing stocks of packaging to be finished. However, if substitution to non-GM sources or ingredients takes place then there would be no need to make GM declarations and therefore no change to labelling or packaging would be required.

Evidence from other countries suggests that there is reluctance by food companies to label products with any sort of GM label. To the best of the Consultant's knowledge there have been very few cases where manufacturers have labelled for GM content if required to by regulation [1]. For the purpose of the main analysis we are assuming that no products will be labelled as containing GM ingredients. The cost implications if companies do choose to label is examined as part of the sensitivity analysis (e.g. in response to changing consumer perceptions regarding the acceptability of GM foods – see *Section 5.4.2*) and some example costs of relabelling are presented in *Box 5.1*.

Box 5.1 ***Costs of Relabelling Products***

- Importers estimate the cost of printing and sticking additional labels on individual packaged units range from 20 cents to 50 cents per pack.
- Costs associated with changing the print cartridges and redesign costs for 'wrapper' type packaging depends upon the number of colours. To change a single colour cartridge costs HK$2,000 per cartridge. If a typical package has 4 cartridges this would costs 4 x $2,000 = HK$8,000.
- In the case of Tetra Pak packaging the minimum order quantity is 1 million units and therefore the turnover of the product will determine whether packaging will be discarded in the timeframe for the changeover period. To add extra information on a Tetra Pak package for example an extra ingredient line entails a redesign cost of HK$3000-4000 per product. To add a 'starburst' with artwork redesign may cost 10 times as much as a line change.

Source: Findings from consultations

Further, it is noted that some companies may need to undertake a relabelling exercise if the list of ingredients is altered in response to the regulation. For example, a manufacturer may decide that rather than switching from GM corn starch to non-GM corn starch, which would not trigger product relabelling, the corn starch would be replaced with potato starch, which would change the

[1] For example, information from Greenpeace suggests that only a couple of products have been labelled as containing GM in Europe (one biscuit product in Holland and one bacon-bits product in the UK). Furthermore, conversations with the Food Standards Australia and New Zealand suggested that to the best of their knowledge none of the products on Australian supermarket shelves are labelled as containing GM.

ingredients list and hence the product label. This situation has been included into reformulation costs (see below).

5.1.2 *Costs of Reformulation of Products*

When manufacturers do not wish their product to carry a 'GM' label, reformulating a product is one strategy used to avoid the need for labelling for GM. The Consultant has defined reformulation costs as encompassing both the actual redesign of the product (and label) and/or the initial sourcing of alternative ingredients.

Where substitutes are an option, such as in the case of some sugars derived from other food crops such as from sugar cane or sugar beet or starches derived from potato or tapioca, then substitution away from corn and soya products may be easily achievable. However, some soya and corn derivatives provide functional, textural and taste characteristics, which are not easily substituted as this may result in changes in taste, colour or other properties. In these cases the food manufacturer will need to make a decision on whether to purchase the ingredient from a non-GM source (with associated IP premia - perhaps from European countries or specialised companies in the US), work within the threshold and exemptions or, in the case where suitable substitutes are not easily available and food manufacturers still do wish to not label GM content, withdraw the products.

Box 5.2 *Evidence from Overseas*

France - A 1999 survey of 94 companies by the French Ministry for Economics, Finance and Industry revealed that over 50% of these enterprises had undergone reformulation of their products to avoid labelling. Most of these companies had 'attestations by their suppliers, 14 enterprises were able to present traceability documents and 19 had analytical certificates'.
Australia - Discussions with the Food Standards Australia and New Zealand suggests that, to date, no products have been labelled as containing GM, indicating that most have been reformulated.
UK - Four supermarkets provided information to Greenpeace (Marks and Spencer, Sainsbury's, Safeway's and CWS Retail) that suggests that the costs of reformulations, and where necessary moving to certified non-GM ingredients, have been absorbed into the costs of products with no overall price increase. Initial price premia associated with soya/maize raw materials declined as the supply chain for non-GM materials became more widely established.

Hong Kong based food manufacturers and retailers who have already undergone reformulation note that it has not changed their retail price - in reality their retail prices are a response to market pressures and have, in some cases, been decreasing - additional ingredient and reformulation costs have been internalised. Thus while such costs might be imposed on manufacturers they may not be passed on to consumers.

In this study reformulation costs are being treated as a one-off cost and will be applied to the manufacturer at the product level. Based on information received from the trade to date we are utilising a reformulation cost of HK$44,000 per product requiring reformulation (this is based on information provided by a multinational food conglomerate). This cost of reformulation includes research and development (R&D) associated with redesigning the

product recipe, resourcing of suppliers, production run trials and testing the shelf life [1] of the food product for changes in rancidity and other characteristics. The estimate is an average per product reformulation cost that was based on total cost for reformulation of approximately 90 products. While, for reasons of confidentiality, it is not possible to determine exactly which products were reformulated, we were assured that this figure represented a broad cross section of products sold across the Asia Pacific region. As such it is reasonable to assume that the average is representative of the whole market given that the food conglomerate is known to produce products in all of the key food categories. The food categories covered include beverages, cheese, dressings, spreads, chocolates, snacks (chips, biscuits, crackers, cookies), sauces, ready-made meals, pastas, ready-made desert mixes, cereals, frozen pizzas, luncheon meat, and hot dogs.

This reformulation cost assumes that manufacturers examine all potential sources of GM content and then redesign the product accordingly. This assumption has been made based on the evidence that the majority of manufacturers, once they have opted to remove or monitor GM ingredients have generally chosen to 'GM cleanse' the entire production system as the most practical approach.

This figure of HK$44,000 has been used in the absence of Hong Kong specific data as none was identified during consultations with the trade. The food manufacturing trade in Hong Kong considered that to estimate a specific reformulation cost separately from ongoing product development and manufacturing costs was a difficult undertaking and one that many had either not yet considered or could not isolate from other costs. Further those members of local trade that did have an opinion on reformulation costs considered that the costs were dependent upon a number of factors including the number of ingredients (i.e. single or multiple) involved and the nature of the ingredients (main ingredients, sub components, flavours, carriers) involved. Members of the local food manufacturing trade that expressed an opinion on the HK$44,000 reformulation costs did not consider it an unreasonable figure and in one case indicated that it would likely be lower [2].

In addition, it should be noted that in most cases in Hong Kong, the process of altering the product to avoid labelling is unlikely to be as costly as that adopted by the multinational food conglomerate. This is because:

- In many cases it will be possible to either swap or substitute the ingredient for a non-GM ingredient or GM-free equivalent without the need for a comprehensive R&D programme;

[1] R & D testing lasts the duration of the shelf life which in some cases is at least 6 months. Whilst not all manufacturers will undertake such comprehensive testing, this reformulation approach is consistent with quality producers of packaged goods. As such it may represent the high end of reformulation costs

[2] Food manufacturers contacted included: multinationals with local manufacturing operations; multinationals with regional manufacturing operations; bakeries; soft drink manufacturers; noodle manufacturers; soya sauce manufacturers; and, corn starch and oil manufacturers.

- Given the proposed Hong Kong exemptions local manufacturers would not need to complete 'GM-cleanse' their products. The multinational choose to "GM cleanse" the system and therefore examined all the ingredient and sub components of the ingredients (e.g. the carriers used in flavourings, dilutants, extenders etc.). This involved extensive contact with all the ingredient suppliers and ingredient manufacturers. It is likely that Hong Kong manufacturers will not necessarily choose to change some ingredients and food additives as they may be exempt or be present if very small quantities.

- This reformulation cost was for highly processed foods with multiple ingredients. If a product has only single ingredients that needs changing then the cost would be less.

- The reformulation programme included an extensive R&D programme that lasted 18 months. This included a 6-month testing for shelf life, testing for flavour and textural changes. A local manufacturer of fresh products (e.g. bakery products) may not undergo such a rigorous R&D programme.

Thus, it is predicted that the $44,000 reformulation costs adopted in the analysis is likely to be slightly on the high side for most products.

As discussed previously, information from the trade on whether products have already been reformulated has been taken into account in the analysis. That is, if the product has already been reformulated the cost of doing so will not be included. In addition, if a product is known to be manufactured outside Hong Kong by an overseas manufacturer (e.g. one that is not domiciled in Hong Kong) who also sells the "same" product in a jurisdiction with GM labelling requirements then no reformulation cost has been attributed to the options under consideration. This is because any additional reformulation costs, if they arise, will be borne by the overseas manufacturer and will hence have no direct economic consequence to Hong Kong [1].

5.1.3 *Ongoing Costs*

We have defined ongoing costs as those required to ensure the non-GM-status of products. These costs will include those associated with IP, which comprised segregation and document control, as discussed below, and additional premiums for non-GM foods.

Food companies are likely to adapt their approach to the regulatory environment. Therefore, the ongoing costs for businesses within Hong Kong will depend upon: the final option adopted; and the methods of verification

[1] While the costs of producing and delivering the product to Hong Kong might alter, the shelf price of the product is unlikely to as this is more a result of by market dynamics and the consumers willingness to pay. For example, over the last decade a number of "global products" (e.g. Wrigley's chewing gum, Nestlé's Kit Kat bars etc) sold in Hong Kong are now being produced in the region rather than in Europe or the US, as was previously the case. While the cost of production has changed, the end consumer has not seen any difference in prices. The additional costs or revenue accrues to the manufacturer/multi-national brand. This will impact the brand's own economy (where its shareholders reside) and manufacturing base, and will have no direct economic consequence to Hong Kong.

required by the authorities. The food industry is diverse, and in practice the approaches to comply with regulations, and associated costs will vary widely depending upon various company-specific factors including:

- the motivations driving the development of the system.
- the number of products lines and the (quality) position within the marketplace.
- the stage in and length of the supply chain.
- the complexity of operation.
- the physical make-up of the processing/manufacturing plant.
- verification requirements to meet regulations.
- the degree of assurance required by the various actors.
- the food producers company policy with respect to their own assessment of risks and integration in their own QM program.

GM products are visually indistinguishable from their non-GM counterparts, creating an asymmetry of information between the suppliers and purchasers. Verification of GM-status is integral to establishing the GM-status of products and complying with regulations. Several approaches to verifying GM/non-GM-status have been suggested. These are outlined in *Table 5.1*.

Table 5.1 ***Methods of verification, supervision and certification***

	Advantages	Disadvantages
Analytical testing at selected points in the market channel	Provides assurances that the sample selected for testing meets the standards of the buyer.	Limitations, costs and uncertainties of testing and sampling. Testing methodologies have not been universally accepted.
	Focuses on attributes of the product rather than the process by which it was produced and delivered.	Analytical testing of refined products where novel DNA is no longer detectable is not sufficient to guarantee the identity of raw materials or end products. Further, it will not satisfy requirements for GM-free type of definitions.
Accept producer assurances at the first handler and maintain identity through the channel	Provides paperwork guaranteeing the identity and origin of the product along the supply chain.	Reliability depends upon all the commitment of all parties involved and relies on those earlier up the supply chain meeting standards and avoiding cross contamination. In practice without prior contracts or arrangements with the producer, the reliability of producer validation and certifications may be questionable.
Verification of suppliers from seed to final processing through 3rd party supervision and certification	Minimises the risk of misinformation, questionable methods and incomplete knowledge on the part of the producer or distributor.	Costs associated with 3rd party certification likely to be significant.
	Independent certification audit by a 3rd party or a recognised body is already established for premium quality corn and soya beans (organic, pesticide - free & variety specific).	Guarantees the process but not necessarily the product.

Source: Contents of table adapted from IFT Expert Report on Biotechnology and Foods, IFT, 2000

Content Attribute Verification - Analytical Testing

The simplest form of verification is that of analytical testing. This minimal type of compliance approach is used to ensure that any raw materials used meet non-GM requirements. The reliability of this method requires the sampling to be representative and the testing methods to be accurate. If a final product tests positive then it is already too late to take action. This type of method is used early in the supply chain or for raw materials, and for greater certainty testing needs to be used in combination with other approaches.

The numbers of tests performed on behalf of food producers will depend upon:

- testing requirements (if any) to meet any regulations; and

- the food producers company policy (i.e. acceptance of supplier assurances etc) with respect to their own assessment of risks as it relates to brand protection.

Testing procedures will depend upon the 'processed status' of product (i.e. how close is the product to the original grain or it is a highly processed derivative). The degree of processing will influence the type, complexity and number of tests that would be needed to determine the GM-status of a food product. These factors are further impacted by the detection limits and whether quantitative or qualitative results are required. Much of the testing costs for any given individual product will depend upon:

- standards and protocols surrounding tests;
- threshold established and therefore sensitivity of tests required;
- the nature of permissible exemptions; and
- number of individual traits tested for.

Estimates for GM testing in Hong Kong are presented in the table below.

Table 5.2 ***Testing Costs Estimates***

Type of Test	Source	Cost per Test	Turn around Time
ELISA	IFT report	HK$ 78 per sample	5-20 minutes
	Selected HK labs	HK$40 - 700 per test	2-8 hours
	American Crop Protection Association	HK$581 -775	2-4 days (in the US)
Screening tests	Selected HK labs	HK$600- 1200	2-3 days
Qualitative Tests	Selected HK labs	HK$600 - 1200	7 days
Quantitative Tests	Selected HK labs	HK$ 2000 - 2200 HK$ 2200	7 days
PCR (Screening, Qualitative and Quantitative)	Alberta Canola Producers Association (Price in US)	HK$1550 - 4650	5-14 days (in the US)
	Strategic Diagnostics (Price in US)	HK$ 125 to 300 per test	Minimum 3 days

It should be noted that the threshold level (e.g. 1% or 5% in the options) does not impact the price of testing.

Process Method Verification

An approach to verifying the GM-status of products is that of a paper audit trail [1] where documentation accompanies all products throughout the supply chain. These sorts of systems require linkage between all the sectors of the supply chain. In the absence of international standards, trade associations

[1] This type of approach has also been termed traceability (the US prefer the term 'traceback') and has been used to enable product recall in case of food safety alerts. Disagreement as to precise definitions of traceability systems exists and guidance on the application and relevance of traceability to inspection and certification systems are currently under review by a Codex Working Group .

and industry have provided food manufacturers with 3rd party certification and independent audit schemes. Some of these audit systems offer non-GM certification to assure supply sources.

Aside from product testing and paper audit trail, measures to segregate GM and non-GM ingredients as they pass through the supply chain may be required. The costs associated with such segregation, relate to the cleaning of equipment and storage facilities, and the opportunity costs of the downtime when this occurs. In addition, costs are generated by production activity because more lines may need to be run and/or runs have to be shortened to allow both GM and non-GM products to be produced within existing capacity limits. It should be recognized, however, that segregation costs vary from none to considerable, depending on the context for compliance. For example, (for all of the options under consideration for this Study) segregation costs would not be incurred at processing facilities that choose to go entirely non-GM (but may occur further up the supply chain).

Identity Preservation

Taking these measures further is the concept of IP systems. These programmes aim to create a transparent communication and information system between all stages of the supply chain and thereby minimize the risk of cross contamination. IP systems usually combine the physical measures of analytical testing, segregation with organizational measures of staff training, documentation, commitment by all involved parties of the supply chain and 3rd party verification of raw materials supplied. Therefore through the combination of all these methods, IP systems are intended to verify the content and the process of the supply chain. Typically IP systems will involve a contract between the supplier and end user. Many European food manufacturers have already adopted IP systems (1) as part of risk management strategies.

Manufacturers with overseas experience have suggested that where provisions for compliance are made via endorsement of due diligence and verifiable documentation (i.e. paper trail), compliance is easier to achieve than under a system requiring full analytical testing and IP systems. Further, options that allow for more ingredients to be exempted would lower the total cost of achieving compliance (this is not to say of course that such an option meets other objectives).

In conclusion, the costs of all of these verification systems will vary widely depending upon the system adopted, the degree of assurance required and the timeframe for implementation.

(1) The UK Food and Drink Federation have produced a technical standard for the Supply of Identity Preserved Non-Genetically Modified Food Ingredients and Products. Requirements include clear documentation, strict segregation, audit trails, companies drawing up & implementing a policy statement, and thorough cleaning and inspection of equipment at every stage of the supply chain.

Integration of IP into a quality management system

Many food processors will already have in place QA systems to ensure the standard of the final product. These measures may include analytical methods, combined with organisational measures, such as training, audits and supporting record management systems. Some processors will already have audit trails and segregation systems in place. In cases, where HACCP [1] or QA programs are already established, full IP systems can then be integrated into unified systems and the extra testing costs would be incorporated into the current practices of the manufacturer. However, initiating an IP system from a lower starting point, i.e. where a QA system is not already in place, can be a considerable undertaking both in terms of changes to production processes as well as in terms of cost. This is likely to be the case for smaller businesses. Such an undertaking would involve specific design, training of staff, documentation, and verification of suppliers. Other costs of IP may stem from the opportunity costs associated with segregation of production lines. Ultimately, IP costs will be dependent upon the supply chain and the specifics of each food manufacturer.

Results from Consultations

Companies in Hong Kong had difficulty in identifying where the impacts of any future regulatory requirements may fall. Companies that had already chosen to use non-GM ingredients had varying approaches; some companies adopted fully integrated IP systems; some relied on supplier assurances; while others tested for GM-status of selected ingredients, some companies had not yet considered the GM issue.

A food manufacturer, Company P, that has chosen to become non-GM, has integrated its IP system (and associated set up costs) into its existing Quality Management (QM) system. The company has internalised any increased raw material costs and has not increased retail prices for its products. In the absence of regulations, company P adopted a 0.5% threshold level allowing for adventitious contamination. Company P believes that its approach is commensurate with its positioning in the market as offering quality products and assurance to customers. As the IP component have already been absorbed into the existing QM system, there will be no additional set up costs brought about through labelling regulations changes and ongoing compliance costs would be costs of maintaining the IP system (testing, 3rd party certification etc) and any premium for non-GM raw materials.

Company Q has recently switched suppliers of a corn ingredient to a new supplier in China. In doing so, contractual agreements were drawn up with the new supplier to supply non-GM ingredients and to provide accompanying certification. This switch has not affected the purchase price (in fact the price from the new Chinese supplier is lower). In addition, Company Q now has an arrangement with a laboratory to provide 3rd party certification and random checks of the incoming raw ingredient.

(1) Hazard Analysis and Critical Control Point is a process control system to ensure food safety.

Company R has spent the last 2 years converting to non-GM. This process has involved contacting all of their suppliers and asking if they were prepared to supply non-GM ingredients. Where suppliers were unwilling or unable to guarantee the non-GM-status of ingredients, Company R looked for alternative suppliers. Company R tests each product line for GM-status as part of their QA. Their testing approach is to only test if they change any of the raw ingredients within the product line. Whilst they have not employed any extra staff for this process, the switch in identifying and sourcing non-GM ingredients has been time consuming. In terms of overall cost the increased premia for non-GM and testing costs are considered minimal compared to overall production costs and have not resulted in prices increases.

Company S, imports food products from around the world and Asia. These imported products are sold in retail outlets and are also sold to the catering trade. They have not estimated how many of their products would be affected but consider that consumers are sensitive to the 'GM issue'. For example they stopped importing a European product that was relabelled with a GM content label. They have not seen any differences in wholesale prices on Australian, Korean or Japanese products since GM labelling changes were introduced in those countries.

Selecting an Estimate for Ongoing Costs

Given the significant variance in approaches available to ensure the non-GM-status of a product and the absence of more detailed information relevant to Hong Kong, the study utilises the estimates of ongoing costs presented in *Table 5.3* below. These are based on the National Economic Research Associates (NERA) study (*Economic Appraisal of Options for Extension of Legislation on GM Labelling, 2001*). The NERA estimates for per tonne costs of compliance were "based on collation and analysis of figures that are quoted in the literature and include both segregation and traceability costs." As the proposed options are not specifically requiring segregation and traceability systems [1] these costs are likely to be at the higher end of estimates of maintaining the non-GM-status of products in Hong Kong.

The Consultants have assumed that the difference between Options II & IV and Options III & V is a factor of two (i.e. changing from a one percent threshold, as considered in the NERA study, to a five percent threshold halves the ongoing costs). This assumption has been made in the absence of any available study on the costs associated with a five percent threshold (other studies have only considered the one percent threshold). It should be noted that the factor of two is intended to be illustrative of the likely difference in ongoing costs, as various members of the food trade have noted that they expect to see a price difference. However, no information is available from either studies or the trade as to how much this price differential is likely to be.

[1] Traceability is defined in standard ISO 8402 as "the ability for the retrieval of the history and use or location of an article or an activity through a registered identification".

Table 5.3 ***Possible Ongoing Costs (HK$)***

Option	Soya	Maize/Corn	Oilseed Rape
Option I	-	-	-
Option II & IV	112	72	122
Option III & V	223	154	244

Note: Compliance costs associated with other potential GM crops are not included in the main analysis. For cotton, the survey only identified one product as containing cottonseed oil (and the unit costs for oilseed rape was used for the ongoing costs for this product), for potato [1], squash, papaya (and other commercialised GM crops) this is because they currently account for less than 1% of their respective global production (and are therefore readily available from non-GM sources). The possible implications of increased commercialisation of these and other GM crops are considered in the sensitivity analysis.

This conservative approach to ongoing costs is necessary due to the considerable uncertainties associated with the actual ingredients of products in Hong Kong. It is not possible, nor indeed practicable, to try and identify the exact ingredients and associated ongoing costs associated with every products on the Hong Kong market.

All studies to-date concede, explicitly or implicitly, that their cost estimates are not absolute, but instead represent a "stake in the ground" resulting from an informed estimation exercise rather than being derived from concrete empirical evidence, which understandably is in short supply. Thus, it not reasonable to expect this Study to offer a per tonne compliance cost estimate that can be definitively argued to be "more accurate" than the one based on NERA's meta analysis. The ongoing costs identified by NERA explicitly assume that products require 'segregation and traceability' systems - which faithful compliance with the proposed Hong Kong options would require. Individual companies may choose to do less, but this study should make an estimate assuming compliance in the most diligent way. Indeed, the price premium for 'Non-GMO Soya bean Futures over 'US Soya bean Futures' on the Tokyo Grain Exchange suggested an average price differential of US$8.7 per tonne (calculation based on average futures contracts for next six months, dated 2nd October 2002) and this is lower than the NERA ongoing costs. This commodity price differential relates to the cost of purchasing the product in Japan and does not cover subsequent segregation costs (e.g. costs when transporting, storing, handling etc). While these segregation costs are implied by the Hong Kong options, costs associated with 'traceability systems' are not. These probably accounts for the higher NERA ongoing estimates. We therefore believe that the NERA estimates are better indications of the likely ongoing cost implications of the Hong Kong options if faithfully complied with by the food trade.

Analytical Testing Costs

The main analysis includes testing costs. We have assumed that the food trade undertakes testing of products to ensure the integrity of their systems to

[1] While no ongoing costs have been assumed for potato, the cost of reformulating products containing potato has been included in the main analysis.

maintain the non-GM-status of their products and ensure compliance with the Hong Kong standards.

During consultations with the trade we determined that this is likely to be up to twice per product line in the first year and once thereafter [1]. We have used a cost of HK$ 3,200 per test batch (assumed to be both a screening test and a quantitative text). The basis of this cost are the prices presented in *Table 5.2* for screening and quantitative tests [2].

5.1.4 *Government Costs*

FEHD developed three possible enforcement scenarios for any future regulatory provision. The range of scenarios (high, medium and low as shown in *Table 5.4*) reflects the current uncertainty over the likely degree of enforcement that will be required to ensure compliance with the implemented option. They involve different approaches to staffing, sampling, warning and prosecutions with the 'high' scenario being the most rigorous enforcement scenario entailing correspondingly higher costs than the 'low' scenario. They are outlined in *Table 5.4*.

Table 5.4 ***Proposed Enforcement Scenarios for Labelling in GM Food in Hong Kong***

Item	Scenario:	High	Medium	Low
Health inspectors involved in the enforcement (full time)		3	2	1
Samples for testing of GM materials per annum		1 200	350	100
Warning letters issued per annum		80	40	30
Number of possible prosecutions per annum		24	12	8
Enforcement Cost (HK$)		2,615,436	1,695,121	866,094
Testing Cost (HK$)		2,160,000	630,000	180,000
Total (HK$)		**4,775,436**	**2,325,121**	**1,046,094**

Notes: (1) Enforcement cost includes the staff and overhead costs associated with enforcing the legislation.
(2) It is estimated that there will be 40 complaints involving 100 samples to be taken for testing per annum for all three scenarios.
(3) For low scenario, samples will be taken in connection with complaint investigation only.
(4) For medium scenario, it is assumed that 250 samples will be taken for the purpose of routine surveillance.
(5) For high scenario, it is assumed that 1100 samples will be taken for the purpose of routine surveillance.
(6) An average of three tests at a price of HK$ 600 per test has been assumed in calculating testing costs. The Government Laboratory provided this cost.
(7) For all scenarios, it is assumed that all possible prosecutions will be pleaded guilty.

5.2 *APPLYING THE METHODOLOGY*

The above section described ERM's broad approach to assessing the quantitative costs associated with each of the options. This section explains in more detail how the approach is being applied.

[1] This approach was confirmed with both food manufacturers who had undergone reformulation and local laboratories.

[2] This price is derived by considering the typical price for screening tests (HK$1,000) and for quantitative tests (HK$2,200).

A reasonable estimate of the economic burden that a GM food labelling scheme might place on the Hong Kong public can be secured by estimating the cost implications of a scheme on a representative basket of goods that makes up the Household Expenditure Survey published by Government. Thus, ERM obtained from CSD a breakdown of the various commodity categories under the food section of the Household Expenditure Survey. The top-level of commodity groups for the food section of the Household Expenditure Survey are shown in *Table 5.5*.

Table 5.5 ***Breakdown of Average Monthly Household Expenditure on Food***

	Commodity Group	HK$/Month/Household
2	Rice	60
3	Other cereals and cereal preparations	43
4	Bread, cakes, biscuits and puddings	151
5	Salt-water fish	155
6	Fresh-water fish	103
7	Other fresh sea products	81
8	Processed sea products	89
9	Pork, locally slaughtered	206
10	Beef, locally slaughtered	36
11	Live poultry	90
12	Meat, frozen	86
13	Meat, canned	7
14	Meat, others	95
15	Fresh vegetables	190
16	Processed vegetables	11
17	Fresh fruit	170
18	Processed fruit	6
19	Dairy products	91
20	Eggs	19
21	Edible oils	32
22	Beverages	101
23	Sugar	5
24	Confectionery	34
25	Flavourings and additives	28
26	Foods, others	252

Note: Category 1 is the sum of categories 2 through 26 and not included here.
Source: 1999/2000 Household Expenditure Survey, Census and Statistics Department

CSD also provided a further breakdown for some of the groups listed above for use in the analysis, but due to confidentiality restrictions this data has not been included in this report.

A supermarket survey was undertaken to gather specific information on a range of individual items that would fall into each of the commodity groups, together with some general information on the nature of the commodity group itself. Data gathered included:

- major brands and concentration of market share.
- number of combinations of different package sizes and styles.
- range of countries of origin for products, and dominant countries.
- average size of items.
- average cost of items.

- GM ingredients present in product, and position in the ingredients list (major, minor, etc).

The above data, together with a database of products sold in Hong Kong and additional secondary research, was used to estimate the fraction of products within each category that would be: unaffected; reformulated/re-sourced; withdrawn from the market; or, labelled as containing GM ingredients, under each of the labelling options. Each commodity category will likely have several "trigger GM ingredients" that would require that the manufacturer/supplier take a course of action (label, withdraw, reformulate). These "trigger ingredients" for each product category are presented in more detail in *Annex F*.

Given the small size of Hong Kong's packaged food market (relative to other economies in the region), the large number and variety of manufacturers providing food products in Hong Kong, and the difficulty in soliciting from manufacturers/suppliers what their likely course of action might be under various labelling scenarios, it is important to appreciate the level of uncertainty inherent in any estimate of the proportion of products that will be reformulated/resourced or withdrawn from the market. Therefore, to estimate the proportion of products that will be reformulated, withdrawn etc., ERM has considered the following factors:

- How concentrated is the market and what are the major brands (using secondary data sources, supermarket survey and annual unit sales volumes)?
- From which countries are the products sourced (using supermarket survey and Hong Kong trade statistics, where possible)?
- Are there alternative countries for sourcing this product (ie is it a global brand with multiple manufacturing facilities)?
- Are these products sold in a GM labelling regulated market elsewhere?
- Have manufacturers declared their products sold in the Hong Kong market to be non-GM?
- Is the packaging Hong Kong specific, region specific or global specific (using supermarket survey)?

The above approach has been applied to all product categories and the resulting cost implications for the trade have been incorporated into an economic and financial analysis. This analysis, for each of the options, is presented in *Annex G*.

The economic analysis differs from the financial analysis in that it includes costs associated with Government enforcement.

Recognizing the uncertainties underlying the approach the analysis identifies a range for the possible impacts of each option. The principal driver for this range is the treatment of highly refined products. The lower bound of the analysis assumes that highly refined products (such as oils and hi-fructose corn syrup) are not reformulated as they would be exempted. This is in line with the various options under consideration that exempt the labelling

requirements of highly processed products. For illustrative purpose, the main analysis also covers an upper bound scenario in which the highly refined products are reformulated as otherwise some GM DNA might be detected. This reflects a more stringent regulatory regime in case the GM content of highly refined products should also be labelled.

The economic and financial analysis uses the Hong Kong Government's standard discount rate of 4% to obtain net present values of the impacts over a ten-year period.

5.3 *RESULTS OF THE ANALYSIS*

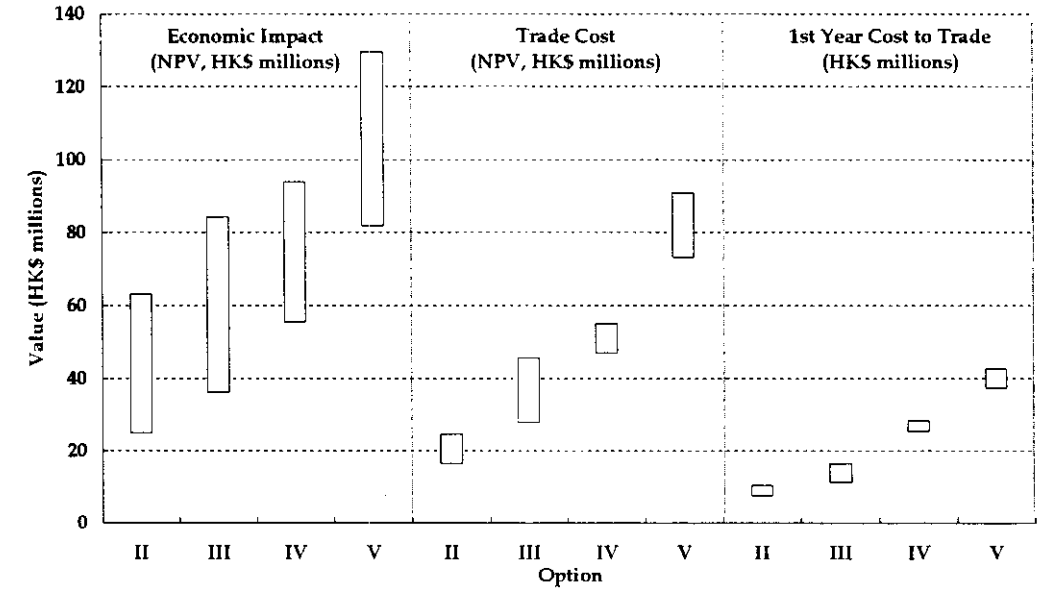
Table 5.6 and *Figure 5.1* present the results of the economic and financial analysis.

Table 5.6 ***Cost Implications (HK$ millions)***

Option	Economic Costs (NPV, HK$ millions)		Trade Costs (NPV, HK$ millions)		1st Year Costs (HK$ millions)	
	Min	*Max*	*Min*	*Max*	*Min*	*Max*
I	-	-	-	-	-	-
II	24.8	63.3	16.3	24.6	7.4	10.6
III	36.2	84.5	27.7	45.8	11.1	16.5
IV	55.5	93.9	47.0	55.1	25.3	28.4
V	81.7	129.7	73.2	91.0	37.3	42.7

Note: As discussed in *Section 5.2*, the min scenario assumes that highly refined products such as oil and high fructose corn syrup (HFCS), are not reformulated (as they would be exempted). The max scenario assumes that these products (oil and HFCS) are reformulated to ensure that any DNA that might be detected is not of a GM type.

Figure 5.1 ***Cost Implications (HK$ millions)***



5.4 *SENSITIVITY ANALYSIS*

As discussed throughout this section a number of assumptions have had to be made in undertaking this assessment. Whilst we have sought to ensure that these assumptions reflect the actual situation as much as is practical, we must recognise the potential for different results to be produced, should alternative assumptions have been adopted relating to a number of key items. Therefore a sensitivity test on the result of the appraisal has been undertaken, to quantify the impact of altering some of the more fundamental assumptions of the main analysis.

Specifically, the sensitivity test involves the following assumptions:

- the inclusion of crops currently undergoing field trials (e.g. rice and wheat) and not in common usage (e.g. potatoes, squash and papaya).
- the food industry will choose not to label their products as containing GM.
- the reformulation and ongoing costs.

5.4.1 *Inclusion of more GM crops*

Compliance costs associated with certain GM crops, other than corn, soya and rape are not included in the main analysis. For potato [1], squash, papaya (and other commercialised GM crops) this is because they currently account for less than 1% of their respective global production (and are therefore readily available from non-GM sources). The possible implications of

[1] The main analysis does include reformulation costs for potato but does not include any ongoing costs.

increased commercialisation of these and other GM crops currently undergoing development are examined using the approach outlined below.

Analysis of the GM crops currently under development suggests the following food categories are most likely to be additionally impacted by increased commercialisation of GM crops:

- Rice
- Other cereals and cereal preparations (wheat)
- Bread, cakes biscuits and puddings (wheat, potato starch)
- Fresh vegetables (potatoes, squash, radicchio and tomatoes)
- Processed vegetables (squash, radicchio and tomatoes)
- Fresh fruit (papaya, bananas, cantaloupe, and pineapples)
- Processed fruit (papaya, bananas, cantaloupe and pineapples)
- Dairy Products (chymosin, lactic acid bacteria)
- Edible oils (peanut and sunflower oil)
- Beverages (yeasts, sugar beet)
- Sugars (sugar beet)
- Confectionary (sugar beet)
- Flavouring and additives (all)

The commercialisation of the underlying products (in each of these food groups) and possible impact on these products (of the various options) will depend on a multitude of technical, social and political factors and is extremely difficult to predict accurately. As such we have:

- Assumed that that no new crops will be sufficiently commercialised to impact Hong Kong retail food products before 2005. 2005 is estimated as the Chief Executive Officer (CEO) of Monsanto, the worlds largest producer of GM crops, recently stated that this was the earliest it expected to gain regulatory approval for its products in either Europe or Brazil (Financial Times, August 19th 2002).

- Estimated that for Option V, the most stringent option, the maximum number of products impacted by the commercialisation of other GM-crops is 5,000 and that this is unlikely before 2011. The number of products impacted has been determined by analysing the product catalogue for a major supermarket in Hong Kong, selecting those products that could be impacted by the increasing commercialisation of GM crops in the future and adjusting the results to reflect information on the overall size and nature of the food market, the number of companies that already have a no-GM policy and that are manufacturing products for countries where GM food labelling legislation already exists. The 2011 timeframe has been estimated by considering the likelihood of significant commercialisation over the next ten years given current consumer resistance and regulatory barriers to GM crops.

- Assumed that under Option IV, as for the main analysis, only 66% of these 5,000 products are impacted (due to the difference between the 1% and 5% threshold).

- Utilised the ratios, of the number of products impacted under Options II & III to the number of products impacted under Options IV and V, identified by the main analysis to estimate the maximum number of products impacted by future crops under Options II & III. This equates to 1,272 products under Option II and 1,904 under Option III.

- Assumed that no new GM ingredients are designated under Options II and III before 2008.

As an upper bound estimate, the Consultants believe that 5,000 products could be impacted by the advent of additional GM crop varieties. The two major factors would be wheat and sugar. These two ingredients are used in virtually all food products available on the market. Although currently corn - a GM variety available crop - is found in a wide range of products, the products' manufacturers are able to find alternative ingredients (egg replacing corn starch with wheat starch), this option may not be available in the future. Further, companies that have been able to secure a GM-free policy and/or product range may be forced to engage more actively in order to retain their status. This would be particularly true following the wide spread availability of GM sugar beet and GM wheat derived ingredients. For example, consider the use of sugar: there are over 40 different varieties of sweetened beverages on the market; virtually all confectionary will be impacted, as will ice creams, canned fruit, sauces, and canned and processed meats. The availability of GM wheat will impact noodles, breakfast cereals, baked products (such as biscuits), cake mixes, breads, and any product that uses flour as a binding agent or as a filler to bulk out the product. The average supermarket stocks between 5,000 and 10,000 products. It is therefore conceivable that with the inclusion of rice, sugar, flour, corn, and other ingredient staples as being potentially GM, the number of products impacted by the proposed legislation will run into the thousands.

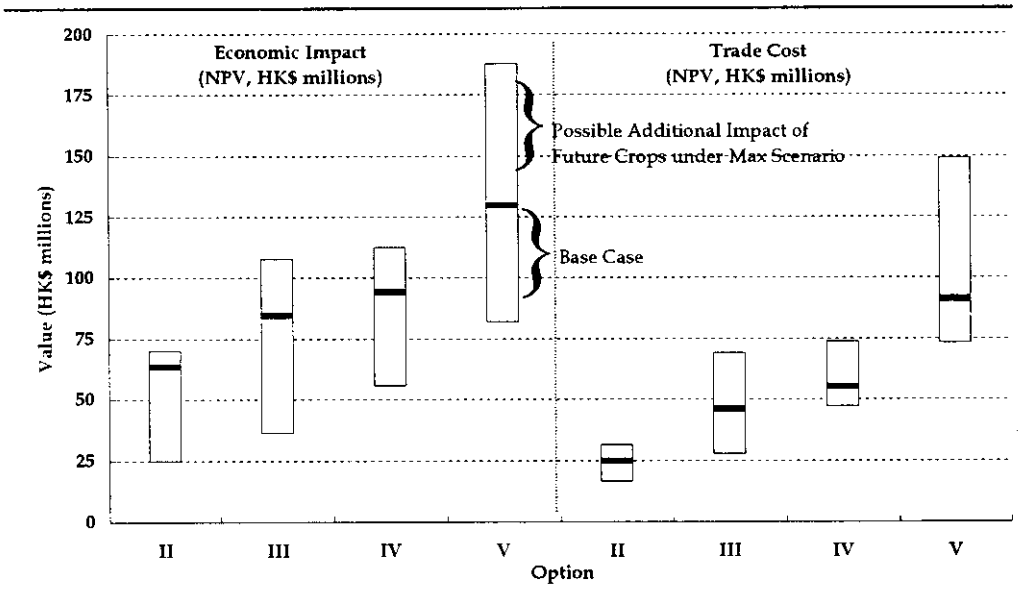
The results of this analysis are illustrated in *Table 5.7* and *Figure 5.2*. It should be noted that these results are considered the maximum possible impact of the increased commercialisation of existing and planned GM crops.

Table 5.7 ***Impact of Future Products (HK$ millions)***

Option	Economic Costs (NPV HK$ millions)		Trade Costs (NPV HK$ millions)	
	Min	*Max*	*Min*	*Max*
Lower Bound (A)				
II	24.8	63.3	16.3	24.6
III	36.2	84.5	27.7	45.8
IV	55.5	93.9	47.0	55.1
V	81.7	129.7	73.2	91.0
Upper Bound (B)				
II	28.6	70.3	20.1	31.6
III	42.0	107.9	33.5	69.2
IV	66.3	112.5	57.8	73.8
V	113.1	188.0	104.7	149.3
Maximum Increase (B-A)				
II	3.9	7.0	3.9	7.0
III	5.8	23.4	5.8	23.4
IV	10.8	18.7	10.8	18.7
V	31.5	58.3	31.5	58.3

Notes: (1) The min scenario assumes that oil and highly refined product such as oil and high fructose corn syrup (HFCS), are not reformulated (as they would be exempted). The max scenario assumes that these products (oil and HFCS) are reformulated to ensure that any DNA that might be detected is not of a GM type.
(2) The lower bound assumes that no future products will be impacted, while the upper bound assumes that 5,000 products will be impacted. The maximum increase represents the difference between these two bounds.

Figure 5.2 ***Sensitivity Analysis of Future Crops (HK$ millions)***



5.4.2 *Labelling of Products as Containing GM*

As discussed in *Section 5.1*, the main analysis assumes that no one will label their products as containing GM. The possible implications of some products being labelled as containing GM is examined using the approach outlined below.

- The cost of labelling products (as described in *Box 5.1*) are assumed to be limited to the redesign cost of HK$4,000 per product.

- To illustrate the impact of the labelling we have assumed that 25%, 50% and 75% of the impacted products choose to label instead of reformulating.

The results of this analysis are illustrated in *Table 5.8*.

Table 5.8 ***Labelling Sensitivity Analysis (HK$ millions)***

Option	Economic Costs (NPV, HK$ millions)		Trade Costs (NPV, HK$ millions)		1st Year Costs (HK$ millions)	
	Min	*Max*	*Min*	*Max*	*Min*	*Max*
Baseline						
II	24.8	63.3	16.3	24.6	7.4	10.6
III	36.2	84.5	27.7	45.8	11.1	16.5
IV	55.5	93.9	47.0	55.1	25.3	28.4
V	81.7	129.7	73.2	91.0	37.3	42.7
Labelling 25%						
II	20.9	57.4	12.4	18.7	5.7	8.1
III	29.5	73.4	21.1	34.7	8.5	12.7
IV	44.4	80.8	35.9	42.1	19.4	21.9
V	64.3	108.0	55.8	69.3	28.7	32.8
Labelling 50%						
II	17.	51.5	8.5	12.8	4.0	5.7
III	22.9	62.3	14.4	23.6	6.0	8.8
IV	33.3	67.7	24.8	29.0	13.6	15.3
V	47.0	86.3	38.5	47.6	20.1	22.9
Labelling 75%						
II	13.1	45.6	4.6	6.9	2.3	3.2
III	16.2	51.3	7.7	12.5	3.4	5.0
IV	22.2	54.7	13.7	15.9	7.8	8.7
V	29.6	64.6	21.1	25.9	11.5	13.1

Notes: The min scenario assumes that highly refined product such as oil and high fructose corn syrup (HFCS), are not reformulated (as they would be exempted). The max scenario assumes that these products (oil and HFCS) are reformulated to ensure that any DNA that might be detected is not of a GM type.

The results indicate that there could be cost advantages to companies from pursuing a labelling strategy (as opposed to reformulating). However, discussions with the trade suggest this approach is unlikely to gain acceptance given consumer concerns regarding GM foods.

5.4.3 *Reformulation and Ongoing Costs*

The following assumptions have been made in examining the reformulation and ongoing costs used in the main analysis:

- to examine the implications on the results of the analysis of underestimating these costs we have increased them by 50% and 100%; and,

- to examine the implications on the results of the analysis of an overestimation of these costs we have decreased them by 50%.

The results of this analysis are illustrated in *Table 5.9*.

Table 5.9 ***Reformulation and Ongoing Cost Sensitivity Analysis***

Option	Economic Costs (NPV HK$s)		Trade Costs (NPV HK$s)		1st Year Costs (HK$ millions)	
	Min	*Max*	*Min*	*Max*	*Min*	*Max*
Baseline						
II	24.8	63.3	16.3	24.6	7.4	10.6
III	36.2	84.5	27.7	45.8	11.1	16.5
IV	55.5	93.9	47.0	55.1	25.3	28.4
V	81.7	129.7	73.2	91.0	37.3	42.7
x 2						
II	36.5	81.7	28.0	43.0	13.9	19.9
III	57.5	121.4	49.0	82.7	21.0	31.3
IV	87.7	132.6	79.2	93.8	47.4	53.4
V	133.4	196.9	124.9	158.2	70.1	80.4
x 1.5						
II	30.6	72.5	22.2	33.8	10.6	15.2
III	46.8	102.9	38.4	64.2	16.0	23.9
IV	71.6	113.2	63.1	74.5	36.3	40.9
V	107.5	163.3	99.0	124.6	53.7	61.6
x 0.5						
II	18.9	54.1	10.4	15.4	4.1	5.9
III	25.6	66.0	17.1	27.3	6.2	9.2
IV	39.4	74.5	30.9	35.8	14.2	16.0
V	55.8	96.2	47.3	57.4	20.9	23.9

Notes: The min scenario assumes that highly refined products such as oil and high fructose corn syrup (HFCS), are not reformulated (as they would be exempted). The max scenario assumes that these products (oil and HFCS) are reformulated to ensure that any DNA that might be detected is not of a GM type.

The above analysis suggests that the analysis, and the resulting impact on the economy and the trade, is sensitive to the underlying assumptions regarding reformulation and ongoing costs. However, the significance of this sensitivity is minimal when compared to the overall expenditure on food products. That is not to say that individual factors within the supply chain may not be significantly impacted by the proposed options, but rather that the overall impact on the economy and the trade is unlikely to be particularly significant.

5.5 *AFFORDABILITY ANALYSIS*

The affordability analysis focuses on individual operators in the food trade who may be significantly impacted by the proposed options. Specifically this analysis looks at small and medium sized importers and local food manufacturers. These two are selected for analysis as discussions with trade representatives suggested considerable concern for their livelihood.

The Government of the HKSAR defines small and medium-sized enterprises (SMEs) as: "Any manufacturing businesses which employ fewer than 100 persons in Hong Kong; or any non-manufacturing businesses which employ fewer than 50 persons in Hong Kong". This definition has been adopted in undertaking this analysis.

5.5.1 *Small and Medium Sized Importers*

Case studies of operators in Hong Kong identified Company L, a small importer and distributor of food products into Hong Kong. They employ 5 people and clients are primarily supermarkets chains and outlets. Discussions with Company L indicate that of the 12 product lines that they import per annum, 3 could potentially contain GM ingredients.

CSD data for importers of food suggest that on average food importers have an average of around 5 employees, a turnover of HK$ 20 million and profitability of around 3.5%, although companies with less than 10 employees having only average 2% profitability (see *Table 5.10*).

Furthermore, the CSD data suggests that there are a few large food importers, but over 99% of importers are SMEs (employing less than 50 people). Discussions with a major retailer in Hong Kong suggested that on average these small importers typically import 3 to 4 product lines.

Table 5.10 *Food Importers, by number of employees*

Importers (grouped by no. of employees)	Total no. of establishments in each group	Total no. of employees in each group	Total turnover of each group (HK$ millions)	Profit (%)(1)
< 10	3,551	9,290	45,750	2.0%
10 - 49	330	5,523	21,722	6.2%
> 50	34	3,301	11,999	4.7%
Total	3,914(2)	18,114	79,470	3.5%

Source: Data supplied by Census & Statistics Department for the year 2000.
Note: (1) Profit is total turnover minus total costs expressed as a percentage of turnover.
(2) The total no of establishments does not sum directly due to the necessary rounding of data collected and analysed by Census & Statistics Department

Table 5.11 *Food Importers, by Total Turnover*

Importers (grouped by turnover, HK$ millions)	Total no. of establishments in each group	Total no. of employees in each group	Total turnover of each group (HK$ millions)	Profit (%)(1)
< 1	833	909	196	-22.7%
1 - 5	1,199	2,715	3,180	8.5%
5 - 10	578	1,730	4,105	7.0%
10 - 50	908	5,546	18,718	2.0%
> 50	395	7,214	53,271	3.6%
Total	3,914(2)	18,114	79,470	3.5%

Source: Data supplied by Census & Statistics Department for the year 2000.
Note: (1) Profit is total turnover minus total costs expressed as a percentage of turnover.
(2) The total no of establishments does not sum directly due to the necessary rounding of data collected and analysed by Census & Statistics Department

In order to illustrate the potential impact on small importers we have developed three scenarios based around Company L and the CSD data. Each of the scenarios assumes a company with average turnover for the sector (HK$ 20 million per annum), average profitability for companies with less than 10 employees (2%) and a variable number of products that are potentially impacted (3 for scenario A, 6 for scenario B and 12 for scenario C). In order to illustrate the possible impact on these scenarios we have assumed that, to

protect against possible liability arising from the GM regulations, they randomly sample 2 items from potential GM food product lines in the first year after implementation of the standard, and 1 in subsequent years. Cost of testing is assumed to HK$ 3,200 per item.

The results of this approach on these three scenarios (labelled A, B & C) are presented in *Table 5.12* below.

Table 5.12 ***Possible Impact on Small Importers***

	Turnover (HK$)	Profit (%)	Profit (HK$)	No. of Products	Cost of testing (HK$)		Cost of testing (as % of profit)	
					1st Year	*Subsequent*	*1st Year*	*Subsequent*
A	20,000,000	2.0%	400,000	3	19,200	9,600	5%	2%
B	20,000,000	2.0%	400,000	6	38,400	19,200	10%	5%
C	20,000,000	2.0%	400,000	12	76,800	38,400	19%	10%

If the Products Tested Meet the Regulations

As discussed previously small importers normally average 3 to 4 product lines. For these average importers, the cost of testing would not be that significant as it would only account for less than 10% of the first year of profit as revealed in the above analysis, and less than 5% thereafter. However, if a small importer imported up to 12 products that are potentially impacted then the impact on profitability is higher at around 19% in the first year, and as such could be more significant to the importer.

Furthermore, if the value of the testing exceeds the potential product related profit the importer might choose to abandon the product. For a company with 2% profitability the annual purchase value of the product would have to be less than HK$ 320,000 in the first year for all product-associated profit to be wiped out. This annual purchase value is plausible for small importers. For example, a company with a 2% profit on a product valued at HK$ 5 per unit would have to import at least 64,000 units to cover the cost of undertaking a batch of tests on two samples. As such, the cost of the testing regime could result in some small importers abandoning the import of certain products if their market share and/or the demand for the product does not warrant the expense of testing. The impact on the choice of consumers as a result of the drop-out of the products is set out in *Section 5.5.3*.

If the Products Tested do not Meet the Regulations

Assuming that the importer is unable to obtain a contractual guarantee of the product's GM-status from the manufacturer (due to, perhaps, the limited size of the order) and testing reveals that a product does not meet the regulations, the importer could choose to label the product as containing GM (to reduce their liability). The cost of labels is around 50 cents per unit. *Table 5.13* illustrates three scenarios that assume that the importer just tests once in the first year and then chooses to label the product as containing GM thereafter.

Table 5.13 ***Impact of GM Labelling***

	No. requiring labelling	Average no. of units	Cost of labelling	Cost of testing	Total Loss of Profit (HK$)		Total Loss of Profit (%)	
					1st Year	Subsequent	1st Year	Subsequent
A	1	150,000	75,000	3,200	78,200	75,000	20%	19%
B	2	150,000	150,000	6,400	156,400	150,000	39%	38%
C	4	150,000	300,000	12,800	312,800	300,000	78%	75%

The analysis suggests that if four products did test positive for GM material and the importer chooses to label, the resulting costs would be significant and wipe out most of the profit for that year and in subsequent years. As such the importer might choose to either re-export it to a different market or dispose of it. However, if sufficient grace period is to be offered before the labelling requirements are put into force, the importer would be able to run out the existing stock and hence the impact on the importers' profit would not be that significant.

5.5.2 *Small and Medium Sized Local Manufacturers*

While the study was not able to obtain any useable information from consultations with small and medium sized food manufacturers in Hong Kong, CSD data suggests many such establishments exist. *Table 5.14* and *Table 5.15* provide summary data on food manufacturing establishments in Hong Kong. Further details and a breakdown of the various types of food manufacturing sectors in Hong Kong can be found in *Annex E*.

Table 5.14 ***Food Manufacturers in Hong Kong, by number of employees***

Manufacturers (grouped by no. of employees)	Total no. of establishments in each group	Total no. of employees in each group	Total turnover of each group (HK$ millions)	Profit (%)(1)
1 - 99	482 (249)(2)	7,047 (4,935)(2)	(2,687)(2)	(7%)(2)
>100	33 (16)(2)	12,695 (6,901)(2)	(4,394)(2)	(18%)(2)
Total	515	19,742	16,327	15%

Source: Data supplied by Census & Statistics Department for the year 2000. Further details can be found in *Annex D*

Note: (1) Profit is total turnover minus total costs expressed as a percentage of turnover.
(2) Turnover and cost data are not available for all sectors due to confidentiality concerns so numbers in brackets provide information for those sectors that are available. See *Annex D* for further details.

Table 5.15 Food Manufacturers in Hong Kong, by Total Turnover

Manufacturers (grouped by turnover, HK$000s)	Total no. of establishments in each group	Total no. of employees in each group	Total turnover of each group (HK$ millions)	Profit (%)[1]
<5,000	309 (291)[2]	1,672 (1,543)[2]	(487)[2]	(9%)[2]
5,000 - 20,000	115 (102)[2]	2,451 (2,077)[2]	(1,089)[2]	(6%)[2]
>20,000	91 (76)[2]	15,619 (11,702)[2]	(9,921)[2]	(16%)[2]
Total	515	19,742	16,327	15%

Source: Data supplied by Census & Statistics Department for the year 2000. Further details can be found in *Annex D.*

Note: (1) Profit is total turnover minus total costs expressed as a percentage of turnover.
(2) Turnover and cost data are not available for all sectors due to confidentiality concerns so numbers in brackets provide information for those sectors that are available. See *Annex D* for further details.

The CSD data illustrates that the bulk (>93%) of food manufacturers in Hong Kong are SMEs, and that 60% of food manufacturers have a turnover of less than $5 million per annum. For these SMEs the average turnover is HK$ 1.7 million per annum [1] and an average of just over 5 employees [2]. In order to examine the possible implications to small operators in this sector the following scenario has been developed based on this data. For each scenario we have used variable profit rates to reflect the divergence in profitability within the sector.

- Small manufacturer A with a turnover of HK$ 1.7 million per annum, a profit of 5% and 5 employees, produces 200,000 units of one packaged food product that requires reformulation.
- Small manufacturer B with a turnover of HK$ 1.7 million per annum, a profit of 10% and 5 employees, produces 200,000 units of one packaged food product that requires reformulation.
- Small manufacturer C with a turnover of HK$ 1.7 million per annum, a profit of 15% and 5 employees, produces 200,000 units of one packaged food product that requires reformulation.

In analysing the possible first year impact on these scenarios we have assumed:

- reformulation costs of HK$ 44,000.
- ongoing costs of HK$223 per tonne of GM ingredients (ongoing cost associated with securing GM-free soya).
- GM ingredient constitutes 20% by weight of final product (and final product weighs 250g).
- manufacturers undertake one batch of tests per annum (costing HK$3,200) to confirm compliance with the legislation.

(1) HK$ 487 million divided by 291 companies.

(2) 1672 employees divided by 309 companies.

This provides the results illustrated in *Table 5.16* below.

Table 5.16 ***Impact to Small Manufacturers***

	Turnover (HK$)	Profit	Profit (HK$)	One-off cost (HK$)	Ongoing (HK$)	Testing (HK$)	% of Profit	
							1st Year	Subsequent
A	1,700,000	5%	85,000	44,000	2,230	3,200	58%	6%
B	1,700,000	10%	170,000	44,000	2,230	3,200	29%	3%
C	1,700,000	15%	255,000	44,000	2,230	3,200	19%	2%

The above analysis illustrates that costs to small manufacturers could potentially be very significant in the first year (although less significant thereafter) even without any additional final product testing. It is however acknowledged that the reformulation cost of HK$ 44,000 is on the high side for a small manufacturer in Hong Kong as they are unlikely to develop (or need to develop) a very sophisticated system to ensure the GM-status of their products, particularly if they only have one product line. For example, the identification and substitution (or replacement) of the potentially GM ingredient is likely to be an easier and cheaper solution.

5.5.3 *Results of the Affordability Analysis*

The above affordability analysis suggests:

- For small and medium sized importers the various mandatory options (e.g. Options II, III, IV and V) could result in them withdrawing some products from the market **if**:
  - they are unable to obtain a contractual guarantee of the product's GM-status from the manufacturer (due to, perhaps, the limited size of the order); and/or,
  - the cost of testing the GM-status is a significant proportion of the possible profit obtained from that product.

  The above scenarios are only likely if the manufacturer of the imported product is not interested in retailing to markets that have GM labelling requirements. Given the significant size of the markets currently covered by GM labelling requirements this is only considered likely for a small number of products. Analysis of the data collected during the study identified that between 0.3% and 0.7% of products might fall into this category. This range was calculated through identification of a 95% confidence interval for packaged food products imported to Hong Kong that are: likely to be impacted by the regulations (due to their content); sold in small quantities; and, unavailable in jurisdictions with existing GM labelling requirements. For all packaged food products (approximately 20,000 products) this represents a potential loss of between 58 and 134 products under Option V. It should be noted that this is considered an upper range.

The principal drivers of any decision to drop a product are the failure to secure a contractual guarantee from the manufacturer and the size of the order, as opposed to its actual ingredients. As such, it is not possible to accurately predict the difference in impact between the different options as this information is not available. However, it is of course likely that the most stringent option (Option V) will impact significantly more importers than the least stringent (Option II). Using the results of the main analysis to compare the likely ratios of products impacted under the different options provides the resulted presented in *Table 5.17*. This represents the worst possible case in terms of the number of importers impacted by the proposed options (e.g. one importer is significantly impacted for every product that is dropped from the market). These are considered the maximum possible impact to importers under the options and is considered unlikely that all their employees would loose their jobs. Rather their employers might be significantly impacted during the first year of operation of any GM labelling requirement.

Table 5.17 ***Maximum Number of Importers & Employees Significantly Impacted***

Option	Max no. of importers significantly impacted (1)	Max no. of employees impacted (2)
II	35	133
III	50	191
IV	93	354
V	134	511

Notes: (1) Based on the maximum total number of products that could be impacted (134) with the breakdown between options relying on the ratios derived from the main analysis. Assumes that, at worst, one importer company is significantly impacted per product. Breakdown between options relies on the ratios derived from the main analysis.
(2) Based on the average number of employees per small or medium sized food importer for 2000 (3.82 employees). Assumes that, at worst, all employees of a significantly impacted company will be effected.

The above analysis just considers those small and medium sized importers that are likely to be *significantly* impacted by the proposed options (1). Analysis of available statistics on food importers in Hong Kong suggest that around 2,800 small and medium sized importers are likely to be importing products that contain potential GM ingredients (2). It is noted, however, that only a proportion of these 2,800 companies will face any significant costs due to the proposed options. Some will be able to confirm the GM-status with the product's manufacturers and if necessary re-label the products as part of routine labelling. Indeed, some would not face any financial impact at all, as any costs associated with the options are likely to be passed back along the supply chain to manufacturers. As illustrated by the main analysis, *at most* the reformulation and associated costs associated with 790 products (under Option V) are likely to be passed onto Hong Kong companies. Some proportion of these costs will fall on locally manufacturers so the number of importers facing any sort of financial impact is likely to be less than 790

(1) Significant impact is defined as wiping out the majority or all of product related profit in any one year.

(2) This number was derived by considering a breakdown of importers by food types, and identifying those food types that potentially contain GM ingredients. A breakdown of importers by food type can be found in *Annex E*.

(under Option V), although more than those *significantly* impacted as outlined in *Table 5.17* above.

- For small manufacturers in Hong Kong the introduction of labelling requirements could have significant financial impacts during its first year of implementation.

  Analysis of Census and Statistics Department data suggests that a **maximum** of around 149 small food manufacturers companies could be impacted in this manner under Option V. This analysis was undertaken by considering small and medium sized food manufacturers in Hong Kong:

  - that are potentially impacted by the proposed options;
  - that use ingredients that are likely to require complex reformulation (e.g. not just re-sourcing); and,
  - that produce food for the packaged food market (as opposed to selling food unpacked, to wet markets, hotels and restaurants).

  This analysis suggests that:

  - there are six categories of manufacturers that are likely to be impacted [1];
  - these six categories represent 373 small and medium sized companies; and,
  - many of these 373 companies do not sell packaged food (e.g. bakeries and noodles are sold unpackaged or direct to the catering trade), and most will not require complex reformulation (as most will simply be able to re-source alternative non-GM ingredients, which are widely available in Hong Kong) [2]. As such, it is assumed that the majority (60%) of these 373 companies will not be significantly impacted. Forty percent of 373 is 149 companies.

  The principal driver of this impact is the reformulation cost. It is noted, however, that the assumed reformulation cost might be slightly on the high side for the reasons explained in *Section 5.1.2*. Moreover, given sufficient grace period for the implementation of the labelling requirements, there is no need for the small manufacturers to reformulate all products within one year. They can absorb the reformulation cost over a longer period of time (e.g. more than one year) so as to reduce the impact on the annual revenue and profit. As such, the actual impact on most small manufacturer's revenues and profits

[1] Dairy products; Bakery products; Vermicelli, noodles and similar farinaceous products; Cocoa, chocolate and sugar confectionery; Food Products n.e.c. and Soft drinks and carbonated water industries. See *Annex D* for full breakdown.

[2] This analysis is derived from the consultants supermarket survey, consultation with manufactures and review of available literatures on the food trade in Hong Kong.

will probably be lower and the number of companies significantly impacted is likely to be less.

Individual companies existing practices and product ingredients drive the actual number of food manufacturers significantly impacted. As such, it is not possibly to accurately predict the difference in impact between the different options as this information is not available for all the companies operating in Hong Kong. However, it is of course likely that the most stringent option (Option V) will impact significantly more manufacturers than the least stringent (Option II). Using the results of the main analysis to compare the likely ratios of manufacturers impacted under the different options provides the resulted presented in *Table 5.18*. Again, it is noted that these are considered the maximum possible impact to manufacturers under the options and manufacturers might be significantly impacted during the first year of operation of any GM labelling requirement.

Table 5.18 ***Maximum Number of Manufacturers & Employees Significantly Impacted***

Option	Max no. of manufacturers significantly impacted (1)	Corresponding max no. of employees impacted (2)
II	39	568
III	56	812
IV	103	1,503
V	149	2,177

Notes: (1) Based on the maximum total number of companies that could be impacted (149) with the breakdown between options relying on the ratios derived from the main analysis.
(2) Based on the average number of employees per small or medium sized food manufactures for 2000 (14.61 employees). Assumes that, at worst, all employees of a significantly impacted company will be effected.

5.6 *GM-FREE SCENARIOS*

As discussed in *Section 2.3* the Study considered three GM-free options:

- *The status quo,* where there is no specific requirement for GM-free and equivalent claims;
- *Require documentation,* where anyone making a GM-free or similar negative claim must be able to provide IP or similar documentation to verify the status of the product; and
- *Prohibit GM-free Claims,* where GM-free and equivalent negative claims are prohibited.

The economic and financial impacts of each of these three options are discussed below.

5.6.1 *The Status quo*

GM-free and similar negative labelling is currently practised voluntarily by the trade, thus any financial impacts of choosing to label a product as GM-free

are likely to be related to the trade's own decisions and not those of Government action. In most cases the trade will choose to label if the financial benefits, from increased revenues due to either price premiums, branding issues or consumer preferences, outweigh or are equal to the costs associated with maintaining and proving the product's GM-status, including labelling and any liability associated with false claims.

Thus, there is no direct financial or economic impact of continuing the status quo.

5.6.2 *Requiring IP or Similar Documentation*

If the Administration requires that anyone making GM-free or similar negative claims should be able to provide documents to verify the status of the products, some of the existing products sold with a GM-free label may be impacted; i.e. those that do not currently maintain a documentation system.

Existing data regarding how many products carried GM-free or equivalent negative claims are not readily available from the local trade and supermarket chain. A preliminary analysis conducted by FEHD revealed that among 1,305 products, 6.6% (86 products) made GM-free or equivalent negative claims. Of these products some 78% (67 products) were considered likely to already have documentations such as IP documentation [1].

Given the uncertainty surrounding both the costs to individual companies of providing IP documentation and the number of products that would need to secure such documentation, a range of possible outcomes have been identified. This suggests that the total cost to companies having to develop IP documentation systems could be anywhere between HK$ 5.6 million and HK$ 14.7 million. This range is based on an assessment of the number of products requiring IP documentation (between 161 and 421 [2]), an average total value for these products (HK$ 700,000 [3]) and an IP cost of 5% of the total value of the product [4]. The wide range is a reflection of the uncertainty surrounding: the number of products that currently have a GM-free label but do not have a documented IP system; and the likely cost of developing a documented IP system. Furthermore, it should be noted that the bulk of these cost are unlikely to have any direct impact on Hong Kong as the companies identified as making these GM-free or equivalent claims are not

(1) Products with IP documentation included: those that are produced in a locality that requires IP documentation to substantiate GM-free or equivalent negative claims; those that are produced in the UK and labelled as organic (organic certification in the UK requires auditable documentation systems); and products produced by manufacturers who are known to currently maintain IP documentation systems. Where nothing was known about the products origin or manufacturing practices then it was assumed that an IP documentation system was not currently in place.

(2) The survey covered 1,305 products of which 86 had GM-free or negative labelling. Of these only 19 required IP documentation. Calculating a 95% confidence interval for this survey finding and applying it to the overall size of the packaged food market, of around 20,000 products, provides the lower and upper bound.

(3) Based on the total value of the packaged food market in Hong Kong and the approximate number of products on sale.

(4) 5% of the product price was quoted as an upper bound of the cost of IP systems in *The Non-GMO Source* (January 2002). The values quoted in the publication ranged from 0.5% to 5% of the product value with the higher costs (5%) reflecting the low tolerance level for GM-free.

Hong Kong companies and the concerned products are not manufactured in Hong Kong.

There are also likely to be ongoing costs associated with maintaining an IP or similar documentation system but these are unlikely to be as significant as establishing the documentation system. Indeed, in many cases, it is likely that these can be integrated into existing management and quality practices with no additional cost.

It is possible that there will be enforcement costs associated with verifying GM-free claims on labels, and this will be an additional economic impact. However, these GM-free claim related enforcement costs are likely to lie within the costs associated with the 'medium to high enforcement' scenario detailed in *Table 5.4*.

Another contributory to the uncertainty in assessing the impact of this option is the possibility that some traders may remove GM-claims from their products, rather than establish an IP system. This is likely to reduce the overall costs of compliance under this option (see analysis below).

5.6.3 *Prohibit GM-Free Claims*

If the Administration prohibits the use of GM-free and similar negative labelling claims the cost to the trade of such an action would be the cost of re-labelling products making such claims.

As for the previous option, given the uncertainty surrounding the number of products that would need to re-label, a range of possible outcomes have been identified. This suggests that the cost to the trade of this option could be anywhere between HK$ 4.2 million and HK$ 6.3 million. This range is based on an assessment of the number of products that are currently labelling their products as GM-free or equivalent (between 1,049 and 1,587 [1]) and a cost of re-labelling of HK$ 4,000 [2]. The wide range is a reflection of the uncertainty surrounding the number of products that currently have a GM-free label. These costs are more likely to fall on Hong Kong companies (e.g. importers and retailers) than on overseas companies.

It should be noted, however, that given sufficient lead time and warning the cost of re-labelling can be worked into any periodic/routine changes that might occur and/or allow existing stocks of labelled products to be finished. This would reduce the cost to industry significantly.

Again, as for the previous option, it is possible that there will be enforcement costs associated with this prohibition and this will be an additional economic impact. However, these enforcement costs are likely to lie well within the

(1) The survey covered 1,305 products of which 86 had GM-free or negative labelling. Calculating a 95% confidence interval for this survey finding and applying it to the overall size of the packaged food market, of around 20,000 products, provides the lower and upper bound.

(2) As identified in *Box 5.1*.

costs associated with the 'medium to high enforcement' scenario detailed in *Table 5.4.*

In addition, it should be noted, that prohibiting GM-free and equivalent labelling could have a cost to consumers in terms of reducing their ability to make informed decisions. It would also be unfair to companies that most diligently ensure that their products are GM-free. There would also be practical difficulties in defining what all the equivalent negative claims to be prohibited. For example, should "organic" claims be prohibited as well?

5.6.4 *Conclusions*

The analysis suggests that prohibiting GM-free and equivalent negative labelling is likely to have lower costs to the trade than requiring them to product IP documentation. However, prohibiting GM-free and equivalent negative labelling might limit consumers' choices. On the other hand, the costs of re-labelling are more likely to fall on Hong Kong companies (e.g. importers and retailers) than are the costs of supplying IP or similar documentation (which are more likely to fall on manufacturers outside Hong Kong).

6 CONCLUSIONS AND BARRIERS TO IMPLEMENTATION

6.1 FINDINGS

6.1.1 *Cost Implications to the Food Trade*

The financial analysis suggests that there will be cost implications for the food trade under Options II to V. Under Option I (status quo) there are no increases in costs to the trade.

The majority of these cost impacts are likely to be in the first year when companies examine, potentially reformulate and test their products to ensure compliance with the legislation.

These financial costs to the trade range between HK$ 16 million (lower bound for Option II) to HK$ 91 million (upper bound for Option V).

Options IV and V are significantly more expensive than Options II and III (HK$ 47 million to HK$ 91 million vs HK$ 16 million to HK$ 46 million). This difference is principally accounted for by the more inclusive nature of Option IV and V, which cover all food ingredients rather than the top 5 ingredients (under options II and III).

Furthermore, analysis suggests:

- Under all options, the costs to the trade could increase significantly when, and if, more GM crops are commercialised. For Option V the costs could increase by up to 64%, for Option IV the costs could increase by up to 34%, for Option III the costs could increase by up to 51% while under Option II the costs could increase by up to 28%. The relatively higher potential increases under Options III and V reflect the more stringent 1% threshold under these options.

- If companies choose to label their products as containing GM ingredients instead of reformulating (to avoid labelling) then the overall impacts on the trade are likely to be lower. However, this approach is unlikely given that objections to GM foods are often more widely publicized than advantages advanced by proponents of GM food or scientific safety assessment. Thus companies would not want to risk losing the market. One manufacturer stated that even a loss of 5% of market share would not be acceptable and therefore it would convert to non-GM.

- The magnitude of the cost implications to the trade is understandably sensitive to assumptions made about the costs associated with reformulating and maintaining GM-status. While the Consultants have sought to make these assumptions as accurate as possible, it should be recognised that considerable uncertainty exists as to how

individual food companies will react to the legislation, and hence the value of the overall impact on the trade. Costs will be product and company specific.

- Small importers of some product lines may be significantly impacted by the proposed options. This will be the case if they are unable to secure contractual agreements with the product manufacturer as to the product's GM-status. This could result in some products being dropped from the market, especially those products that are not imported in significant quantities and that are not sold in jurisdictions with existing GM labelling requirements (such as Europe, Australia, New Zealand, Japan and Korea).

- Some smaller local manufacturers could be significantly impacted during the first year of implementation of any of the options. It is noted, however, that for most manufacturers these costs are unlikely to be significant and if the costs could be diluted over a longer period of time (more than one year) then the actual impact on the company's revenues and profits might not be so significant. In the current economic climate it is unlikely that the costs incurred will be recoverable from the retailers.

6.1.2 *Economic Costs*

As for the financial analysis, Options II to V will have significant economic costs to Hong Kong. Under Option I (status quo) there are no increases in costs to the economy.

The only difference between the *economic* and *financial* costs are the enforcement costs which range between HK$ 1 million and HK$ 5 million per annum (depending on the enforcement strategy adopted).

However, as for costs to the trade, the majority of economic cost implications are likely to be in the first year when companies examine, potentially reformulate and test their products to ensure compliance with the legislation.

These economic costs range between HK$ 25 million (lower bound for Option II) to HK$ 130 million (upper bound for Option V). As for the financial analysis Options IV and V are significantly more expensive than Options II and III (HK$ 55 million to HK$ 130 million vs HK$ 25 million to HK$ 84 million).

Cost to Consumers

Discussions with food manufacturers and retailers suggest that the costs associated with achieving a certain GM-status are unlikely to be passed onto consumers. Indeed, Hong Kong based food manufacturers and retailers who have already undergone reformulation note that it has not changed their retail price – in reality their retail prices are a response to market pressures and have, in some cases, been decreasing.

However, in order to illustrate the maximum possible impact in the unlikely event that any costs are passed onto the consumer, the study has calculated the financial impact as a percentage of household expenditure on food. This analysis suggests that the maximum possible impact on overall food prices could be between 0.03% (for Option II) and 0.10% (for Option V) in terms of household expenditure.

6.1.3 *GM-Free Scenarios*

The trade may label their products with GM-free or similar negative claims on a voluntary basis because of the potential market niche for these products and they would like to inform their customers of the "non-GM" nature of their products. The Study examined the impact of regulating GM-free or equivalent claims on those products that already carry such claims. Two GM-free scenarios were compared against the status quo. The first requires those making GM-free or similar negative claims to provide sufficient documentation to verify the status of the product. The second prohibits the use of GM-free and equivalent negative claims.

The analysis suggests that prohibiting GM-free and equivalent labelling is likely to incur less costs than requiring them to produce IP documentation. However, prohibiting GM-free and equivalent negative labelling might limit consumers' choices. On the other hand, the additional cost for producing IP documentation would likely be borne by overseas manufacturers while the costs of re-labelling are more likely to fall on Hong Kong companies (e.g. importers and retailers).

6.2 *BARRIERS TO IMPLEMENTATION*

If the Administration chooses to proceed with any of Options II to V the following issues are likely to impact on the implementation of the selected option.

Lack of International Consensus on GM Labelling

Different jurisdictions in the Asia Pacific region, and beyond, have adopted different approaches, terminology and wording requirements for GM and GM-free labelling of food. In addition, the international community, in the form of the Codex Alimentarius Commission of the United Nations, is still working towards a consensual policy on GM food labelling. Agreement is unlikely before 2004. Since Hong Kong has always taken Codex as reference in formulating its food labelling regime, the introduction of a scheme in Hong Kong that does not align with any eventual agreement by Codex and regional schemes would mean further legislative change and would place additional costs on the Hong Kong's food trade as well as confuse consumers.

The Future of GM Crops

New GM crops are continually being developed and commercialised and as such there remains considerable uncertainty over the extent of the financial

and economic impact of any GM labelling scheme. If a lot more GM crops are commercialised, and in the absence of any international agreement on their labelling, the impact on the Hong Kong food trade could be higher than that predicted by this Study.

Lack of International Consensus on GM Testing

International consensus on GM detectability and quantification limits and methodologies has not yet been reached. The Codex Working Group [1] on Analytical Methods has published a list of validated methods, but these are still up for discussion. Most of these methods use PCR methodologies to screen or qualitatively test for specific rDNA. Only a sub-group of the methods can provide quantitative results. As with many Codex committees, consensual agreement on methods may not be reached in the near future.

As such, areas that are likely to be 'problematic' or meet with resistance from different stakeholders include:

- threshold established and therefore sensitivity of tests required;
- number of individual traits tested for (and how to cope with future traits);
- standards and protocols surrounding tests; and
- means of verification for non-rDNA biotechnology products.

Currently, the UK Food Standards Agency [2] is of the view that 0.1% is the technical limit at which meaningful conclusions can be drawn on the presence of novel DNA. Commercial testing laboratories suggest that the limits below which there is uncertainty are: 0.01% for detectable limits; and 0.1% for quantification.

The lack of international consensus raises the issues of which limits and methods the HKSAR Government should adopt and whether these should be mandated to the food trade. In addition, if these limits and methods were not agreed prior to the implementation of GM labelling regulations, the lack of internationally accepted standards might preclude effective enforcement by the Administration.

Proficiency Certification of Independent Laboratories

A query raised by stakeholders was the reliability and independence of laboratories. Some manufacturers would like to see a certification scheme for testing laboratories, to verify the quality of the services that they would receive and to ensure that their products meet the requirements of export markets and any labelling requirement that the HKSAR Government is to implement. This raises the issue as to whether the HKSAR Government

(1) Working group under the Codex Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology

(2) FSA press release, December 2000

should provide such an accreditation scheme prior to the implementation of any regulations mandating GM labelling. It should be noted, however, that accrediting private laboratories would require much time and human resources.

Difficulties with Top 5 Ingredients Approach

Companies change ingredients and suppliers on a continual basis. A label may state emulsifier but this might be comprised of three different emulsifiers. Companies would be reluctant to give compositional analysis by particular ingredient, as this is proprietary brand-specific information and commercially highly sensitive. Further, it was suggested by one of the testing laboratories that it can be difficult to establish which ingredient within the food product is responsible for the novel GM-DNA detected. For example, if one of the top 5 ingredients had GM content of 3%, whilst another had a GM content of 5% or above (but is not one of the top 5 ingredients), the food product when tested may register novel GM-DNA content over the threshold. In order to prove the product met the requirement of the standard, the food producer would need to provide details of the ingredients to the regulatory agency and further testing would be required. Again, the company may be reluctant to share this commercially sensitive information.

Documentation

There are currently no international standards on IP and similar documentation systems for certifying the GM content of products. As such the introduction of any labelling scheme, whether negative or positive labelling, that relied on such documentation could be problematic.

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Annex A

Review of International Labelling Regimes

A1 GM LABELLING REGIMES (IMPENDING OR CURRENT).

A1.1 AUSTRALIA AND NEW ZEALAND

Initially Australia and New Zealand adopted labelling of significantly changed characteristics but have since revised their regulations and have enforced mandatory labelling of GM foods from December 2001. This policy shift was driven by 2 factors: 1) response to consumer anxiety and the need to update the overall labelling regimes, and 2) the harmonization of the Australian and New Zealand markets. The Australia New Zealand Food Regulation Ministerial Council (ANZFRMC) (formerly the Australian and New Zealand Food Standard Council (ANZFSC)) is responsible for implementing these major changes in food regulation and adopting a new Food Standards Code.

Labelling is now mandatory for all food products that contain more than 1% of GM material. Some GM foods may require additional GM labelling under the standard. Additional GM labelling is required where the food has altered characteristics, or where the food carries identified ethical, cultural or religious concerns with respect to the genetic modification. Altered characteristics means that when compared to matching conventional foods the GM food is different in relation to:

- composition or nutritional values;
- anti-nutritional factors or natural toxicants;
- factors known to cause allergic responses in particular sections of the population; or
- its intended use.

Foods produced from conventional animals fed on GM stockfeed or crops do not have to be labelled as 'genetically modified' because they do not fall under the definition of a food produced using gene technology.

If the food or ingredient is listed in the standard as requiring additional GM labelling, specified labelling provided in the standard must be included in addition to the indication that the food is genetically modified. This requirement applies even if it is otherwise exempt from the general labelling requirement.

A recent article (1) noted that *"loopholes in the law and global indecision on how to identify GM foods have effectively neutralised the labelling regulations. Of the 100,000 items on supermarket shelves only an estimated 5% were expected to require labelling. Evidence from the food industry suggests that this figure could be as low as 2%"*.

(1) David Robertson, Far Eastern Economic Review, 7th February 2002

Exemptions

The Food Standards Australia and New Zealand (FSANZ, formerly the Australian and New Zealand Food Authority (ANZFA)) exempt the following categories under their "genetically modified" label standard:

- **Highly refined foods**, such as refined oils, sugars and starches that have undergone refining processes that have the effect of removing DNA and/or protein.
- **Additives and processing aids** that do not carry forward novel DNA or novel protein to the final food.
- **Flavourings** (including individual aromatic, carrier and other components) at no more than 1 g/kg (0.1%) in the final food as consumed.
- **Food intended for immediate consumption that is prepared and sold from food premises and/or vending vehicles.** This includes food prepared and sold from outlets such as restaurants, take-away outlets, caterers, or self-catering institutions where consumers can request information on the GM status of their foods from the vendor.

Determination of Novel DNA in the Final Food Product

FSANZ define novel DNA and/or novel protein to mean "DNA or protein that, because of the use of gene technology, is different in chemical sequence or structure from that in the matching conventional food".

Some processing methods have the effect of removing DNA and /or novel protein that may have been present in the original food or ingredient. These categories of food fall into the exemption categories outlined below.

FSANZ give further clarification on the exemptions:

(a) Highly refined foods

Highly refined foods are foods such as oils, sugars and starches, which have undergo refining processes that result in purified products from which DNA and protein has been removed. Refining processes do not always have the same effect and testing may be needed to establish that the specific processes used have removed DNA and protein in the refined product.

Processes that may be used to purify foods or ingredients include, but are not limited to:

- high temperature extraction;
- filtration and centrifugation;
- solvent extraction (aqueous or organic);
- distillation;
- crystallisation;
- dialysis and fractionation;

- coagulation and precipitation;
- caustic, acidic or oxidative purification; and
- fermentation and enzymic digestion.

Examples of highly refined foods are:

- crystalline sugars and sugar syrups;
- purified oils and their derivatives; and
- purified starches and derivatives.

Semi- or minimally refined foods are produced using simple processes such as crushing or husking which may not remove DNA and/or protein. For example, cold pressed or crudely refined oils may contain proportions of DNA and/or protein and therefore under FSANZ standards these categories may require labelling. In these circumstances, FSANZ suggested requesting further information from the supplier and/or undertaking appropriate testing.

(b) Food additives and processing aids

Food additives and processing aids are defined by FSANZ as:

"substances intentionally added to foods to achieve a technological function and normally remain present in the final food. Examples are preservatives, antioxidants and thickeners.

Processing aids are used in small amounts to perform a technological function in the processing of raw materials, foods or food ingredients and are normally not present in the final food. An example is the enzyme amylase used in some processes to clarify fruit or sugar juices."

FSANZ exempt both processing aids and food additives from GM labelling "unless they themselves are, or they contain, novel DNA or novel protein and the novel DNA or novel protein remains in the final food".

Lists of food additives and processing aids approved for use in food production are given in *Table A1.*

(c) Flavourings

Flavourings are a class of food additive that are concentrated natural or synthetic preparations added to foods to give taste and/or odour. They are used in small concentrations and are not meant to be consumed alone. Flavourings are at a concentration of less than 1 g/kg (0.1%) in the majority of foods in which they are used but may be above this level in some highly flavoured products.

Where a flavouring containing a permitted GM component (including individual carriers) is added to a food and the concentration of that flavouring is no more than 1 g/kg (0.1%) in the final food, no "genetically modified" label of the flavouring is required.

Table A1 ***Permitted Processing Aids Derived from GM varieties as at June 2001, FSANZ***

α-Acetolactate decarboxylase is produced by a genetically manipulated strain of Bacillus subtilis containing the gene for α-acetolactate decarboxylase isolated from Bacillus brevis and inserted using plasmid pUW235.
α-Amylase produced from a genetically manipulated strain of Bacillus licheniformis containing the gene for α-amylase isolated from Bacillus stearothermophilus and inserted using plasmid pPL1117.
α-Amylase produced from a genetically manipulated strain of Bacillus subtilus containing the gene for α -amylase isolated from Bacillus stearothermophilus and inserted using plasmid pPN1413.
Lipase produced from a genetically manipulated strain of Aspergillus oryzae containing the gene for lipase isolated from Humicola lanuginose and inserted using plasmids pBoe1960 and p3SR2.
Hemicellulose endo-1,4-ß-xylanase produced from a genetically manipulated strain of Aspergillus oryzae containing the gene for hemicellulase isolated from Thermomyces lanuginosus and inserted using plasmids pA2X1T1 and pToC90.
Hemicellulose endo-1,4-ß-xylanase produced from a genetically manipulated strain of Aspergillus oryzae containing the gene for hemicellulase isolated from Aspergillus aculeatus and inserted using plasmid pToC237.
Mucorpepsin produced from genetically manipulated strain of the fungus Aspergillus oryzae containing the gene for aspartic proteinase isolated from Rhizomucor miehei and inserted using the vector Escherichia coliK12.
Chymosin produced from genetically manipulated organisms Aspergillus niger var. awamori, Escherichia coliK12 strain GE81 orK luyveromyces lactisCHY1.

FSANZ Notifications to WTO

FSANZ notified the TBT Committee on 10 October 2000, and the SPS Committee, of potential changes to future labelling requirements due to an agreement to revise Standard A18 of the Food Standards Code which regulates the sale of food and food ingredients (other than additives and processing aids), which are produced using gene technology. The Standard requires the labelling of food when novel DNA and/or protein is present in the final food and also where the food has altered characteristics. The new requirement came into effect in December 2001.

A1.2 *EUROPE*

Since 1997 European legislation has made labelling of GM food mandatory for:

- products that consist of GMO or contain GMO.
- products derived from GMO but no longer containing GMO if there is still DNA or protein resulting from the genetic modification present.

The labelling of genetically modified foods is currently based on the provisions of article 8 of Regulation (EC) No 258/97 on novel foods and novel foods ingredients.

The labelling of GM maize varieties and GM soya varieties which did not fall under Regulation 258/97 are covered by Regulation (EC) 1139/98 concerning

the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms as amended by Regulation (EC) 49/2000.

In addition, all GM additives and GM flavourings have to be labelled according to Regulation (EC) 50/2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings.

In accordance with the general labelling rules of Directive 90/220/EEC, the labelling of 4 out of the 8 authorised GMOs for use in feed is mandatory.

Genetically modified seed varieties must be labelled in accordance with Council Directive 98/95/EEC.

Further details are available from http://europa.eu.int/comm/food/fs/gmo/gmo_index_en.html.

Ongoing initiatives

On 25 July 2001 the Commission prepared two proposals for new Regulations: a proposal for a Regulation on traceability and labelling of GMOs and products produced from GMOs and a proposal for a Regulation on GM food and feed. The measures laid out in these proposals require the traceability of GMOs throughout the food chain from farm to table and provide consumers and farmers with information by labelling all food and feed consisting of, containing or produced from a GMO.

A1.3 *CANADA*

On 12 September 1995, Health Canada notified the TBT Committee of a proposed amendment to the Food and Drug Regulations (Schedule No. 948). It was proposed that there be a new category within the Food and Drug Regulations that would "define the concept of "novel food" and provide for notification prior to the sale or advertising for sale of such products" in order to protect "human safety".

Foods that were to be considered as "novel" under the proposal include:

> Substances/processes that have previously not been used as food in Canada; food substantially modified from the traditional product/process; food modified by genetic manipulation; food containing micro-organisms.

It is suggested that the criteria for defining "novel foods" was based on the draft European Union Directive on Novel Foods and Food Ingredient.

Canada's 1995 proposed guidelines were for the *voluntary* labelling of GMO foods requires the "labelling of a product when the product differs significantly from its traditional counterpart in terms of nutritional content, composition, intended use, or if the food carries a health or safety risk (e.g. allergenicity) that can be mitigated through labelling". Canada states that

"this approach provides important information to consumers and is consistent with Canada's WTO obligations".

A *voluntary national standard* for the labelling of "Foods Obtained or Not Obtained through Genetic Modification" was proposed in 1999 by the Canadian Council of Grocery Distributors and other stakeholders including the Canadian General Standards Board. A first draft standard was released for public comment from August to November 2001. It is understood that a second draft of the standard has been created (incorporating significant comments received on the first draft) and will be circulated in late 2002.

On 23 May 2000, Canada submitted a Communication to the TBT Committee concerning *The Development of a Voluntary Standard for the Labelling of Foods Derived From Biotechnology*. Canada is pressing for a *voluntary labelling regime* rather than a mandatory one on the grounds that this is the "less trade restrictive approach for providing information to consumers".

Health Canada and the Canadian Food Inspection Agency cooperate on matters related to food labelling.

A1.4 *THAILAND*

Thailand notified the SPS Committee (and also the TBT Committee on 15 October 2001) on 5 October 2001 of the intention to introduce *mandatory labelling* for specific GM foodstuffs, which are as follows:

(1) Soya bean; (2) Tofu; (3) Dried Soya bean curd, soya bean refuse, yabu; (4) Natto (fermented soya bean); (5) Soya bean milk; (6) Soya bean paste; (7) Cooked soya bean; (8) Canned or bottled or retort pouch soya bean; (9) Roasted soya bean flour; (10) Roasted soya bean; (11) Food containing items 1 to 10 as main ingredient; (12) Food containing soya bean flour as main ingredient; (13) Food containing soya bean protein as main ingredient; (14) Food containing green soya bean as main ingredient; (15) Food containing soya bean sprouts as main ingredient; (16) Corn; (17) Corn snack; (18) Corn flour; (19) Popcorn; (20) Frozen or chilled corn; (21) Canned or bottled or retortable corn; (22) Food containing corn flour as main ingredient; (23) Food containing corn grits as main ingredient; (24) Food containing items 16 to 21 as main ingredient. According to Thai Food and Drug Administration Notification No. 251 (2545), which covers GMO labelling, labelling of negative claims (i.e., non-GMO, GMO free, No GMO ingredients, etc.) is prohibited (2)."

A1.5 *JAPAN*

In April 2001, Japan introduced labelling regulations requiring 5 designated agricultural products and 24 processed food items containing over 5% of approved GM material to be labelled as such. However, labelling is only

(2) Personal Communication with Darunee Edwards, National Center for Genetic Engineering and Biotechnology

required if a GM ingredient is a main ingredient. An ingredient is considered a "main ingredient" if it is one of the top three constituents of the food by weight and if it comprises at least five percent of the food by weight.

The 24 foods currently subject to labelling requirements were selected because they are made from ingredients that could include the products of biotechnology, and because it is possible to detect the genetically-introduced DNA or protein in the foods. If companies want to label their products as being "Non-GM", they must also provide certification to show that proper IP handling procedures were followed. Responsibility for this certification lies with suppliers, and not with Japan's food importers or manufacturers.

Box A1.1 ***Products covered by Japan's Labelling Legislation***

Agricultural Products

1. Soya bean (including green soya beans and soya bean sprouts)
2. Corn
3. Potato
4. Rapeseed
5. Cottonseed

Processed Food Items

1. Tofu (soya bean curd) and fried tofu
2. Dried soya bean curd, soya bean refuse, yuba
3. Natto (fermented soya bean)
4. To-nyu (soya milk)
5. Miso (soya bean paste)
6. Cooked soya bean
7. Canned soya bean, bottled soya bean
8. Kinako (roasted soya bean flour)
9. Roasted soya bean
10. Item containing food of items 1 to 9 as a main ingredient
11. Item containing soya bean (for cooking) as a main ingredient
12. Item containing soya bean flour as a main ingredient
13. Item containing soya bean protein as a main ingredient
14. Item containing edamame (green soya bean) as a main ingredient
15. Item containing soya bean sprouts as a main ingredient
16. Corn snacks
17. Corn starch
18. Popcorn
19. Frozen corn
20. Canned or bottled corn
21. Item containing corn flour as a main ingredient
22. Item containing corn grits as a main ingredient
23. Item containing corn (for processing) as a main ingredient
24. Item containing food of items 16 to 20 as a main ingredient

It is understood that processed potato products (eg mashed potatoes, frozen french fries, potato starch, potato snacks etc) and high oleic acid soya bean are going to be added to the list of food items from 2003.

Food products containing less than 5% of approved GM crops such as corn and soya beans can be labelled as "Non-GM" and the processor must be able to show that all GM ingredients were handled on an IP basis from production through processing. If the GM content of these 24 processed foods exceeds 5%, they must be labelled either "GM ingredients used" or "GM ingredient

not segregated". Other exemptions from labelling include refined edible oils and sauces, where the original GM proteins can no longer be detected. Packages less than 30 cm^2 are also exempt from requirements. Labelling is not required for animal feed.

Notifications to the WTO

The Japanese National Tax Agency notified the TBT Committee on 25 March 2002 of the "revision of standards for labelling for liquor made from genetically modified agricultural products".

A1.6 TAIWAN

Voluntary labelling of GM food was introduced by the Department of Health from 1 January 2001 while mandatory labelling of designated foods containing GM soya bean or corn will be introduced in three stages starting from January 2003.

Food products containing an ingredient of genetically modified soya bean or corn that is more than five percent (5%) by weight of finished product shall be labelled with the words "Genetically Modified" (GM) or "Containing Genetically Modified". Food products made of non-GM soya bean or corn may be labelled with the words "Non-GM" or "Not GM".

Non-GM soya bean or corn adventitiously or accidentally commingled with less than five percent (5%) of GM varieties during harvesting, storage, transporting, or other reasonable causes, may be labelled as Non-GM.

Soya sauce, soya bean oil (salad oil), corn oil, corn syrup, and corn starch etc. made of GM soya bean or corn are exempted from the GM labelling requirement.

Effective dates for mandatory labelling:

- On January 1, 2003, mandatory GM food labelling will take effect for soya bean and corn products in the raw agricultural form, including soya bean meal (flour), corn grit/meal (flour).
- On January 1, 2004, mandatory GM food labelling will take effect for primarily processed soya bean and corn products, including tofu, dried tofu, soya milk, soya curd, frozen corn, canned corn, and soya protein products.
- On January 1, 2005, mandatory GM food labelling will take effect for all other processed soya bean and corn products with the exception of those highly processed food items including soya sauce, soya bean oil (salad oil), corn oil, corn syrup, and cornstarch etc., which do not contain fragments of transgene or its protein.

Import Inspection Scheme

The Bureau of Standards, Metrology and Inspection and Department of Health agreed to perform labelling inspections on packaged food only. Continuing uncertainties exist surrounding the identification methodologies for all commercial bioengineered soya bean and corn varieties.

Identification of bioengineered soya bean and corn varieties is a time and capital intensive process so that there will be no specific import inspections initiated for bio - engineered variety checks at the port of entry. As to voluntary non- GM food labelling, the Food Sanitation Bureau plans to review the non-GM certificates provided by suppliers instead of conducting expensive laboratory testing.

A1.7 KOREA

Korea adopted GM labelling regulations in March 2001 for agricultural commodities and for designated processed products in July 2001. Korea set a threshold of 3% GM of raw materials. Only designated food items that contain GM soya bean, corn or bean sprouts as a major food ingredient (i.e. as one of the top five ingredients) have to be labelled. Minor ingredients are exempt from labelling. The system is applied to 27 different types of goods including bread, corn flour, tofu, Korean pepper sauce and canned corn. The designated food items are detailed in *Box A1.2*.

Box A1.2 ***Products Covered by Korean Labelling Legislation***

1. Bean flour among processed bean products classified under the ordinary processed food category
2. Corn flour among processed grain products classified under the ordinary processed food category
3. Processed bean products containing bean or bean flour classified under ordinary processed food category
4. Processed grain products containing corn or corn flour classified under the ordinary processed food category
5. Canned beans among processed bean products classified under the ordinary processed food category
6. Canned corn among processed grain products classified under the ordinary processed food category
7. Bread (bakery goods) and rice cakes classified under the confectioneries category
8. Dried confectioneries (e.g. cookie, biscuits) classified under the confectioneries category
9. Tofu (soya bean curd) classified under the tofu category
10. Processed tofu classified under the tofu category
11. Whole tofu classified under the tofu category
12. Soya milks
13. Infant formula classified under the special nutritional food category
14. Formula for the growth period classified under the special nutritional food category
15. Grain formula for infant/baby classified under the special nutritional food category
16. Other infant/baby food classified under the special nutritional food category
17. Nutritional supplementary food classified under the special nutritional food category
18. Doenjang (soya bean paste) classified under the seasoning food category
19. Gochujang (hot pepper soya bean paste) classified under the seasoning food category
20. Chungkukjang (fermented soya bean paste) classified under the seasoning food category
21. Mixed bean paste classified under the seasoning food category
22. Hard boiled foods classified under the Kimchi/pickles category
23. Meju (fermented dry soya bean paste - Korean soya bean koji) classified under the other food category
24. Corn starch among starches classified under the other food category
25. Processed corn products for popcorn classified under the other food category
26. Other food products using, as major raw materials, bean, corn and bean sprouts
27. Other food products using, as major raw materials, any of the above (1 thru 26)

The following processed products are automatically exempted from GM labelling requirements:

- final food products that do not contain GM DNA or foreign protein.
- soya bean lecithin when used as a food additive, not a food ingredient.
- soya sauce.
- soya bean and corn oil.
- beer, whiskey, brandy, liquor, distilled liquor, other alcoholic beverages, etc. among foods categorized under alcoholic beverages.
- a food product categorized as a "saccharide" under the Korean Food Code (e.g. starch syrup, dextrin, glucose, oligosaccharide, fructose, etc.).

Over the first six months of the system, the administration focused on guiding food companies to follow the regulations rather than punishing violators. When food makers are uncertain about whether ingredients they use contain GMOs, they will have to identify products by saying the foods could contain bioengineered materials. Companies breaking regulations for the first time will be banned from manufacturing and selling products for between 15-30 days.

Notifications to WTO

The Korean Ministry of Health and Welfare notified the SPS Committee on 1 May 2000 of legislation amended by the National Assembly of the Republic of Korea (Amendment of Food Sanitation Act (Available in Korean, 38 pages)), "in order to mitigate restrictive controls on food businesses" for food safety, including consideration of a *mandatory* GM labelling regime provision.

The amended provisions are as follows:

Provide legal basis for *labelling* foods and food additives made of/from raw genetically modified materials; delete provisions related to pre-market inspection for selected foods; mitigate the food service business control system while enforcing the responsibilities of business and increase protection for the young; rationalise the education/training requirements for employees and employers of food businesses; delete the provisions related to food safety managers in food businesses; rationalise the license system for nutritionists; mitigate the requirement for the foundation of business associations; enforce the destruction of non-conforming foods.

A1.8 *SOUTH AFRICA*

The Government of South Africa is planning to implement a regulation for the labelling of GM foodstuffs based on health concerns through hypersensitivity. The *(Draft) Regulations Governing the Labelling of Foodstuffs Obtained through Certain Techniques of Genetic Modification*, Government Notice No. R. 366 of 4 May 2001 were notified to the WTO SPS Committee on 22 February 2002 by the South African Department of Health. There may be other aspects of the labelling regime that are TBT related.

A1.9 *SWITZERLAND*

Already in force in Switzerland is the Food Ordinance of 1 March 1995, which states that foodstuffs, additives and processing aids, which were or contained genetically modified organisms, have to be labelled as "GMO-Product". The Federal Office of Public Health of Switzerland notified the SPS Committee on 21 October 1998 of a proposal to amend Article 22 of the Ordinance as in the current form only products that were 'free' from GMOs and purified from genetic material were exempt from the labelling rule. This rule required that any conventional products that had been in contact with GMO-derived

products or traces thereof had to be labelled as "GMO-Product". The Swiss found this rule to be "impracticable".

To this end, the amended labelling rule now only requires labelling of a product "if the GMO-derived part in a product is above a defined threshold". The result is that there are now two distinct product-labelling categories: those that are a "GMO-Product" and those that are "free of GMOs". The proposed date for entry into force of the new labelling Ordinance was 15 January 1999. Products labelled under previous regulations could retain the 'old' label until 31 December 1999 and GM foodstuffs that were newly approved had to be labelled with the 'new' criteria from January 1 2000.

GM foods for sale in restaurants and so forth also have to be labelled under Article 23 of the Ordinance.

A1.10 *CHINA*

China passed Regulations on Safety Control of Agricultural GMO (Ag GMO).

Implementation of China's Ag GMO measures is outlined in three documents. These are: 1) measures on GMO safety evaluation; 2) measures on GMO Imports, and; 3) measures on GMO labelling. The measures on GMO labelling became effective from 20th March 2002 while other measures will be effective from 20 September 2003. Details are available at: http://www.agri.gov.cn.

Measures on GMO safety evaluation

The measures cover GM animals, plants and micro-organisms and include products directly processed from GM agricultural products, GM planting seeds, breeding livestock, poultry, fish fry, pesticides, veterinary medicines, fertilizers and additives containing GM ingredients.

In essence, an Ag GMO safety certificate is required for the above categories of GMOs before examination, registration, evaluation and approval formalities are started. After which GMOs are subject to safety evaluation to determine the level of safety class. The costs of the relevant testing and safety evaluation in order to achieve relevant safety evaluation documents fall on the producer or the importer. Independent Technical Inspection Agencies (who have met the appropriate conditions and capacity) can carry out technical inspection to appraise and examine the Ag GMOs.

Ministry of Agriculture will establish a nationwide Ag GMO monitoring system to guide the Ag GMO safety monitoring system. Failure to abide by the Ag GMO safety systems will be penalized under a number of Articles of the Regulations.

Measures for the Safety Administration of Agricultural GMO imports

Imported Ag GMOs for safety administered fall under three categories in accordance with the Ag GMOs usage: testing and research; production; and, raw materials.

Imported Ag GMOs require accompanying documentation that covers certification, safety protection applications and registrations documents. For import of Ag GMOs to be used as raw materials, if the raw materials are viable, import records need to be kept with documentation relating to source, storage and transportation. The Ministry of Agriculture will make a decision within 270 days of receiving the application forms.

Measures for Ag GMO Labelling Administration

Introduce a system to standardize the selling, production and consumption of GMO's and protect consumers' rights to be informed. An approved list will be published by the Agricultural Administrative Department. All listed GMOs require labelling. The Ministry of Agriculture shall be in charge of nationwide examination and supervision of GMO labelling. Agricultural administrative department of local governments will be in charge of local administration and supervision of Ag GMO labelling.

The State Administration for Quality Supervision, Inspection, and Quarantine (AQSIQ) shall be in charge of label inspection at port.

Responsibility for labelling of listed Ag GMOs lies with the producer, packer and individuals concerned. If the original packaging is opened for the purpose of sale, the seller shall re-label the Ag GMOs.

Regulations concerning the actual placing of a label on a product include wording, format and that the label should be easy to notice.

Labelling wording and format will follow:

1) For GM planting seeds, breeding livestock, poultry, fish fry and microorganisms and products with genetically modified animal, plant or microbe ingredients such as planting seeds, breeding livestock, poultry, fish fry, pesticides, veterinary medicines, fertiliser and additives shall be directly labelled "genetically modified XX".

2) Products made directly from Ag GMOs shall be labelled "genetically modified XX products" or "with XX as raw materials".

3) Products made from Ag GMOs or materials with GM ingredients that no longer contain GM ingredients of the GM ingredients cannot be detect in the final products for sales shall be labelled "This product is made from genetically modified XX, but the product no longer contains genetically modified ingredients".

For snack foods or unpackaged food sold without labels, label boards at point of sales are required.

Labels for imported food require approvals from the Ministry of Agriculture, and copies of the label need to be submitted to the AQSIQ, the Ministry of Trade and Economic Cooperation (MOFTEC).

The responsibility for labelling falls to the seller of the good. Sellers need to check the goods and the labels when procuring the items.

Ag GMOs included under the labelling system are:

1. soya bean for planting, soya bean, soya bean flour, soya bean oil, and soya bean meal;
2. corn seeds for planting, corn, corn oil, and corn flour (including corn flour with harmonized schedule codes 11022000, 110111300, 11042300);
3. rape seed for planting, rape seed, rape oil and rape meal;
4. cotton seed for planting;
5. tomato seed for planting, fresh tomato, and tomato sauce.

In addition the Ministry of Health, on 1 June 2002, enacted administrative measures (*"Administration Measures for Genetically Modified Food Hygiene."*) that require the labelling of GM products. These measures will become effective from 20 September 2003 and they include:

- food products (including raw material and its processed food) that contains GM organism and/or GM expressed product shall be labeled as "GM XX food" or " made from GM XX food".
- GM food that derives from potential allergic food shall also be labeled "this product is modified from XX food gene, those who are allergic to XX food should take caution".

Notifications to the WTO

The Chinese Government chose not to notify the TBT Committee of the proposed regulations and has thus formally breached the transparency provisions of the TBT Agreement. In its defence, it claims that this regulatory development pre-dated China's membership of the WTO. The transparency issue is merely a sidebar which deflects attention from the more salient issue of whether the Chinese regulations breach international trade law.

The Chinese Government did however, notified the SPS committee of the new regulations (The Ministry of Agriculture notified SPS committee on 19 April 2002 while the Ministry of Health notified the SPS committee on 26 June 2002).

A2 ENFORCEMENT APPROACHES ADOPTED

A2.1 JAPAN

In 2001, the Ministry of Health, Labor and Welfare (MHLW) requested a larger budget to strengthen inspection of foods. MHLW requested 269 million yen for Japanese Fiscal Year 2002 (April 2002 - 2003). This was an increase of 90 million yen over the JFY 2001 budget.

2001 testing was at 5% of total imports for certain raw food products. It was stated that MHLW plan to double the number of samples, focusing on processed foods. Tests would be carried out using the testing services of local prefectural office health authorities.

To strengthen verification of test results, MHLW propose to improve the accuracy of the analytical testing by reputable testing organisation utilized by local health authorities. Technical seminars will also be held for officials from local authorities.

Total biotechnology food tests for imported foods in 2002 will total 1,362 samples.

MHLW intend to sample shipments for biotechnology products that have not been approved in Japan for food use, as well as testing quantitatively for approved biotechnology corn and soya bean traits to confirm compliance with "non-GM" labelling requirements.

Testing for Unapproved Biotechnology Foods

Corn and corn derivatives

For unapproved biotechnology corn CBH351 (StarLink): Total 136 samples.

A. Corn kernels: US: 33 samples, Argentina and other countries: 25 samples.

B. Ground corn processed foods (corn grits, corn flour, corn meal, etc, in which proteins newly expressed by genetic modification are nor physio-chemically altered) 14 samples.

C. Other processed foods of corn: 64 samples.

Papaya and its processed foods

For unapproved 55 - 1 papaya: total 823 samples.

A. Fresh papaya: US: 789 samples. Other countries: 28 samples.

B. Papaya processed foods (limited to dried papaya): 6 samples.

Potato processed products

For unapproved biotechnology potato (New Leaf Y): Total 240 samples.

Testing for Approved Biotechnology Foods to Confirm Compliance With "non-GM" Labelling Requirements

For presence ratios of approved biotechnology corn: total 45 samples.

Corn and ground corn processed foods (corn grits, corn flour, corn meal, etc. in which proteins newly expressed by genetic modification are not physio-chemically altered).

A. Corn kernels: US 16 samples; Argentina and other countries 15 samples.

B. Ground corn processed foods: 14 samples.

Soya bean and ground soya bean processed foods (those in which proteins newly expressed by genetic modification are not physio-chemically altered).

A. For the presence ratio of approved biotechnology soya bean: Total 118 samples.

B. Soya beans (including edamame – green soya beans and soya bean sprouts) and ground soya bean processed foods: US 44 samples. Other countries 74 samples.

A2.2 KOREA

Unprocessed Commodities

On 19th Feb 2001 the Ministry of Agriculture (MAF) released a 3 step plan outlining enforcement of labelling requirements for unprocessed agricultural commodities, soya beans, corn and bean sprouts.

1) (Jan – Feb) 2 month promotion, education programmes. Sending letters to industry and conducting preliminary monitoring in markets, analysis and others.

2) (March – August) MAF will continue to focus on education and guidance programs to industry. MAF will also conduct visits, public relations and education programs.

3) After September 1 – MAF will regulate GMO labelling in full using 'social verification' (e.g. documentation, others) and scientific verification (e.g. test monitoring).

- Emphasis for 6 month period would be on education with MAF giving guidance and advise, instead of imposing penalties.

- Person responsible for labelling is the seller (this includes importers, wholesalers, retailers, bean sprout producer).
- Penalties for false labelling: jail sentence for three-year or less or fine for 30 million won.
- Penalties for no labelling: fine for 10 million won or less.

Processed Food

Korean Food and Drug Administration (KFDA) and MAF initiated a country tour in June 2001, on a joint explanation session on biotech labelling. Industry, related associations and the general public were invited to the session aimed at providing general information on biotechnology.

A2.3 *IRELAND*

The Food Standards Authority Ireland's (FSAI's) approach to enforcement has been to undertake a 'supermarket sweep' of likely products. Survey results from 1999/2000 of 103 samples found 13 samples with maize and soya products to test positive for GM content. Of these 13 positive results, 2 were from unapproved GM ingredients and the companies were contacted with instructions to remove the products from sale. A more recent survey of 37 soya products found that 18 samples tested positive for soya content but all were under the threshold level. However 6 of these samples were mislabelled as 5 indicated that they contained no GM ingredients and 1 was labelled as organic.

A2.4 *UK*

The UK took a similar approach with the UK's Food Standard Authority undertaking similar random testing approximately every 6 months. In January 2002 tests of 203 baked goods (bread, cakes and buns) 15% tested positive for traces of GM soya, however only 3 of these samples were above the 1% threshold. The Food Authorities (3) work with the industry and decide whether to make the results publicly available or publish them within industry. Local food authorities and port health authorities are responsible for enforcement. Conviction for an offence results in a fine in the order of £5,000. In response to the later regulations issued in 2000 (Genetically Modified and Novel Foods (Labelling) (England) Regulations 2000), the UK government has stated that it intends to issue further guidance notes to accompany these regulations.

(3) "Food Authorities" are defined in the Food Safety Act 1990, but in effect this refers to the Trading Standards Officers or Environmental Health Officers in Local Authorities.

A2.5 DENMARK

Denmark has also adopted a similar random testing approach. In 2000, 103 tests of food products containing soya bean and corn ingredients were conducted. Of the 103 samples, 25 had no detectable traces of DNA, 25 contained GMO products under the 1% threshold whilst 8 were tested to show GMO at levels between 2 and 3 % (and therefore above the EU permissible level). These products included meat products with soya bean protein, cake mix containing corn and a protein drink. For the 8 products found with a 2-3% GM level, the companies all claimed to have had non-GM verification from their suppliers. The companies subsequently recalled their products.

Annex B

Crops Approved for Food Use

B1 FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ) PERMITTED CROPS

Table B1.1 FSANZ Permitted Crop List

Crop	Trait	Applicant	Approval Date
Canola	Glyphosate tolerant canola GT73	Monsanto Australia	24-Nov-00
Canola	Glufosinate ammonium tolerant canola topaz & glufosinate ammonium tolerant canola with fertility traits	Aventis CropScience	Pending Gazettal
Corn	Insect-resistant corn Mon 810	Monsanto Australia	24-Nov-00
Corn	Glyphosate tolerant corn	Monsanto Australia	24-Nov-00
Corn	Insect-resistant corn (Bt-176)	Syngenta Seeds	31-Jul-01
Corn	Insect-resistant, glufosinate ammonium tolerant corn line (Bt-11)	Syngenta Seeds	31-Jul-01
Corn	Glufosinate ammonium tolerant corn T25	Aventis CropScience	Pending Gazettal
Cotton	Insect resistant cotton	Monsanto Australia	28-Jul-00
Cotton	Glyphosate tolerant cotton 1445	Monsanto Australia	24-Nov-00
Cotton	Cotton resistant to bormoxynil	Stoneville Pedigreed Seed Company and Aventis CropScience	Pending Gazettal
Potato	Colorado Potato Beetle resistant potato	Monsanto Australia	31-Jul-01
Potato	Colorado Potato Beetle resistant potato with resistance to potato leaf roll virus	Monsanto Australia	31-Jul-01
Potato	Colorado Potato Beetle resistant potato with resistance to potato virus Y	Monsanto Australia	31-Jul-01
Soya	Glyphosate tolerant soya bean	Monsanto Australia	28-Jul-00
Soya	High oleic acid soya beans	Du Pont	24-Nov-00
Sugarbeet	Glyphosate tolerant sugarbeet GTSB77	Monsanto Australia	Pending Gazettal

Source: www.foodstandards.gov.au/whatsinfood/gmfoods/gmcurrentapplication1030.cfm as at 13 December 2002

Directive 258/97/EC introduced a pre-market approval system for all novel foods and superseded the marketing consent provisions of EC Directive 90/220. Supplemental risk assessment guidance was also provided by the Commission in Recommendation 97/618/EC.

Two GMOS were approved by 90/220/EEC for use in the human diet (one maize, one soya variety) and eight were approved for use in animal feed. No GM food has so far been authorised under the Novel Foods Regulation, but eleven products, assessed to be substantially equivalent to existing conventional foods, have been notified via the fast-track system.

Table B2.1 EU approved crops

Crop	Trait	Applicant	Approval Date
GM products – approved for human consumption under directive 90/220/EEC as of March 2001			
Soya	Soya beans tolerant to glyphosate	Monsanto	3 April 1996
Corn	Bt-maize tolerant to glufosinate ammonium (Bt-176)	Ciba-Geigy	23 January 1997
Notifications Pursuant to Article 5 of Regulation (EC) N° 258/97			
Canola	Processed oil from genetically modified canola seed, transformation event TOPAS 19/2 and all conventional crossed	AgrEvo	9 June 1997 (24 June 1997)
Canola (oilseed rape)	Processed oil from genetically modified oilseed rape seed derived from: i) male sterile MS1Bn (B91-4) oilseed rape line and all conventional crosses; ii) fertility restorer RF2Bn (B94-2) oilseed rape line and all conventional crosses; iii) hybrid combination MS1XRF2 iv) fertility restorer RF1Bn (B93-101) oilseed rape line and all conventional crosses; v) hybrid combination MS1XRF1	Plant Genetic Systems	10 June 1997 (24 June 1997 again 28 July 1998)
Canola (oilseed rape)	Refined oil from glyphosate tolerant oilseed rape line GT73	Monsanto	10 November 1997 (21 November 1997)
Corn	Food and food ingredients produced from maize flour, maize gluten, maize semolina, maize starch, maize glucose and maize oil derived from the progeny of maize line MON 810	Monsanto	10 December 1997 (6 February 1998)
Corn	i) Starch and all its derivatives; ii) crude and refined oil; iii) all heat-processed or fermented products obtained from hominys, grits and flour (dry milled fragments) obtained from the genetically modified maize, tolerant to glufosinate ammonium, transformation event T25 and all the varieties derived from	AgrEvo	12 January 1998 (6 February 1998)
Corn	Food and food ingredient products derived from the original transformant Bt11 crossed with the Northrup King Company inbred line	Novartis	30 January 1998 (6 February 1998)

Crop	Trait	Applicant	Approval Date
	#2044 (maize), as well as from any inbred and hybrid lines derived from it and containing the introduced genes		
Corn	Novel foods and novel food ingredients produced from gentically modified maize line MON 809	Pioneer Overseas Corporation	14 October 1998 (23 October 1998)
Canola (oilseed rape)	Processed oil from genetically modified oilseed rape derived from Falcon GS 40/90	Hoechst Schering, AgrEvo GmbH	21 October 1999 (8/9 November 1999)
Canola (oilseed rape)	Processed oil from genetically modified oilseed rape derived from Liberator L62	Hoechst Schering, AgrEvo GmbH	21 October 1999 (8/9 November 1999)
Canola (oilseed rape)	Processed oil from genetically modified oilseed rape derived from: • the male sterile MS8 (DBN 230-0028) oilseed rape line and all conventional crosses; the fertility restorer RF (DBN212-0005) oilseed rape line and all conventional crosses; • the hybrid combination MS8 x RF3	Plant Genetic Systems	21 October 1999 (8/9 November 1999)
Bacillus subtilis	Riboflavin from Bacillus subtilis as nutrient	F. Hoffman - La Roche Ltd.	20 March 2000 (26 April 2000)

Source: Downloaded from European Community website on 13 December 2002.

Notes: For notifications under *Article 5 of Regulation (EC) N° 258/97* the 'approval dates' are the notification dates, with the dates in brackets being the date transmitted to Member States.

B3 *US FDA LIST OF COMPLETED CONSULTATIONS ON BIOENGINEERED FOODS*

The following text has been taken (and adapted) from the FDA website. Full text and associated links can be found at the FDA website: www.cfsan.fda.gov/~lrd/biocon.html

The US FDA recommended in the 1992 Statement of Policy: "Foods derived from New Plant Varieties" (1) and further in the 1997 'consultation procedures' (2) that all developers should consult with FDA to identify and discuss relevant safety, nutritional and / or other regulatory issues regarding bioengineered foods. Following these consultations, the procedures recommend that the developer then submit a summary of its scientific and regulatory assessment to the FDA for evaluation.

In the Federal Register of January 18, 2001 (the premarket notification proposal; 66 FR 4706), FDA issued a proposed rule that would require that developers submit a scientific and regulatory assessment of the bioengineered food 120 days before the bioengineered food is marketed. In the premarket notification proposal, FDA recommends that developers continue the practice of consulting with the agency before submitting the required premarket notice.

Most bioengineered plants are considered "regulated articles" under regulations of the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA). At some stage of research and development of a regulated article that is intended for use as a food crop, a developer requests from APHIS a determination of the article's regulatory status. For additional information about APHIS' regulation of bioengineered plants, see www.aphis.usda.gov/biotech.

The safe use of pesticidal substances is regulated by the Environmental Protection Agency (EPA). Thus, a bioengineered food that is the subject of a consultation with FDA may contain an introduced pesticidal substance that is subject to review by EPA. FDA has identified each bioengineered food that contains an introduced pesticidal substance with an asterisk (*). For additional information about EPA's regulation of bioengineered foods that contain a pesticidal substance, see www.epa.gov/pesticides.

The table below lists all completed FDA consultations regarding bioengineered foods.

- Identifies the food crop that was modified;

(1) Federal Register of May 29, 1992, (57 FR 22984)
(2) Guidance on consultation procedures: foods derived from new plant varieties, Office of Premarket Approval, Center for Food Safety and Applied Nutrition and Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration. October 1997

- Uses an asterisk to identify a bioengineered food that contains an introduced pesticidal substance, which is subject to regulation by EPA;
- Describes the intended effect of the modification;
- Provides the date of the agency's letter responding to the submission and a hyperlink to the text of that letter; and
- Provides the date of the agency's final memorandum regarding the submission and a hyperlink to the text of that memorandum.

This list is current as of February 25, 2002, and therefore, does not show any consultations completed after that date.

Table B3.1 ***Completed Submissions Organized by Year***

Food	Trait	Applicant	FDA Letter	FDA Memo
Tomato	Delayed softening due to reduced pectin degradation	Calgene	May 17, 1994	May 17, 1994
Soya bean	Tolerance to the herbicide glyphosate	Monsanto	Jan. 27, 1995	Sep. 19, 1994
Tomato	Delayed softening due to reduced ethylene synthesis	Monsanto	Apr. 5, 1995	Sep. 19, 1994
Tomato	Delayed softening due to reduced pectin degradation	Zeneca	Apr. 5, 1995	Sep. 20, 1994
Cotton	Tolerance to the herbicide Bromoxynil	Calgene	Apr. 5, 1995	Sep. 20, 1994
Potato*	Resistance to Colorado potato beetle	Monsanto	Apr. 5, 1995	Sep. 23, 1994
Squash*	Resistance to ZYMV and WMV2	Asgrow	Apr. 5, 1995	Oct. 3, 1994
Tomato	Delayed ripening due to reduced ethylene synthesis	DNA Plant Technology	Apr. 5, 1995	Oct. 4, 1994
Cotton*	Resistance to cotton ballworm, pink bollworm, and tobacco budworm	Monsanto	June 1, 1995	Apr. 11, 1995
Oilseed rape (Canola)	Tolerance to the herbicide glyphosate	Monsanto	Sep. 26, 1995	Apr. 24, 1995
Oilseed rape (Canola)	Tolerance to the herbicide glufosinate	AgrEvo	Apr. 20, 1995	Mar. 17, 1995
Corn*	Resistance to European corn borer	Ciba Geigy	July 14, 1995	July 14, 1995
Oilseed rape (Canola)	High laurate canola oil	Calgene	July 13, 1995	Apr. 4, 1995
Cotton	Tolerance to the herbicide glyphosate	Monsanto	Sep. 8, 1995	June 14, 1995
Corn	Tolerance to the herbicide glufosinate	AgrEvo	Dec. 14, 1995	Dec. 12, 1995
Tomato	Delayed fruit ripening due to reduced ethylene synthesis	Agritope	Mar. 20, 1996	Feb. 22, 1996
Corn*	Resistance to European corn borer	Northrup King	May 22, 1996	May 22, 1996
Corn* (Btk)	Resistance to European corn borer	Monsanto	July 24, 1996	Mar. 5, 1996
Corn	Tolerance to the herbicide glufosinate	Dekalb Genetics	Mar. 8, 1996	Jan. 25, 1996

Food	Trait	Applicant	FDA Letter	FDA Memo
Cotton	Tolerance to the herbicide sulfonylurea	DuPont	June 28, 1996	Apr. 10, 1996
Corn	Male sterility; tolerance to glufosinate MS3	Plant Genetic Systems	June 7, 1996	Mar. 15, 1996
Oilseed rape (Canola)	Fertility restorer; tolerance to glufosinate	Plant Genetic Systems	Apr. 4, 1996	Mar. 25, 1996
Oilseed rape	Male sterility; tolerance to glufosinate	Plant Genetic Systems	Apr. 4, 1996	Mar. 25, 1996
Potato*	Resistance to Colorado potato beetle	Monsanto	Apr. 4, 1996	Mar. 25, 1996
Corn*	Resistance to European corn borer	Monsanto	Sep. 25, 1996	Sep. 18, 1996
Corn*	Resistance to European corn borer; Tolerance to the herbicide glyphosate	Monsanto	Nov. 5, 1996	Sep. 6, 1996
Soya bean	High oleic acid soya bean oil	DuPont	Mar. 14, 1997	Dec. 5, 1996
Corn*	Resistance to European corn borer	Dekalb Genetics	Mar. 11, 1997	Mar. 11, 1997
Papaya*	Resistance to PRSV	U of Hawaii	Sep. 12, 1997	Sep. 12, 1997
Squash*	Resistance to the viruses CMV, ZYMV and WMV2	Seminis Vegetable Seeds	July 10, 1997	July 1, 1997
Radicchio	Male Sterility; tolerance to glufosinate	Bejo Zaden	Oct. 22, 1997	Oct. 16, 1997
Canola	Tolerance to the herbicide glufosinate	AgrEvo	Aug. 25, 1997	May 29, 1997
Corn	Male sterility; tolerance to glufosinate	Pioneer Hi-Bred	Dec. 24, 1998	Dec. 11, 1998
Sugar beet	Tolerance to the herbicide glufosinate	AgrEvo	Oct. 8, 1998	Sep. 9, 1998
Corn*	Resistance to several lepidopteran insects; Tolerance to the herbicide glufosinate	AgrEvo	May 29, 1998	May 29, 1998
Cotton*	Tolerance to the herbicide bromoxynil; Resistance to certain lepidopteran insects	Calgene	Jan. 28, 1998	Dec. 12, 1997
Potato*	Resistance to Colorado potato beetle and PLRV	Monsanto	Jan. 8, 1998	Jan. 2, 1998
Potato*	Resistance to Colorado potato beetle and PVY	Monsanto	Jan. 8, 1998	Jan. 2, 1998
Flax	Tolerance to the herbicide sulfonylurea	U of Saskatchewan	May 15, 1998	May 24, 1998
Corn	Tolerance to the herbicide glyphosate	Monsanto	Feb. 13, 1998	Feb. 10, 1998
Tomato*	Resistance to certain lepidopteran insects	Calgene	Feb. 24, 1998	Feb. 3, 1998
Soya bean	Tolerance to the herbicide glufosinate	AgrEvo	May 15, 1998	Apr. 21, 1998
Sugar beet	Tolerance to the herbicide glyphosate	Monsanto and Novartis Seeds	Nov. 3, 1998	Sep. 28, 1998
Canola	Fertility restorer; Tolerance to glufosinate	AgrEvo	Sep. 16, 1998	Aug. 5, 1998
Canola	Male sterility; Tolerance to glufosinate	AgrEvo	Sep. 16, 1998	Aug. 5, 1998
Canola	Degradation of phytate in animal feed	BASF	July 2, 1999	Mar. 4, 1999
Canta -loupe	Delayed fruit ripening due to reduced ethylene	Agritope	Dec. 9, 1999	Oct. 20, 1999

Food	Trait	Applicant	FDA Letter	FDA Memo
Canola	Tolerance to the herbicide bromoxynil	Rhone-Poulenc	Oct. 20, 1999	Oct. 13, 1999
Rice	Tolerance to the herbicide glufosinate	Aventis Crop Science	Aug. 31, 2000	Aug. 30, 2000
Corn	Male Sterility; tolerance to glufosinate	Aventis Crop Science	Apr. 4, 2000	Apr. 4, 2000
Corn	Tolerance to the herbicide glyphosate	Monsanto	Oct. 18, 2000	Oct. 19, 2000
Corn*	Resistance to certain lepidopteran insects; tolerance to the herbicide	Dow AgroSciences LLC	May 18, 2001	June 8, 2001
Corn*	Resistance to Coleopteran insects, including corn rootworm; resistance to aminoglycoside antibiotics	Monsanto	Dec. 31, 2001	Dec. 31, 2001

Table B4.1 Approved Crops - Japan

Crop	Trait	Applicant	Date of review
Potato	Insect resistant	Monsanto Japan	30-Mar-01
Potato	Insect resistant	Monsanto Japan	30-Mar-01
Potato	Insect resistant Virus resistant	Monsanto Japan	14-Sep-01
Potato	Insect resistant Virus resistant	Monsanto Japan	14-Sep-01
Potato	Insect resistant	Monsanto Japan	14-Sep-01
Soya bean	Glyphosate tolerant	Monsanto Japan	30-Mar-01
Soya bean	High oleic acid	DuPont K.K.	30-Mar-01
Sugar Beet	Glufosinate tolerant	Aventis Crop Science Shionogi	30-Mar-01
Corn	Insect resistant Glufosinate tolerant	Syngenta Seed	30-Mar-01
Corn	Insect resistant	Syngenta Seed	30-Mar-01
Corn	Insect resistant	Monsanto Japan	30-Mar-01
Corn	Glufosinate tolerant	Aventis Crop Science Shionogi	30-Mar-01
Corn	Glufosinate tolerant	Monsanto Japan	30-Mar-01
Corn	Insect resistant Glufosinate tolerant	Monsanto Japan	30-Mar-01
Corn	Glyphosate tolerant	Monsanto Japan	30-Mar-01
Corn	Glyphosate tolerant	Monsanto Japan	30-Mar-01
Corn	Glufosinate tolerant	Aventis Crop Science Shionogi	30-Mar-01
Corn	Insect resistant Glufosinate tolerant	Syngenta Seed	30-Mar-01
Corn	Insect resistant	Monsanto Japan	21-Feb-02
Rapeseed	Glyphosate tolerant	Monsanto Japan	30-Mar-01
Rapeseed	Glufosinate tolerant	Aventis Crop Science Shionogi	30-Mar-01
Rapeseed	Glufosinate tolerant	Aventis Crop Science Shionogi	30-Mar-01
Rapeseed	Glufosinate tolerant	Aventis Crop Science Shionogi	30-Mar-01
Rapeseed	Glufosinate tolerant	Aventis Crop Science Shionogi	30-Mar-01
Rapeseed	Glufosinate tolerant	Aventis Crop Science Shionogi	30-Mar-01
Rapeseed	Glufosinate tolerant	Aventis Crop Science Shionogi	30-Mar-01

Crop	Trait	Applicant	Date of review
Rapeseed	Glufosinate tolerant	Aventis Crop Science Shionogi	30-Mar-01
Rapeseed	Glufosinate tolerant	Aventis Crop Science Shionogi	30-Mar-01
Rapeseed	Glufosinate tolerant	Aventis Crop Science Shionogi	30-Mar-01
Rapeseed	Glufosinate tolerant Male sterility	Aventis Crop Science Shionogi	30-Mar-01
Rapeseed	Glufosinate tolerant Recovering male sterility	Aventis Crop Science Shionogi	30-Mar-01
Rapeseed	Oxynyl tolerant	Aventis Crop Science Shionogi	30-Mar-01
Rapeseed	Glufosinate tolerant	Aventis Crop Science Shionogi	30-Mar-01
Rapeseed	Glyphosate tolerant	Monsanto Japan	14-Sep-01
Cotton	Glyphosate tolerant	Monsanto Japan	30-Mar-01
Cotton	Bromoxynil tolerant	Stoneville Pedigreed Seed	30-Mar-01
Cotton	Bromoxynil tolerant	Stoneville Pedigreed Seed	30-Mar-01
Cotton	Insect resistant	Monsanto Japan	30-Mar-01
Cotton	Insect resistant	Monsanto Japan	30-Mar-01
Cotton	Bromoxynil tolerant	Stoneville Pedigreed Seed	30-Mar-01

Source: www.mhlw.go.jp/english/topics/food/sec 01.html. downloaded 13 December 2002

Annex C

CODEX Analytical Testing Methods

CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY SECOND MEETING OF THE WORKING GROUP ON ANALYTICAL METHODS

Appendix 4

Methods Reported by Member Countries Revised as of March 1, 2002

Information on all methods reported by member countries have been summarised in the attached list.

Most of the methods are based on the polymerase chain reaction (PCR). They are suitable to either screen for or to specifically detect recombinant DNA (rDNA). Several PCR methods can also be used to quantify the amount of rDNA.

Some of the reported methods are based on the detection of a heterologous protein.

Some information have also been provided on DNA extraction methods.

The list of methods is organised as follows:

Part I summarises the detection methods as follows:

- Each method is associated with the reporting country (listed in alphabetical order) and the food source and/or the target for which it has been designed (column 1). Those methods
which meet CODEX criteria for the selection of methods of analysis[1] are marked with an asterisk.

- For PCR based methods the sizes of the amplicons are given (column 2).

- Information on the validation status and the type of method (screening for common heterologous genetic elements, qualitative detection or quantification of rDNA) is given in columns 3 - 6.

Part II contains the information provided on DNA extraction methods. The methods are referred to the reporting countries. Information on the validation status is given in column 3.

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[1] Codex Alimentarius Commission Procedural Manual, 12th Edition, p.65 and Codex Alimentarius Checklist of Information, Volume 13-1994, Chapter 1.2 Design, Conduct and Reporting of Results of Collaborative Study Supporting the Endorsement of the Method.

I. Detection Methods

Country / *Food Source / Target*	*Size of amplicon*	*Interlab.*[1]	*Screening*	*Qual.*[2]	*Quant.*[3]
Argentina					
CaMV 35S Promotor					
35S-1/35S-2	195 bp	☐	☑	☑	☐
NOS-Terminator					
NOS-1/NOS-3	180 bp	☐	☑	☑	☐
Austria					
CaMV 35S Promotor					
35S-F/35S-R	207 bp	☐	☑	☑	☐
Maize Bt 11 (Novartis)					
Q_IVS2-2/PAT-B	129 bp	☑	☐	☐	☑
IVS2-2/PAT-B	189 bp	☑	☐	☑	☐
Maize Event 176 (Maximizer, Novartis)					
Q_Cry2-F/Cry2-R+BTSYN	129 bp	☑	☐	☐	☑
Cry03/Cry04	211 bp	☑	☐	☑	☐
Maize MON810 (Yield Gard Corn, Monsanto)					
VW01/VW03	170 bp	☑	☐	☑	☐
Protein_CrylA	- bp	☑	☐	☑	☐
Maize T25 (Liberty link, Aventis Crop Science formerly AgrEvo)					
T25-F7/T25-R3	209 bp	☑	☐	☑	☐
NOS-Terminator					
NOS-1/NOS-4a	182 bp	☐	☑	☑	☐
Oilseed rape TOPAS 19/2 (Liberty link, Aventis Crop Science formerly AgrEvo)					
35S-af2/Pat-r1	194 bp	☐	☐	☑	☐
Soybean Roundup Ready (Monsanto)					
35S-af2/Petu-r1	171 bp	☑	☐	☑	☐
Protein_EPSPS	- bp	☑	☐	☑	☐
Q_RR1-F/RR1-R	74 bp	☑	☐	☐	☑
Tomato ZENECA 282F					
PG34f/PG34r	384+180 bp	☑	☐	☑	☐
Belgium					
CaMV 35S Promotor					
35S-5/35S-10	233 bp	☐	☑	☑	☐
35S-3/35S-6	147 bp	☐	☑	☑	☐
35S-cf3/35S-cr4	123 bp	☑	☑	☑	☐

Country	*Food Source / Target*	*Size of amplicon*	*Interlab.*[1]	*Screening*	*Qual.*[2]	*Quant.*[3]
	Maize Bt 11 (Novartis)					
	PAT1/PAT2	221 bp	☐	☐	☑	☐
	Cry01/Cry02	184 bp	☐	☐	☑	☐
	PAT-b/IVS2-2	189 bp	☐	☐	☑	☐
	PAT3/PAT4	171 bp	☐	☐	☑	☐
	Maize Event 176 (Maximizer, Novartis)					
	Cry01/Cry02	184 bp	☑	☐	☑	☐
	Cry03/Cry04	211 bp	☑	☐	☑	☐
	DD2/DD8	184 bp	☐	☐	☑	☐
	Maize MON809 (Pioneer Hi-Bred)					
	Cry01/Cry02	184 bp	☑	☐	☑	☐
	Maize MON810 (Yield Gard Corn, Monsanto)					
	35S-mg1/mg4	174 bp	☐	☐	☑	☐
	Cry01/Cry02	184 bp	☑	☐	☑	☐
	Protein_CrylA	- bp	☑	☐	☑	☐
	Maize StarLink (CBH 351, Aventis)					
	Cry9c1f/Cry9c1r	297 bp	☐	☐	☑	☐
	Cry9c2f/Cry9c2r	136 bp	☐	☐	☑	☐
	Cry9c3f/Cry9c3r	147 bp	☐	☐	☑	☐
	Cry9c4f/Cry9c4r	150 bp	☐	☐	☑	☐
	Maize T25 (Liberty link, Aventis Crop Science formerly AgrEvo)					
	Ampol5/DPA23	352 bp	☐	☐	☑	☐
	NOS-Terminator					
	HA-NOS118-f/HA-NOS118r	118 bp	☑	☑	☑	☐
	NOS-3a/NOS-4	213 bp	☐	☑	☑	☐
	Oilseed rape MS8 (Aventis)					
	BAR3/BAR4	191 bp	☐	☐	☑	☐
	Oilseed rape MS8xRF3 (SeedLink, Aventis)					
	BAR3/BAR4	191 bp	☐	☐	☑	☐
	Oilseed rape RF3 (Aventis)					
	BAR3/BAR4	191 bp	☐	☐	☑	☐

Country	Food Source / Target	Size of amplicon	Interlab.[1]	Screening	Qual.[2]	Quant.[3]
	Soybean Roundup Ready (Monsanto)					
	35S-af2/Petu-r1	171 bp	☑	☐	☑	☐
	35S-af2/Petu-r1	171 bp	☑	☐	☑	☐
	Protein_EPSPS	- bp	☑	☐	☑	☐
	Q_35S-af2/Petu-r1	171 bp	☐	☐	☐	☑
	Q_35S-CTP-302F/RRS-35S-CTP-384R	83 bp	☐	☐	☐	☑
	S3/S4	129 bp	☑	☐	☑	☐
Canada						
	CaMV 35S Promotor					
	35SP-1/35SP-5R	221 bp	☐	☑	☑	☐
	NOS-Terminator					
	NOSP-1/NOSP-2R	167 bp	☐	☑	☑	☐
	npt II gene (Kanamycin resistance)					
	NptII-3/NptII-4r	271 bp	☐	☑	☑	☐
	Potato NewLeaf (Monsanto)					
	E9T-1/E9T-2R	267 bp	☐	☑	☑	☐
Czech Republic						
	CaMV 35S Promotor					
	35S-1/35S-2	195 bp	☐	☑	☑	☐
	NOS-Terminator					
	NOS-1/NOS-2	n bp	☐	☑	☑	☐
Denmark						
	CaMV 35S Promotor					
	Q_35S-A/35S-B	227 bp	☐	☑	☐	☑
European Commission						
	CaMV 35S Promotor					
	* 35S-cf3/35S-cr4	123 bp	☑	☑	☑	☐
	* 35S-1/35S-2	195 bp	☑	☑	☑	☐
	NOS-Terminator					
	* HA-NOS118-f/HA-NOS118r	118 bp	☑	☑	☑	☐
	* NOS-1/NOS-3	180 bp	☑	☑	☑	☐
	Soybean Roundup Ready (Monsanto)					
	* Protein_EPSPS	- bp	☑	☐	☐	☑
Finland						
	CaMV 35S Promotor					
	35S-cf3/35S-cr4	123 bp	☑	☑	☑	☐

Country	*Food Source / Target*	*Size of amplicon*	*Interlab.*[1]	*Screening*	*Qual.*[2]	*Quant.*[3]
	Maize Event 176 (Maximizer, Novartis)					
	Q_Duplex-Zein/35S (Biosmart)	n bp	☑	☐	☐	☑
	Cry03/Cry04	211 bp	☑	☐	☑	☐
	Q_ZEIN/35S	n bp	☐	☐	☐	☑
	Maize MON810 (Yield Gard Corn, Monsanto)					
	Protein_CrylA (SDI Bt Cry I Ab Test Kit)	- bp	☑	☐	☑	☐
	Maize StarLink (CBH 351, Aventis)					
	Gene Scan Europe-Kit	133 bp	☐	☐	☑	☐
	NOS-Terminator					
	HA-NOS118-f/HA-NOS118r	118 bp	☑	☑	☑	☐
	npt II gene (Kanamycin resistance)					
	TN5-1/TN5-2	173 bp	☑	☑	☑	☐
	Soybean Roundup Ready (Monsanto)					
	Q_Duplex-Lectin/35S (Biosmart)	n bp	☑	☐	☐	☑
	Q_RR-Soya-Kit, Gene Scan Europe	n bp	☐	☐	☐	☑
	35S-af2/Petu-r1	171 bp	☑	☐	☑	☐
	Protein_EPSPS (SDI GMO Soya Test Kit)	- bp	☑	☐	☑	☐
Germany						
	CaMV 35S Promotor					
	Q_35S	n bp	☐	☑	☐	☑
	35S-promotor_2	n bp	☐	☑	☑	☐
	35S/Bar	n bp	☐	☑	☑	☐
	35S-1/35S-2	195 bp	☑	☑	☑	☐
	(Q_confidential6)	82 bp	☑	☑	☐	☑
	Lactobacillus curvatus Cc2, Katalasegen katA					
	KatA-f/KatA-r	1025 bp	☑	☐	☑	☐
	Maize Bt 11 (Novartis)					
	(Q_confidential5)	105 bp	☐	☐	☐	☑
	Enhancer/Toxin	n bp	☐	☐	☑	☐
	* IVS2-2/PAT-B	189 bp	☑	☐	☑	☐
	PAT/PAT	n bp	☐	☐	☑	☐
	Maize BTXtra DBT418 (deKalb)					
	Vector/Promotor	n bp	☐	☐	☑	☐

Country	*Food Source / Target*	*Size of amplicon*	*Interlab.*[1]	*Screening*	*Qual.*[2]	*Quant.*[3]
Maize Event 176 (Maximizer, Novartis)						
	Q_CDPK/Cry1A(b)	n bp	☐	☐	☐	☑
	BAR/BAR	n bp	☐	☐	☑	☐
	Q_Cry2-F/Cry2-R+BTSYN	129 bp	☑	☐	☐	☑
	CDPK/Cry04	n bp	☐	☐	☑	☐
	Cry/Cry	n bp	☐	☐	☑	☐
	* Cry03/Cry04	211 bp	☑	☐	☑	☐
	* Cry05/Cry06	134 bp	☑	☐	☑	☐
Maize MON80100						
	CTP/Gene	n bp	☐	☐	☑	☐
Maize MON802						
	CTP/Gene	n bp	☐	☐	☑	☐
Maize MON809 (Pioneer Hi-Bred)						
	CTP/Gene	n bp	☐	☐	☑	☐
Maize MON810 (Yield Gard Corn, Monsanto)						
	Prom/Intron	n bp	☐	☐	☑	☐
	(Q_confidential3)	92 bp	☐	☐	☐	☑
	* VW01/VW03	170 bp	☑	☐	☑	☐
Maize Roundup Ready (GA21, Monsanto)						
	CTP/CTP	n bp	☐	☐	☑	☐
	(Q_confidential2)	103 bp	☐	☐	☐	☑
Maize StarLink (CBH 351, Aventis)						
	Prom/Enh	n bp	☐	☐	☑	☐
	(Q_confidential1)	120 bp	☐	☐	☐	☑
Maize T25 (Liberty link, Aventis Crop Science formerly AgrEvo)						
	T25-F7/T25-R3	209 bp	☑	☐	☑	☐
	35S-af2/Pat-r1	194 bp	☐	☐	☑	☐
	(Q_confidential4)	84 bp	☐	☐	☐	☑
	Prom/PAT	n bp	☐	☐	☑	☐
NOS-Terminator						
	NOS-terminator_3	n bp	☐	☑	☑	☐
	NOS-1/NOS-3	180 bp	☑	☑	☑	☐
npt II gene (Kanamycin resistance)						
	TN5-1/TN5-2	173 bp	☑	☑	☑	☐
Oilseed rape RR (Monsanto)						
	PEPC/PEPC	n bp	☐	☐	☑	☐

Country	Food Source / Target	Size of amplicon	Interlab.[1]	Screening	Qual.[2]	Quant.[3]
	Other GMO-screening methods					
	HPT-f/HPT-r	n bp	☑	☑	☑	☐
	APH2-short/APH2-r	215 bp	☑	☑	☑	☐
	Prom/Prom	n bp	☐	☑	☑	☐
	Cat-f/Cat-r	623 bp	☑	☑	☑	☐
	Potato NewLeaf (Monsanto)					
	Prom/Toxin-gene	n bp	☐	☐	☑	☐
	Soybean Roundup Ready (Monsanto)					
	Q_RRS-F/RRS-R	171 bp	☐	☐	☐	☑
	* Q_RR1-F/RR1-R	74 bp	☑	☐	☐	☑
	35S/CTP	n bp	☐	☐	☑	☐
	* 35S-af2/Petu-r1	171 bp	☑	☐	☑	☐
	Tomato FLAVR-SAVR (Calgene)					
	Prom/AB-gene	n bp	☐	☐	☑	☐
	Tomato ZENECA 282F					
	PG34l/t-NOS	351 bp	☑	☐	☑	☐
	PG34l/PG34r	384+180 bp	☑	☐	☑	☐
	HB7/t-NOS	193 bp	☐	☐	☑	☐
	Transgenic coho salmon					
	MT1/GH19	427 bp	☑	☐	☑	☐
Hungary						
	CaMV 35S Promotor					
	35S-1/35S-2	195 bp	☐	☑	☑	☐
Ireland						
	CaMV 35S Promotor					
	Q_35S-cf3/35S-cr4+35S-af1/35S-pt1	123 bp	☐	☑	☐	☑
	35S-1/35S-2	195 bp	☑	☑	☑	☐
	35S-cf3/35S-cr4	123 bp	☑	☑	☑	☐
	Maize Bt 11 (Novartis)					
	bt11-1/Bt11-2	207 bp	☐	☐	☑	☐
	Maize Event 176 (Maximizer, Novartis)					
	Maxim/Maize	226 bp	☐	☐	☑	☐
	Q_35S-afin	207 bp	☑	☐	☐	☑
	PAT-JV1/PAT-JV2	372 bp	☐	☐	☑	☐
	Cry1Ab-1/Cry1Ab-2	184 bp	☐	☐	☑	☐
	Cry03/Cry04	211 bp	☐	☐	☑	☐

Country	*Food Source / Target*	*Size of amplicon*	*Interlab.*[1]	*Screening*	*Qual.*[2]	*Quant.*[3]
	Maize MON810 (Yield Gard Corn, Monsanto)					
	Sttmf3a/Sttmr2a	145 bp	☐	☐	☑	☐
	Mg3/Mg4	149 bp	☑	☐	☑	☐
	Maize Roundup Ready (GA21, Monsanto)					
	GA21-1/GA21-2	207 bp	☐	☐	☑	☐
	Maize StarLink (CBH 351, Aventis)					
	Cry9c-1/Cry9c-2	170 bp	☐	☐	☑	☐
	NOS-Terminator					
	HA-NOS118-f/HA-NOS118r	118 bp	☑	☑	☑	☐
	Oilseed rape Roundup Ready (Monsanto Canola)					
	(Confidential)	n bp	☐	☐	☑	☐
	Protein_EPSPS	- bp	☐	☐	☑	☐
	Soybean Roundup Ready (Monsanto)					
	RR/Soya	172 bp	☐	☐	☑	☐
	Protein_EPSPS	- bp	☑	☐	☑	☐
	35S-af2/Petu-r1	171 bp	☐	☐	☑	☐
Italy						
	CaMV 35S Promotor					
	35S-promotor_1	n bp	☑	☑	☑	☐
	Maize Event 176 (Maximizer, Novartis)					
	(Q_blank2)	n bp	☐	☐	☐	☑
	NOS-Terminator					
	NOS-terminator_2	n bp	☑	☑	☑	☐
	Other GMO-screening methods					
	(blank4)	n bp	☑	☑	☑	☐
	Soybean Roundup Ready (Monsanto)					
	(blank3)	n bp	☐	☐	☑	☐
	(Q_blank1)	n bp	☐	☐	☐	☑
Japan						
	CaMV 35S Promotor					
	35S-2a/35S-2b	220 bp	☑	☑	☑	☐
	Maize Bt 11 (Novartis)					
	adh1-1S IVS6/CrylA(b)	437 bp	☐	☐	☑	☐
	Maize Event 176 (Maximizer, Novartis)					
	PEPC/CrylA(b)	343 bp	☐	☐	☑	☐

Country	Food Source / Target	Size of amplicon	Interlab.[1]	Screening	Qual.[2]	Quant.[3]
	Maize MON810 (Yield Gard Corn, Monsanto)					
	Hsp70/CrylA(b)	199 bp	☐	☐	☑	☐
	Hsp70/CrylA(b)	199 bp	☑	☐	☑	☐
	Maize Roundup Ready (GA21, Monsanto)					
	OTP/CrylA(b)	270 bp	☐	☐	☑	☐
	Maize T25 (Liberty link, Aventis Crop Science formerly AgrEvo)					
	35S/PAT	149 bp	☐	☐	☑	☐
	Soybean Roundup Ready (Monsanto)					
	CTP4/EPSPS-1	179 bp	☑	☐	☑	☐
	CTP4-2/EPSPS-2	121 bp	☑	☐	☑	☐
	CaMV/EPSPS	513 bp	☑	☐	☑	☐
Kotra (Republic of)						
	CaMV 35S Promotor					
	35S 1-5'/35S 1-3'	101 bp	☑	☑	☑	☐
	Q_35S 1-5'/35S 1-3'	101 bp	☑	☑	☐	☑
	Maize Bt 11 (Novartis)					
	Bt11 3-5'/Bt11 3-3'	128 bp	☑	☐	☑	☐
	Q_Bt11 3-5'/Bt11 3-3'	128 bp	☑	☐	☐	☑
	Maize Event 176 (Maximizer, Novartis)					
	Q_E176 2-5'/E176 2-3'	100 bp	☑	☐	☐	☑
	E176 2-5'/E176 2-3'	100 bp	☑	☐	☑	☐
	Maize MON810 (Yield Gard Corn, Monsanto)					
	M810 2-5'/M810 2-3'	113 bp	☑	☐	☑	☐
	Q_M810 2-5'/M810 2-3'	113 bp	☑	☐	☐	☑
	Maize Roundup Ready (GA21, Monsanto)					
	Q_GA21 3-5'/GA21 3-3'	133 bp	☑	☐	☐	☐
	GA21 3-5'/GA21 3-3'	133 bp	☑	☐	☑	☐
	Maize T25 (Liberty link, Aventis Crop Science formerly AgrEvo)					
	Q_T25 1-5'/T25 1-3'	149 bp	☑	☐	☐	☑
	T25 1-5'/T25 1-3'	149 bp	☑	☐	☑	☐
	NOS-Terminator					
	Q_NOSter 2-5'/NOSter 2-3'	151 bp	☑	☑	☐	☑
	NOSter 2-5'/NOSter 2-3'	151 bp	☑	☑	☑	☐
	Soybean Roundup Ready (Monsanto)					
	Q_RRS01-5'/RRS01-3'	121 bp	☑	☐	☐	☑
	RRS01-5'/RRS01-3'	121 bp	☑	☐	☑	☐

Country	Food Source / Target	Size of amplicon	Interlab.[1]	Screening	Qual.[2]	Quant.[3]
Netherlands						
	CaMV 35S Promotor					
	35S-cf3/35S-cr4	123 bp	☑	☑	☑	☐
	Q_CaMVf/CaMVr	n bp	☐	☐	☐	☑
	Maize Bt 11 (Novartis)					
	IVS2-2/PAT-B	189 bp	☑	☐	☑	☐
	Maize Event 176 (Maximizer, Novartis)					
	Q_Cry2-F/Cry2-R+BTSYN	n bp	☐	☐	☐	☑
	Cry03/Cry04	211 bp	☑	☐	☑	☐
	Maize MON810 (Yield Gard Corn, Monsanto)					
	VW01/VW03	170 bp	☑	☐	☑	☐
	Maize StarLink (CBH 351, Aventis)					
	(Confidential2)	n bp	☐	☐	☑	☐
	Q_Gene Scan Europe-Kit	n bp	☐	☐	☐	☑
	Maize T25 (Liberty link, Aventis Crop Science formerly AgrEvo)					
	T25-F7/T25-R3	209 bp	☑	☐	☑	☐
	NOS-Terminator					
	HA-NOS118-f/HA-NOS118r	118 bp	☑	☑	☑	☐
	Soybean Roundup Ready (Monsanto)					
	Q_RRS-35S-ctpF/R	n bp	☐	☐	☐	☑
	35S-af2/35S2-1C	352 bp	☐	☐	☑	☐
Norway						
	CaMV 35S Promotor					
	35S-promotor_3	n bp	☑	☑	☑	☐
	35S-cf3/35S-cr4	123 bp	☑	☑	☑	☐
	Maize Bt 11 (Novartis)					
	(Q_blank7)	n bp	☐	☐	☐	☑
	(blank7)	n bp	☐	☐	☑	☐
	Maize Event 176 (Maximizer, Novartis)					
	Cry03/Cry04	211 bp	☑	☐	☑	☐
	(Q_blank5)	n bp	☐	☐	☐	☑
	(blank6)	n bp	☐	☐	☑	☐
	Maize MON810 (Yield Gard Corn, Monsanto)					
	(blank8)	n bp	☐	☐	☑	☐
	(Q_blank6)	n bp	☐	☐	☐	☑

Country	Food Source / Target	Size of amplicon	Interlab.[1]	Screening	Qual.[2]	Quant.[3]
	NOS-Terminator					
	HA-NOS118-f/HA-NOS118r	118 bp	☑	☑	☑	☐
	NOS-terminator_1	n bp	☑	☑	☑	☐
	npt II gene (Kanamycin resistance)					
	NptII/NptII	n bp	☐	☑	☑	☐
	Other GMO-screening methods					
	AmpR	n bp	☐	☑	☑	☐
	Soybean Roundup Ready (Monsanto)					
	(Q_blank4)	n bp	☑	☐	☐	☑
	(blank5)	n bp	☐	☐	☑	☐
	Q_RRS-int f/RRS-int r	n bp	☑	☐	☐	☑
	RRS-int f/RRS-int r	n bp	☑	☐	☑	☐
Portugal						
	CaMV 35S Promotor					
	Q_35S-1/35S-2	195 bp	☐	☑	☐	☑
	Q_35S3-bio/35S2	191 bp	☑	☑	☐	☑
	Q_35S-cf3/35S-cr4+35S-af1/35S-pt1	123+207 bp	☑	☑	☐	☑
	35S-1/35S-2	195 bp	☑	☑	☑	☐
	35S-cf3/35S-cr4	123 bp	☑	☑	☑	☐
	Maize Bt 11 (Novartis)					
	IVS2-2/PAT-B	189 bp	☐	☐	☑	☐
	Maize Event 176 (Maximizer, Novartis)					
	Cry03/Cry04	211 bp	☑	☐	☑	☐
	Q_Cry2-F/Cry2-R+BTSYN	129 bp	☐	☐	☐	☑
	Maize MON810 (Yield Gard Corn, Monsanto)					
	Protein_CrylA	- bp	☑	☐	☑	☐
	Maize T25 (Liberty link, Aventis Crop Science formerly AgrEvo)					
	BAR-AF1/BAR-AR	248 bp	☐	☐	☑	☐
	NOS-Terminator					
	HA-NOS118-f/HA-NOS118r	118 bp	☑	☑	☑	☐
	NOS-1/NOS-3	180 bp	☑	☑	☑	☐
	Soybean Roundup Ready (Monsanto)					
	Q_RR1-F/RR1-R	74 bp	☐	☐	☐	☑
	35S-af2/Petu-r1	171 bp	☑	☐	☑	☐
	Q_35S-af2/Petu-r1	171 bp	☐	☐	☐	☑

Country	*Food Source / Target*	*Size of amplicon*	*Interlab.*[1]	*Screening*	*Qual.*[2]	*Quant.*[3]
	Tomato ZENECA 282F					
	PG34l/t-NOS	351 bp	☑	☐	☑	☐
	PG34l/PG34r	384+180 bp	☑	☐	☑	☐
	Transgenic coho salmon					
	MT1/GH19	427 bp	☑	☐	☑	☐
South Africa						
	CaMV 35S Promotor					
	35S-1/35S-2	195 bp	☐	☑	☑	☐
	Q_35S-1/35S-2	195 bp	☐	☑	☐	☑
	Maize Event 176 (Maximizer, Novartis)					
	Protein_CrylA	- bp	☑	☐	☑	☐
	Protein_CrylA (Strip test)	- bp	☑	☐	☑	☐
	(Q_confidential7)	n bp	☑	☐	☐	☑
	Maize MON810 (Yield Gard Corn, Monsanto)					
	Q_CyrlA3/CrylA-G	211 bp	☐	☐	☐	☑
	Q_Cry01-A1/Cry01-A2	420 bp	☐	☐	☐	☑
	Cry01-A1/Cry01-A2	420 bp	☐	☐	☑	☐
	Protein_CrylA	- bp	☐	☐	☑	☐
	NOS-Terminator					
	Q_NOS/NOS	180 bp	☐	☑	☐	☑
	NOS-1/NOS-3	180 bp	☐	☑	☑	☐
	Soybean Roundup Ready (Monsanto)					
	Protein_EPSPS (Strip test)	- bp	☑	☐	☑	☐
	Q_35S-af2/Petu-r1	171 bp	☐	☐	☐	☑
	35S-af2/Petu-r1	171 bp	☑	☐	☑	☐
	Q_EPSPS2	n bp	☑	☐	☐	☑
Spain						
	CaMV 35S Promotor					
	35S-1/35S-2	195 bp	☐	☑	☑	☐
	Maize Event 176 (Maximizer, Novartis)					
	CryFZ1/CryFZ2	147 bp	☐	☐	☑	☐
	NOS-Terminator					
	NOS-1/NOS-3	180 bp	☐	☑	☑	☐
	Soybean Roundup Ready (Monsanto)					
	CaMV/CTP	109 bp	☐	☐	☑	☐

Country / Food Source / Target	Size of amplicon	Interlab.[1]	Screening	Qual.[2]	Quant.[3]
Sweden					
CaMV 35S Promotor					
Q_35S/35S	82 bp	☑	☑	☐	☑
(Unknown1)	82 bp	☑	☑	☑	☐
(Unknown2)	82 bp	☑	☑	☑	☐
Maize Bt 11 (Novartis)					
Q_IVS2-2/PAT-B	n bp	☑	☐	☐	☑
IVS2-2/PAT-B	189 bp	☑	☐	☑	☐
Maize Event 176 (Maximizer, Novartis)					
Q_PEPC/CrylA(b)	n bp	☑	☐	☐	☑
PEPC/CrylA(b)	343 bp	☑	☐	☑	☐
Maize MON810 (Yield Gard Corn, Monsanto)					
35S/hsp70 intron	n bp	☑	☐	☑	☐
Q_35S/hsp70 intron	n bp	☑	☐	☐	☑
Soybean Roundup Ready (Monsanto)					
Q_RR1-F/RR1-R	74 bp	☑	☐	☐	☑
RR1-F/RR1-R	74 bp	☑	☐	☑	☐
Switzerland					
CaMV 35S Promotor					
35S-1/35S-2	195 bp	☑	☑	☑	☐
Q_35S-A/35S-B	227 bp	☑	☑	☐	☑
Maize Bt 11 (Novartis)					
(Q_unknown1)	207 bp	☐	☐	☐	☑
Nested5	n bp	☐	☐	☑	☐
Maize Event 176 (Maximizer, Novartis)					
Q_CrylA3/CrylA-G	189 bp	☑	☐	☐	☑
Q_35S-f/35S-rev-Multiplex	n bp	☐	☐	☐	☑
Nested2	n bp	☐	☐	☑	☐
Maize MON810 (Yield Gard Corn, Monsanto)					
Nested3	n bp	☐	☐	☑	☐
35S-mg1/Gene	401 bp	☐	☐	☑	☐
Unknown/mg4	149 bp	☐	☐	☑	☐
NOS-Terminator					
Nested4	n bp	☐	☑	☑	☐
NOS-1/NOS-3	180 bp	☑	☑	☑	☐

Country	Food Source / Target	Size of amplicon	Interlab.[1]	Screening	Qual.[2]	Quant.[3]
	npt II gene (Kanamycin resistance)					
	TN5-1/TN5-2	173 bp	☐	☑	☑	☐
	Soybean Roundup Ready (Monsanto)					
	Nested1	n bp	☐	☐	☑	☐
	(Q_unknown2)	169 bp	☑	☐	☐	☑
	Q_RRS/RRS	n bp	☐	☐	☐	☑
	Protein_EPSPS	- bp	☐	☐	☑	☐
Thailand						
	CaMV 35S Promotor					
	35S-1/35S-2	195 bp	☑	☑	☑	☐
	Chilli Pepper, transgenic (Capsicum annuum cv. Bangchang)					
	CPI/CR-II	633 bp	☐	☐	☑	☐
	Maize Event 176 (Maximizer, Novartis)					
	Q_Cry01a/Cry07	89 bp	☐	☐	☐	☑
	Cry01/Cry02	184 bp	☐	☐	☑	☐
	Cry03/Cry04	211 bp	☐	☐	☑	☐
	NOS-Terminator					
	NOS-1/NOS-3	180 bp	☑	☑	☑	☐
	Soybean Roundup Ready (Monsanto)					
	EPSPS/EPSPS	320 bp	☐	☐	☑	☐
	35S-af2/Petu-r1	171 bp	☐	☐	☑	☐
	Q_EPSPS	95 bp	☐	☐	☐	☑
United Kingsdom						
	Maize Event 176 (Maximizer, Novartis)					
	(blank2)	211 bp	☐	☐	☑	☐
	(blank9)	190/151/210 bp	☐	☐	☑	☐
	Soybean Roundup Ready (Monsanto)					
	(blank1)	172/147/180 bp	☐	☐	☑	☐
	(blank10)	172 bp	☐	☐	☑	☐
	No information	n bp	☐	☐	☐	☐
Uruguay						
	Maize Event 176 (Maximizer, Novartis)					
	Protein_CrylA (Envirologic CrylAb/CrylAc Plate kit+strips)	- bp	☐	☐	☑	☐
	Soybean Roundup Ready (Monsanto)					
	Atlin1.0 nested PCR (Biosmart, Promega)	150 bp	☐	☐	☑	☐
	Q_Atlin1.0 nested PCR (Biosmart)	150 bp	☐	☐	☐	☑

Country	*Food Source / Target*	*Size of amplicon*	*Interlab.*[1]	*Screening*	*Qual.*[2]	*Quant.*[3]
USA						
	Soybean Roundup Ready (Monsanto)					
	* Protein_EPSPS	bp	☑	☐	☐	☑

II. Information on DNA Extraction Methods

Country	*Method*	*Interlab.*[1]
Belgium		
	High pure PCR template kit (Roche Diagnostics Inc.) Thermal lysis in presence of proteinase K / separation with silica resin.	☐
	Phenol-chloroform extraction Thermal lysis in presence of SDS+proteinase K / removal of contaminants with phenol-chloroform / alcohol-precipitation.	☐
	CTAB Thermal lysis in presence of CTAB / removal of contaminants with natriumchlorid+chloroform / alcohol-precipitation. Yields DNA of PCR quality	☑
	Polyvinylpirrolidone phosphate (PVP) Thermal lysis in presence of SDS+EDTA / removal of contaminants with PVP+ammonium acetate / alcohol-precipitation. Same as CTAB protocol but faster and cheaper.	☐
	Phenol-chloroform extraction Thermal lysis in presence of SDS+EDTA / removal of contaminants with phenol-chloroform / alcohol-precipitation. High yield of DNA most of the time of PCR quality at a large range of food matrices.	☑
Canada		
	Large scale DNA extraction from plants tissue (leaf or seed) Adapted from Doyle JJ, Doyle JL (1990): Isolation from Plant DNA from Fresh Tissue. Focus Vol. 12 (No. 1) p.13-15	☐
	Micro scale DNA extraction from plant tissue (leaf or seed) Adapted from Möller et al. (1992), Nucl. Acid Res. Vol 20 (No. 22) p.6115-6116	☐
United Kingdom		
	DNA Extraction from certified reference material CTAB, Chloroform, Wizard Clean-up System, Isopropanol	☐
	DNA Extraction from Complex Food Matrix (e.g. pizza, burger, sausages) CTAB, Chloroform, Wizard Clean-up System, Isopropanol	☐
	DNA Extraction from Coated Foods (Meat/fish coated in batter or Crumb CTAB, Chloroform, Wizard Clean-up System, Isopropanol	☐
	DNA Extraction from Soya/Maize Flour and Isolates CTAB, Chloroform, Wizard Clean-up System, Isopropanol	☐

Target: **blank** = no sequence or primer information available
unknown = name of the primers ist not available
confidential = sequence / target information confidential

* in accordance with CODEX criteria for the selection of methods of analysis and internationally agreed performance criteria

1 Interlab. = Method validated by interlaboratory study
2 Qual. = qualitaitve methods
3 Quant. = quantitative methods

Annex D

Food Sector in Hong Kong

D1 THE FOOD SECTOR IN HONG KONG

D1.1 DOMESTIC PRODUCTION AND ORIGIN OF FOOD IMPORTS INTO HONG KONG

Although most food supplies are imported, local production enables Hong Kong to maintain some degree of self-sufficiency and helps stabilize the price and supply of fresh produce.

Table 1.1 *Local Food Production*

Local Production	% Self - sufficiency
Fresh Vegetables	6
Live Poultry	21
Live Pigs	25
Marine Fish	62

Source: Agriculture, Fisheries and Conservation Department for 2001. Marine Fish statistics from Hong Kong Agricultural Situation, Retail Food Sector Report 2001, USDA GAIN Report

Hong Kong's food manufacturing base is small by comparison to population size and whilst there are a few specialist and medium sized food processors most of Hong Kong demand for food is met through imported foods from abroad. Most of Hong Kong local production is for local consumption.

Domestic exports account for only 12% of total output while around 26% of Hong Kong's imported food requirements are imported from mainland China. The US is the second largest importer of foreign foods, occupying a market share of around 14%.

D1.2 HONG KONG CONSUMER

With over 6.8 million people Hong Kong has a high population density. Nearly all of the population live in apartments, where storage space for foods tend to be small. As a result most consumers shop for fresh food daily with and estimated 70-80% of fresh food purchases made at the wet market. Food products are estimated to comprise 12% of the average household total expenditure.

D1.2.1 *The Food Industry in Hong Kong*

The industry includes importers, wholesalers, manufacturers, retailers and exporters - many firms are involved at more than one level of the supply chain (for example a firm might have both import, wholesale and retail operations).

A brief overview of the characteristics by food industry sectors is provided below.

Foreign packaged food products in Hong Kong are imported either directly by the end retailer (in the case of the large supermarkets) or are distributed by agents and consolidators.

Foreign food products are normally handled by importers who bring in shipments on their own accounts and then distribute either directly or through wholesalers or dealers to supermarkets, grocery stores, provision stores, hotels, restaurants, etc. Wholesalers and retailers sometimes purchase directly on their own accounts. Food perishability normally dictates the channel of distribution, the higher the perishability, the more direct the route of distribution involved.

Table 1.2 ***Estimated Importation Pattern of foreign food Products***

Import Route	Proportion
Importers	30%
Wholesalers/ Distributors	35%
Retailers (e.g Supermarkets)	25%
End-users (hotels, restaurants)	10%

Source: Canadian Consulate Report Processed Food and Beverage Market Hong Kong Estimates. 2001

D1.3 *AGENTS, IMPORTERS AND CONSOLIDATORS*

- The Hong Kong **import and export** of food products involves nearly 4,000 businesses, employing some 16,500 people (Census and Statistics Department data). The total turnover of this industry is some HK$ 77 billion.

- The **food wholesale** industry involves nearly 3,000 businesses, employing some 10,000 people. The total turnover of this industry is some HK$ 27 billion.

The majority of wholesalers seek stock from importers who provide them with special terms and credit facilities. Hotels, restaurants and other food establishments do not usually purchase directly from suppliers, but rather from importers or wholesalers on a contractual basis for a period of three to six months. Prices tend to be controlled by importers and the supply situation.

With growing Western interests in oriental food such as soya, soya milk and oyster sauces, there is an increasing demand for export-oriented food products from Hong Kong.

Hong Kong's re-exports of processed food and beverages from the US to the Chinese mainland accounted for around 21% of Hong Kong's total exports of food and beverages in 2000. Hong Kong therefore plays a major gateway role for western food and beverages channelling into the Chinese mainland.

D1.4 *FOOD MANUFACTURING INDUSTRIES*

The following statistics provides an overview of the nature and extent of the Hong Kong food industry (Census and Statistics Department data):

The **food manufacturing** industry has over 500 businesses, employing some 19,700 people. The total turnover of this industry is some HK$ 16 billion. The majority (over 60%) of establishments are small manufacturers employing less than 10 people. The structure of the industry is outlined in *Table 1.3* and *Table 1.4.*

Baking and noodle production are among the largest sectors in Hong Kong's processed food and beverages industry in terms of people employed. Major products of the industry include instant noodles, macaroni, spaghetti, biscuits, pastries and cakes for both domestic consumption and export. Other significant sectors include canning, preserving and pro-cessing of seafood (such as fish, shrimps, prawns, and crustaceans); manufacture of dairy products (fresh milk, yoghurt and ice cream); seasoning and spirits.

Table 1.3 Food Manufacturers in Hong Kong

Sector	No. of employees	No. of Establishments	Total Turnover (HK$ millions)	Profit (%)
Dairy products				
	1 - 99	10	N/A	N/A
	>100	4	N/A	N/A
	Total	14	1,447	27%
Canning and preserving of fruits and vegetables				
	1 - 99	8	244	10%
	Total	8	244	10%
Canning, preserving and processing of fish and crustaceans				
	1 - 99	84	N/A	N/A
	>100	1	N/A	N/A
	Total	85	2,182	9%
Vegetables and imitation animal oils and fats				
	>100	1	N/A	N/A
	Total	1	N/A	N/A
Grain mill products				
	1 - 99	14	N/A	N/A
	>100	1	N/A	N/A
	Total	15	898	9%
Bakery products				
	1 - 99	81	562	11%
	>100	8	1,731	14%
	Total	89	2,293	13%
Vermicelli, noodles and similar farinaceous products				
	1 - 99	122	N/A	N/A
	>100	2	N/A	N/A
	Total	124	1,171	12%
Sugar factories and refineries				
	1 - 99	1	N/A	N/A
	>100	1	N/A	N/A
	Total	2	N/A	N/A
Cocoa, chocolate and sugar confectionery				
	1 - 99	7	109	7%
	Total	7	109	7%
Food products, n.e.c. (2)				
	1 - 99	153	1,772	5%
	>100	8	2,663	21%
	Total	161	4,435	15%
Soft drinks and carbonated waters industries				
	1 - 99	3	N/A	N/A
	>100	7	N/A	N/A
	Total	10	3,548	18%
Total				
	1 - 99	482 (249)(1)	(2,687)(1)	(7%)(1)
	>100	33 (16)(1)	(4,394) (1)	(18%)(1)
	Total	515	16,327	15%

Notes: Data source is *Report on Annual Survey of Industrial Production, 2000. Census & Statistics Department*

N/A is not available as not published due to privacy concerns

(1) Numbers in brackets includes only those categories for which details available.

(2) Food products, n.e.c. means 'food products not elsewhere classified' and includes: almonds, cashew, ground nuts and other nuts (roasted or prepared), dim sum, gourmet powder, ice, potato chips, sauces and soya and food products not elsewhere specified (e.g. salt, processed eggs, honey, glucose products).

Table 1.4 ***Food Manufacturers in Hong Kong***

Sector	Total Turnover (HK$ millions)	Number of establishments	Number of employees	Total Turnover (HK$ millions)	Profit (%)
Dairy products					
	<5,000	3	31	N/A	N/A
	5,000 - 20,000	6	165	N/A	N/A
	>20,000	5	1,346	1,375	28%
	Total	14	1,541	1,447	27%
Canning and preserving of fruits and vegetables					
	<5,000	1	2	N/A	N/A
	5,000 - 20,000	5	151	N/A	N/A
	>20,000	2	153	N/A	N/A
	Total	8	305	244	10%
Canning, preserving and processing of fish and crustaceans					
	<5,000	38	196	95	6%
	5,000 - 20,000	33	282	336	2%
	>20,000	13	708	1,751	11%
	Total	85	1,186	2,182	9%
Vegetables and imitation animal oils and fats					
	>20,000	1	298	N/A	N/A
	Total	1	298	N/A	N/A
Grain mill products					
	<5,000	6	54	N/A	N/A
	5,000 - 20,000	5	152	40	9%
	>20,000	3	238	N/A	N/A
	Total	15	444	898	9%
Bakery products					
	<5,000	56	318	93	10%
	5,000 - 20,000	15	569	157	3%
	>20,000	19	3,853	2,044	14%
	Total	89	4,740	2,293	13%
Vermicelli, noodles and similar farinaceous products					
	<5,000	104	453	176	14%
	5,000 - 20,000	16	259	124	6%
	>20,000	5	521	872	13%
	Total	124	1,233	1,171	12%
Sugar factories and refineries					
	5,000 - 20,000	1	24	N/A	N/A
	>20,000	1	153	N/A	N/A
	Total	2	177	N/A	N/A
Cocoa, chocolate and sugar confectionery					
	<5,000	5	25	N/A	N/A
	5,000 - 20,000	1	34	N/A	N/A
	>20,000	1	66	N/A	N/A
	Total	7	125	109	7%
Food products, n.e.c.(2)					
	<5,000	94	576	123	1%
	5,000 - 20,000	33	816	432	11%
	>20,000	34	5,273	3,880	16%
	Total	161	6,665	4,435	15%
Soft drinks and carbonated waters industries					
	<5,000	3	17	N/A	N/A
	>20,000	7	3,010	N/A	N/A
	Total	10	3,028	3,548	18%

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Sector	Total Turnover (HK$ millions)	Number of establishments	Number of employees	Total Turnover (HK$ millions)	Profit (%)
Total					
	<5,000	309 (291)(1)	1,672 (1,543)(1)	(487)(1)	(9%)(1)
	5,000 - 20,000	115 (102)(1)	2,451(2,077)(1)	(1,089)(1)	(6%)(1)
	>20,000	91 (76)(1)	15,619 (11,702)(1)	(9,921)(1)	(16%)(1)
	Total	515	19,742	16,327,417	15%

Notes: Data source is *Report on Annual Survey of Industrial Production, 2000. Census & Statistics Department*

N/A is not available as not published due to privacy concerns

(1) Numbers in brackets includes only those categories for which details available.

(2) Food products, n.e.c. means 'food products not elsewhere classified' and includes: almonds, cashew, ground nuts and other nuts (roasted or prepared), dim sum, gourmet powder, ice, potato chips, sauces and soya and food products not elsewhere specified (e.g. salt, processed eggs, honey, glucose products).

D1.5 RETAILERS

In total there were some 17,561 (1999 - Canadian HK Food Market Report) retail outlets. The majority of these outlets (15,838) are small independent retail stores (typically family owned and operated) or market stalls located in the wet markets and employ less than 5 employees.

- The **food retail** industry involves nearly 16,000 businesses, employing some 35,000 people. The total turnover of this industry is some HK$ 45.5 billion. Supermarkets dominate the market, with only 3 companies employing over a third of the people engaged.

- Total retail sales of food and drinks in Hong Kong for 2000 reached US$ 6.03 billion.

Food retailing in Hong Kong is split almost evenly between supermarkets, direct delivery firms and smaller retail stores on one hand and the traditional wet markets on the other. The majority of meats, fruits and fresh vegetables are sold in these 'wet markets' although there has been a discernible shift over time and supermarkets are increasing their sales in these areas. Recent estimates proportion share of the food market 46% to the wet markets and small independent retail and 54% to the supermarkets.

D1.5.1 Traditional Markets - Wet Markets

There are about 250 wet markets in Hong Kong.

In November 2000, it was estimated that approximately 87.6% of daily fresh food purchases in Hong Kong were made through wet markets. (Hong Kong government survey of 1.9 million households). The remaining 12.4% chose to purchase fresh food from the supermarkets. More recent surveys indicate that this proportion is falling and *Table 1.5* illustrates the results of one such survey.

Table 1.5 ***Results of 2002 Survey: Purchasing patterns of Fresh Food***

Type of Fresh Food	Proportion of fresh food purchased from wet markets (Q3, 2002)
Fresh Meat	78.5%
Sea Food	88.9%
Vegetables	84.1%
Fruits	57.7%

Source: Taylor Nelson Sofres Survey, 2002

D1.5.2 ***Convenience Stores***

Table 1.6 ***Convenience Stores in Hong Kong***

Retailer Name	Ownership	Year Established	Purchasing Agent
7- Eleven	420	1981	Importers Agents
Circle K	141	1985	Importers Agents

Source: Hong Kong Agricultural Situation, Retail Food Sector Report 2001, USDA GAIN Report

Table 1.7 ***Major Supermarket Profile***

Name of Retailer	Food Sales US$	Number of Outlets	Type of Purchasing agent
Wellcome	Over $1 billion	252	Importers/ Agents Direct Consolidators
Park n Shop	Over $1 billion	200, 51 are superstores	Importers/ Agents Direct Consolidators
China Resources Supermarket	Not available	70	Importers/ Agents Direct Consolidators
Dah Chong Hong	Not available	41	Importers/ Agents
Jusco Stores	Not available	7	Importers/ Agents Direct Consolidators
City Super	Not available	2	Importers/ Agents Direct Consolidators

Source: Hong Kong Agricultural Situation, Retail Food Sector Report 2001, USDA GAIN Report

In the supermarket sector a virtual duopoly exists with two major supermarkets Wellcome and Park n Shop controlling almost 80% of the supermarket turnover.

Annex E

Case Studies

E1.1 CASE STUDY COMPANY L – A SMALL IMPORTER AND DISTRIBUTOR

E1.1.1 *Company Description*

Company L is a small importer and distributor of food products into Hong Kong. They employ 5 people. Clients are primarily supermarkets chains and outlets.

E1.1.2 *Approach to GM*

Company L have identified several prepackaged cereals, cookies and crackers that potentially may have GM content. These products are manufactured in the US and list soya flour and soya lecithin amongst their ingredients.

Changes that they may consider if there are changes in labelling requirements include discontinuation of product line if the labelling threshold is set at 1% GM content.

E1.1.3 *Costs and types of Changes Required*

Company L consider that any change in labelling will incur costs and impact right across the food business. Regardless of which option is chosen, the costs associated with testing and monitoring and additional labelling will be passed on.

E1.1.4 *Views on Options*

Company L expressed a preference for Option I, however they questioned whether most importers and distributors would in practice, implement voluntary labelling.

- Option II – Company L considered that this labelling option would cover most GM food products currently available on the market and would place the burden of procuring and submitting the necessary information to the appropriate authorities entirely on the importer.
- Option III – Company L consider that this option would have the most significant economic impact since it is inclusive of all types of food products and importers may not be able to provide all the necessary documentation.
- Option IV – An economically viable option for importers, allowing some type of exemption.
- Option V – The costs of resources outweigh the benefits of this option if the accuracy of GM detection cannot be verified.

E1.1.5 *Other points raised*

Company L consider that the there has been a noticeable trend in buying sentiments over the past two years towards non-GMO or organic food products among consumers and retail outlets. However, company L consider

that only a small number of consumers are willing to pay the premium associated with organic foods. They consider that at the moment the general public appear to be less concerned about the GM content of a product and more interested in whether a similar product is available at a lower price.

Company L submitted their comments by email. It is clear from their views on options II and III that there is some confusion surrounding allowable exemptions under these options. This issue of exemptions under options II and III has also been raised by other stakeholders, who have also expressed their confusion.

E1.2 CASE STUDY - COMPANY M - A MANUFACTURER OF BAKERY PRODUCTS

E1.2.1 *Company descriptions*

Company M, a sizeable local Hong Kong company, produce cakes and bread for sale in catering establishments and retail outlets. They have a food factory in Hong Kong, producing mooncakes, cakes and bread. The majority of their bread and cake products are sold fresh rather than packaged. Company M have considerable market share in Hong Kong for some of their bakery products.

E1.2.2 *Approach to GM*

Currently Company M does not have a non-GM policy. Whether they implement a non-GM policy in the future will depend upon the market, government policy and consumer preferences.

Ingredients currently used that potentially may have GM content have been identified as canola oil. Canola oil is used as a minor ingredient (<1%) in 50-60% of their cake products. Presently, canola oil is imported from Canada and Malaysia, but could be substituted by alternative vegetable oils. They do not use soya lecithin as an emulsifier and they use wheat flour (rather than soya flour) in their products.

E1.2.3 *Labelling and Reformulation Cost*

Company M considers that the labelling and reformulation cost for packaged food will not be the most significant cost. Instead, they consider that costs of testing would be more significant. They consider that if GM labelling regulations are introduced which affect their products then they would need to increase the frequency of GM testing.

E1.2.4 *Quality Management System*

All of Company M's cake and bread products carry a "Quality Mark" and meet internal quality system standards. One of their products has been HACCP accredited. The cost of maintaining this system is about HK$80,000/month for maintenance, this would be higher if extra testing is required.

E1.2.5 *Views on Options / Impacts of GM Labelling*

They prefer Option (I) Voluntary Labelling as they consider that this option will have minimal impact. They consider that any regulation should be introduced in steps and that mandatory labelling should not be introduced without firm evidence of adverse effects from GM food. They consider that the proposed mandatory options have some ambiguities and need to be clarified.

E1.2.6 *Views on the role of government*

Company M would like to see more information provided by the Government. They consider that the government should provide official testing methods for GM materials. GM testing procedures differ by laboratory and Company M would like to see GM testing brought under a The Hong Kong Laboratory Accreditation Scheme (HOKLAS) scheme in order to standardize procedures.

Company M raised concerns regarding due diligence. They wished to establish where due diligence would lie for example in a situation where they had used raw materials believed to be non-GM raw materials (having accepted importer and supplier assurances), but later Company M's end products were found, by external bodies, to have GM materials.

E1.2.7 *Other Points / Views*

At the moment Company M do not ask their suppliers to provide non-GM raw materials nor to carry out non-GM verification procedures.

Company M will follow government regulations if GM labelling regulations are implemented.

Company M do not consider it practical or possible to test all the food ingredients that they use as the costs would be high and cross contamination may result in false positive GM test results.

E1.3 *CASE STUDY COMPANY X – A MULTI - NATIONAL*

E1.3.1 *Company Description*

Company X is a large multi-national with regional manufacturing plants located across Asia and other parts of the world. Pre-packaged food imported into Hong Kong is manufactured in countries throughout Asia including the Philippines, Indonesia and China. The company have a presence in Hong Kong but use local distributors to supply the supermarkets and convenience stores. Company X manufacture a wide range of food products and have a significant market share. Food categories include biscuits, dairy, confectionary and snack foods.

E1.3.2 *Approach to GM*

Their international policy is to meet the needs of the consumer (in addition to meeting any GM regulations wherever they have been introduced). Consequently all ingredients containing GMOs that require label declaration are/will be substituted and foods are/have been reformulated. There is an overall reluctance by food companies to label for GM as it is thought that the consumer may discriminate against their products. They have taken a worst-case scenario approach and 'GMO cleansed' the system. The rationale for this decision is that even a minor reaction from some consumers could result in a loss of sales, which is unacceptable to the company.

The food industries have agreed amongst themselves not to publish a public policy on GM whist the regulatory environment and marketplace for non-GM ingredients are still evolving and are uncertain. They do not wish to be held to publicly made claims in unforeseen circumstances.

Industry have rejected the term 'GM-free' as it is felt that this is a term open to misuse and misinterpretation and leaves room for unfair practice unless rigorously enforced.

E1.3.3 *Changes required to Products*

With option I where labelling would not be mandatory no changes would be required - therefore this is the preferred industry position.

Any requirements to declare GMOs on food labels will prompt reformulation changes, which in turn may necessitate labelling redesign and artwork changes to reflect change of ingredients.

If labelling is required, is should be least restrictive (Option II). A 5% level takes away a lot of minor components - e.g. starches used from the US which are used at 2-4% by content weight.

Key concerns are for minor components, sub components, especially from flavours, additives and chemically modified products, e.g. starches and sugars. Examples of food ingredients that were found to have used GM ingredients include annatto colouring which is soya based and GM enzymes used to clarify sugar. There is even a need to check the honey used in cereal bars.

To ensure non-GMO labelling, company X have undertaken extensive product changes for many markets including Australia, Philippines, Korea, and Japan. As they have regional manufacturing plants producing for many markets, products exported to Hong Kong, have already been reformulated to be non-GMO.

Costs and types of Changes Required

Any requirement to label will incur costs, even if only to set up compliance requirements and ongoing auditing, this could be significant.

Average costs to labelling artwork and redesign changes have averaged US $2,500 per label - this arose where substitution of ingredients resulted in changes to the ingredient lists. A paper label might cost around US$ 800 to redesign whilst redesigning flexible wrapping may cost US$ 10,000.

The R & D costs for some 88 end products (covering substitution of 40+ ingredients) amounted to US$0.5 million. A full time development program ran for a period of 18 months involving testing for flavour, shelf life, rancidity and other attributes for all products that were reformulated. These 88 products are from across the board and are sold throughout the Asia Pacific region.

In Australia, maintenance of the strict compliance documentation required extensive time and effort. Ongoing compliance involves an audit trail or documentation and/or expensive DNA analysis.

Some export shipments (to China, Korea and Thailand) require certificates of analysis, adding to time, complexity and uncertainty. If testing results in a false positive this can lead to the shipment sitting on the wharf whilst GMO status is established.

Initial set up costs of IP systems are high. After which IP systems are integrated into the QM systems. IP lecithin could be up to 50% (anecdotal estimate) in a tight market whilst other minor ingredients may cost 20-30% more.

Any product brought into the Company X International Organization needs a signed off declaration stating non-GM status. This has led to certification requirements within the same company for products and food ingredients (flavourings, colourings etc) originating from Company X North American division.

E1.3.4 Testing

Company X initially used a testing laboratory in Germany, air-freighting samples to the EU until such time they were confident that local laboratories were proficient and reliable. If they used a local laboratory and they were given a false positive or dubious result, this would still be legal until such time as it was proved to be inaccurate. False results can disrupt the supply chain, and shipments can be stranded on the dockside causing out of stock situations. Which in Hong Kong, would be expensive as out of stock situations are penalised by the supermarket at a rate of US$ 10,000 per SKU/ day (plus the margin loss & customer buys elsewhere).

E1.3.5 *Inadvertent Contamination*

Contamination may not be uniform throughout batches. If an extra bag is added to a production system and this bag is from an alternative source of supply that is GM contaminated. This extra bag can move through the system as a 'hotspot'. If through random sampling at the quayside this hotspot is detected then the entire batch would be rejected. A container load of a cheap product such as biscuits or mayonnaise has a minimum cost value of US$ 50-60,000 (retail value would be much more).

Options IV and V make no reference to inadvertent contamination - e.g. of hotspots. If a batch is contaminated it won't make a 1% threshold, probably would make a 2% threshold.

E1.3.6 *Liability*

Irrespective of where the legal liability lies, the end result is that in order to protect the brand, in reality the liability lies with the manufacturer.

If the contract stipulates non-GM then it is likely that large companies will not pay their supplier in breach of contract. However, it was pointed out that where a small manufacturer was buying from a large food ingredient supplier the contract may include a disclaimer stating the possibility of contamination and known risks, therefore in the event of GM being detected, it would be unlikely that the small manufacturer would 'win' and this could result in the loss of an entire batch leading to severe financial difficulties for smaller companies.

E1.3.7 *Potential Enforcement by Green Groups?*

Enforcement agencies do not want to impose too much on industry and will in most cases accept a paper trail. Some country approaches have been to ignore non-compliant companies. But this leads the enforcement agency open to criticism and undermines credibility of the policy if independent detection of GM occurs.

E1.3.8 *Experiences from Other Countries*

- No impact where labelling is voluntary e.g. USA and Canada.
- Greatest impact where labelling requirement are strict e.g. Australia and New Zealand.
- The least impacts of labelling legislation appears to be Japan. Korea was of some concern initially due to imported ingredients.
- High degree of concern within countries that initially considered GMO bans or restrictive regulations. e.g. Thailand, Philippines, Sri Lanka, Indonesia. Where there has been over reaction this has created uncertainty leading to unnecessary burden on local business - in these type of scenarios business virtually has to shut down.

- Importation of ingredients from many countries including an enormous number of minor components (flavours, additives, processing aids), has created extreme difficulties maintaining a non-labelling requirement.

The Australian Experience – Key Learnings

a) Product reformulation in Australia (highly restrictive legislation) has resulted in an extensive R&D program.

b) Consider that a "whole of Government" approach was not undertaken to reflect cost / benefit to all stakeholders. Extensive cost requirements to industry of around US $5 billion (this study was commissioned by the Australian Food and Grocery Council who represents 85% of food manufacturers in Australia) to maintain identity preservation and compliance.

c) Consider that there was a lack of understanding of cross-contamination of ingredients originating from a long (global) food chain.

d) There was an initial call for the phrase of "may contains" but this was rejected as it was found to be meaningless to consumers.

e) Consider that there was a lack of appreciation of business needs to avoid any issue that may jeopardise any market share, i.e., no company would label for presence of GMOs.

f) Government supported GMO technology but virtually eliminated any usage in food by requiring stringent labelling. Despite (minor) exemptions, there is no support for any use of GMOs in Australian foods and the technology is likely to remain a dead issue within food for the near future.

g) Australian labelling exemptions are:

   i. Highly refined products (no DNA).

   ii. Processing Aids.

   iii. Flavours (only) $\leq$ 0.1% in final product. This level exempts those flavours that are highly concentrated but synthetic flavours are typically used at 0.2% of final product whilst savoury flavours (e.g. spices) are used at 1-2% of final product.

The level adopted for flavours only exempts flavours that are highly concentrated. Synthetic flavours are typically used at 0.2% of final product whilst savoury flavours (e.g. spices) are used at 1-2% of final product and therefore would not be exempt under the Australian scheme.

E1.3.9 *Views on Options*

General preference expressed for Option II.

Acceptance of Option II – Application in Japan, Korea and proposals in other countries (Thailand) have not yielded consumer reactions; and experience is that this provides a better business environment than that in Australia.

If the focus of the option is on major ingredients (i.e. option II and III), this results in lower requirements for documentation, certification and identity preservation requirements in handling raw materials.

Exemptions – The exclusion of low levels of GM ingredients and highly refined products without DNA allows credible compliance at lower cost.

Threshold Level – A low threshold tolerance (e.g. Option V) has been the basis of key concerns in maintaining regulatory compliance.

Future use of Technology – will be enhanced where lower levels of GMOs are permitted without labelling. This will allow initial gradual expansion of usage rather than total elimination of GM technology, which appears to be happening.

E1.3.10 *Other points raised*

The multi-national wanted to know when labelling regulations might be brought in and what is the timetable for the end of the RIA.

E1.4 *CASE STUDY: COMPANY Y – A LOCAL FOOD IMPORTER*

E1.4.1 *Company Description*

Company Y is a local Hong Kong based company.. They are an international trading and distribution company, importing, exporting, wholesaling and retailing a range of food products from around the world. These include edible oils, sugar, soya beans, grains, rice, canned foods, seasoning & condiments, groceries, meat, poultry, seafood wide and other branded products whish are sold to wholesalers and the food industry throughout Hong Kong and China. Company Y is also involved in the business of frozen food processing, serving numerous supermarkets and the catering industry in Hong Kong, Shenzhen and Guangzhou.

E1.4.2 *Edible Oils*

Company Y import soya bean, canola, corn, sesame and peanut oils, which they buy on the world markets. By volume soya bean and canola make up the greatest part of their imports. Soya bean and canola oil are widely used in the food manufacturing industry and are considered to be almost perfect substitutes; i.e. purchase decision will depend upon current availability and price.

Oils are imported into Hong Kong in bulk and in large drums. Company Y then repackage into individual units for sale to the catering trade and retail outlets. Oils are stored temporarily on 'floating warehouses' (barges). Company Y classify their customers into different categories: oil dealers, local distributors, restaurants, baker, food manufacturer and supermarkets.

GM status of Oil

All of the oils that Company Y imports are high-grade refined edible oils. They do not import margarine, palm oils, and lower grade soya, corn, canola or cold pressed oils, which might still contain traces of novel DNA. Therefore they currently do not consider that their products would be affected by the proposed options.

E1.4.3 Soya bean

Hong Kong soya bean market

Company Y estimated that the total edible grade soya bean market into Hong Kong totalled some 35,000 metric tonnes per year. 85-95% of this came from Canada. Company Y estimates that they have 40% of market share and that in total there are 2-3 major importers of soy bean into Hong Kong.

Company Y soya bean trade

All the soya beans that Company Y imports are edible grade soya beans. On average they import 3 shipments of soya beans per month (or 35/ year). Soya beans arrive in 50kg bags and arrive with certification of IP systems. Company Y occasionally test (1-2 times per year) to verify IP certification.

Non-GM forms part of the quality criteria on the contract with their suppliers. This has been the case for the last 3-4 years as all their major customers have demanded non-GM. Typically their customers have demanded a 0.5 threshold level on soya beans for adventitious contamination and this is the threshold that they impose on all of their suppliers. Company Y consider that globally nearly all edible-grade soya beans are now non-GM and as a result they do not pay a premium for non-GM status. A price difference between GM and non-GM exists for the crushing grade soya bean market i.e. soya beans destined to be crushed for the oil and meal (for the processed food and animal feed markets). Company Y do not import the crushing grade soya beans.

95% of the soya beans are imported from Canada with a limited amount coming from China and the US. As their clients have imposed non-GM a part of the quality criteria they rarely import from the US as they estimate that 75% of US soya beans are GM. They do not import from Brazil as these soya beans tend to be crushing / feed grade.

End destination of Soya beans

Company Y's end clients for their imported soya beans are in China and Hong Kong. Domestically, their imports go to:

- 20% soya sauce manufacturers - end product: packaged product.
- 20% soya milk production - end product: packaged product.
- 60 % beancurd processors - 95% of end products (tofu, etc) are destined to wet markets and restaurants where the products are sold unpackaged and unlabelled. The remaining 5% is sold to a packaged tofu manufacturer who produces packaged tofu sold in supermarkets.

The market for fresh green beans and soya bean sprouts is very small and Company Y does not import products for these markets.

E1.4.4 *Other products imported*

Company Y is an authorised rice importer in Hong Kong. For the moment they do not consider rice to fall into the 'potentially GM' category.

Company Y import fresh milk and soya milk products from Singapore. They import 2-3 containers of soya milk per month. This brand is targeted for the mass market and is priced towards the lower end of the soya milk market. This brand is currently labelled as non-GM and is retailed by one of the major supermarkets.

Aside from soya milk and soya bean they don't consider that any of their other imports contain soya as a major ingredient.

All the flour that they import is wheat flour, which at present they do not consider to be 'potentially GM'.

They import potato and corn starch. The corn starch that they import from is all from Europe and they consider that these sources are non-GM.

E1.4.5 *Views on Impacts of GM labelling*

Company Y consider that the majority of their import products do not fall into the 'potentially GM' category. Where re-labelling is required, there would be a one-time cost of redesigning and changing the print cylinder. The costs depend upon the number of colours used on the label. A single colour costs HK$ 2,000, and therefore if a label has 4 colours the total cost would be 4 X HK$2,000 = HK$8,000. Company Y considers that this cost is minimal when compared to the number of product units sold.

E1.5 CASE STUDY COMPANY Z – A LOCAL HONG KONG MANUFACTURER

E1.5.1 *Company Description*

Company Z is a local manufacturer based in the Hong Kong. They are a long established local firm, producing many product lines. They have significant market share in all of their packaged products.

They use over 1000 different ingredients in the manufacture of their products. These ingredients are sourced from many different suppliers.

E1.5.2 *Market Share*

Company Z products are found in all the supermarkets, Circle K and 7-11. Most stores in Hong Kong stock their products, although the largest volumes are sold through the supermarkets.

Company Z exports products to China and Macau. They also have manufacturing plants located in China.

E1.5.3 *Approach to GM*

To date they have identified 8 ingredients with GM content. These ingredients are all minor ingredients (except for 1) and by weight make up 0.5%-1% of the total product (therefore would be exempt under options 2 and 3) and by cost make up maybe 1% of total product cost. These 8 ingredients are used widely in many of their products - 2 of these ingredients are sourced from the US, whilst 2 are flavourings containing ingredients from multiple sources. They are working on reformulating the products that use these ingredients and hope to find suitable substitutes by the end of the year.

In addition, they have already switched 10 other ingredients to non-GM. This resulted in a 33% increase in material costs (for these ingredients- mostly minor) amounting to some HK$ 133,000 per year. These costs were not reflected in retail price changes.

E1.5.4 *Views on options*

Company Z would prefer something similar to the Japanese or Taiwanese system i.e. a phased approach. They consider the European system more difficult to meet as Company Z do not have an IP system in place and think that it would be difficult to test all 1000 ingredients that they use in their 300+ product lines.

E1.5.5 *Threshold levels*

Company Z considers that the difference between the threshold levels makes no difference. Setting an overall GM policy will result in companies working towards a non-GM product.

E1.5.6 *Views on the role of the HK government*

Company Z would like to know what the official testing method would be. They would like a method that is internationally recognized and meets export standards.

They also asked what FEHD's approach towards laboratory testing would be. Will the government accept results from only certified labs or from any laboratory?

What size of sample would be required? Company Z asked how large the sample sizes would be and whether sampling protocols follow US procedures or others?

Company Z would like to see the HKSAR government offer more information on the integration of GM detection into Quality Management systems (e.g. HACCP). The company would also like to see the HKSAR government counter some of the green groups. Company Z consider that whilst the green groups have done a good job in raising awareness of this issue, the green groups then set a time frame that did not allow for the difficulties of operating in the Hong Kong market place.

E1.5.7 *Other lessons encountered*

Company Z are working with their suppliers but they sometimes have a problem with the reliability of their suppliers. They are buying some products from farmers in China and cannot expect these farmers to have sophisticated testing or certificates.

Even when a non-GM certificate is produced or the suppliers say that something is non-GM – they would still need to test to verify these claims. This could lead to an increase in costs, either by the supplier passing on these tests or Company Z having to internalises the costs of the tests themselves.

Annex F

Breakdown by Household Expenditure Categories

Breakdown of Household Expenditure Categories & Rationale for Inclusion

Commodity Subcategory	Sold Packaged & That May Have Detectable GM Ingredient	Discussion
Group 2: Rice		
Rice, main staple; Rice, others	No	There are currently no commercial GM rice crops although some are currently in field trials.
Group 3: Other cereals and cereal preparations		
Instant noodles, rice-sticks, congee, etc	Yes	Some cup noodles contain corn as a minor ingredient. In addition, flavourings may contain soya. However, market leader Nissin noodles communicated to an NGO that it does not use GM ingredients.
Macaroni	Yes	Some macaroni mixes contains corn and/or corn starch. Some manufacturers have already gone GM cleansed their products.
Corn starch	Yes	The market is highly concentrated with the marked dominated by one or two international brands that are packaged locally.
Other flour	Yes	This category includes pancake and other flour based mixes. Many of these products are from Australia or from multinationals' such as Betty Crocker (owned by General Mills/Pillsbury, USA).
Other cereal preparations	Yes	This category includes breakfast cereals - both wheat based and corn based. Cereals are primarily from multinationals brands including General Mills/Pillsbury (Wheaties, Cherrios, Chex, Trix), Kellogs (Special K, Froot Loops, Rice Krispies, Frosted Flakes, mini-wheats), Kraft foods (Post Cereal brands: Grape Nuts, Alpha Bits), Quaker, and Weetabix (Alpen and Weetabix). As well as some lesser know European brands. Some of these cereals contain fructose corn-syrup. Most of the corn based cereals are international brands and therefore can be probably be resourced from non-GM production facilities.
Dried rice sticks; Wet rice sticks; Spaghetti; Wet noodles; Dry noodles; Rice flour; Glutinous rice flour; Bean flour; Wheat flour; Baking powder; Rolled oat (including instant rolled oats)	Yes	There are no commercial GM rice varieties available. Spaghetti is made from wheat. The supermarket surveys did not identify any packaged bean flour. However, it is possible that some of the products might contain minor amounts of corn flour or soya as a flavouring or carrier.
Group 4: Bread, cakes, biscuits and puddings		
Bread	Yes	Potential GM ingredients in bread are corn flour, soya flour, and lecithin. These are minor ingredients and would only be flagged by option IV & V.
European cakes	Yes	This category includes both fresh and frozen cakes. Fresh cakes are primarily sold unpackaged, although some varieties such as Swiss-rolls are packed. These cakes contain an undefined flour, which could be corn or soya flour.
Moon cake	Yes	Moon cakes contain an undefined flour.

Commodity Subcategory	Sold Packaged & That May Have Detectable GM Ingredient	Discussion
Chinese cakes	Yes	These cakes/sweets are sold packaged in supermarkets and speciality stores. They contain an undefined flour.
Chinese puddings and desserts	Yes	Food in this category is sold both fresh/unpackaged and as ready-made mixes. The majority being unpackaged. A significant fraction of the packaged mixes in our survey were made in Australia. Most contained some corn flour, while a smaller fraction contained soya flour.
Biscuits	Yes	There are significant number of international brands this category. The major brands are: McVities (UK), Arnott's (Australia), Cadbury (UK), Jacob's (UK), Lotte (Japan), Nabisco (USA), Nestle (USA).
Group 5: Salt-water fish		
Live grouper; Live bream; Live rabbit fish; Live bam; Live salt-water fish, others; Fresh or chilled golden thread; Fresh or chilled big eye; Fresh or chilled mackerel; Fresh or chilled grouper; Fresh or chilled sole; Fresh or chilled horsehead; Fresh or chilled pomfret; Fresh or chilled hair tail fish; Fresh or chilled bream fish; Fresh or chilled yellow croaker fish; Fresh or chilled rabbit fish; Fresh or chilled croaker fish; Fresh or chilled scad fish; Fresh or chilled lentjan fish; Fresh or chilled flathead fish; Fresh or chilled thread fin fish; Fresh or chilled white bait fish; Fresh or chilled salt-water fish, others	No	The products in this category currently are not impacted by any of the options under consideration.
Group 6: Fresh-water fish		
Live common carp; Live grass carp; Live mud carp; Live big head; Live California Bass; Live snakehead; Live catfish; Live edible tilapia; Live mandarin fish/ fresh water perch; Live fresh-water fish, others; Fresh or chilled grey mullet; Fresh or chilled fresh-water fish, others	No	The products in this category currently are not impacted by any of the options under consideration.
Group 7: Other fresh sea products		
Fresh or chilled prawns and shrimps; Live prawn and shrimps; Live, fresh or chilled lobsters; Live, fresh or chilled crab; Live, fresh or chilled cuttle fish; Live, fresh or chilled squid; Live, fresh or chilled shelled sea products; Live, fresh or chilled sea products, others; Sashimi, salmon, tuna etc; Sashimi, others	No	The products in this category currently are not impacted by any of the options under consideration.
Group 8: Processed sea products		
Chilled or frozen fish preparations	Yes	Potentially contains corn starch.
Chilled or frozen fish ball	Yes	Potentially contains corn starch.
Chilled or frozen minced fish meat	No	Unlikely to contain GM ingredients.
Canned fish; Canned abalones; Canned sea products, others	Yes	The oil used in canning is highly refined but could still contain traces of GM DNA.

Commodity Subcategory	Sold Packaged & That May Have Detectable GM Ingredient	Discussion
Dried sea products, salted/dried fish; Dried sea products, abalones; Dried sea products, compoys; Dried sea products, squid; Dried sea products, oysters; Dried sea products, shrimps; Dried sea products, shark's fin; Dried sea products, octopus; Dried sea products, fish maw; Dried sea products, seaweed; Dried sea products, others; Frozen fish; Frozen shrimps and prawns; Frozen lobsters; Frozen abalones; Frozen sea products, others; Other processed sea products (incl chilled/frozen)	No	Minimal, if any, GM ingredients. Much of this is sold in speciality stores unpackaged.
Group 9: Pork, locally slaughtered		
Fresh pork (lean meat or minced); Fresh pork belly; Fresh pork chop; Fresh spare ribs; Fresh pig's livers; Fresh pig's kidneys; Fresh pig's tongue; Fresh pig's offals, others; Fresh pig's fore shank; Fresh pig's bones; Other fresh parts of pig, others	No	Fresh meat not impacted by options.
Group 10: Beef, locally slaughtered		
Fresh beef/shin beef (including minced); Fresh fillet/steak; Fresh brisket; Fresh ox livers; Fresh ox tongue; Fresh ox offals, others; Fresh ox sinews; Other fresh parts of ox, others; Fresh edible frog; Other fresh meat	No	Fresh meat not impacted by options.
Group 11: Live poultry		
Live/ fresh/ chilled chicken; Live/ fresh/ chilled duck; Live/ fresh/ chilled pigeon; Live/ fresh/ chilled quail; Live/ fresh/ chilled poultry, others; Offals/parts of live/ fresh/ chilled poultry	No	Fresh meat not impacted by options.
Group 12: Meat, frozen		
Chilled/ frozen beef ball	Yes	May contain corn starch.
Chilled/ frozen sausages (all style)	Yes	May contain corn starch.
Chilled/ frozen pork fillet; Chilled/ frozen loin chops; Chilled/ frozen spare ribs; Chilled/ frozen pig's tongue; Chilled/ frozen pig's fore shank; Chilled/ frozen pork, others; Chilled/ frozen beef fillet; Chilled/ frozen beef steak; Chilled/ frozen ox tongue; Chilled/ frozen beef, others; Frozen whole chicken; Frozen chicken wings; Frozen chicken legs; Frozen chicken breast; Frozen chicken claws; Other frozen chicken parts; Other frozen poultry; Chilled/ frozen cooked ham, sliced; Chilled/ frozen back bacon; Chilled/ frozen mutton; Chilled/ frozen barbecue pack; Other chilled/ frozen meat	Yes	Meat cuts have no GM ingredients mixed with them.

Commodity Subcategory	Sold Packaged & That May Have Detectable GM Ingredient	Discussion
Group 13: Meat, canned		
Canned luncheon meat	Yes	Some canned meats might contain corn starch or glucose as a minor ingredient.
Canned ham; Canned sausages; Canned meat, others; Canned poultry	Yes	Some canned meats might contain corn starch or glucose as a minor ingredient.
Group 14: Meat, others		
Roasted pork, Barbecue pork, Other roasted meat, Lo-mei, Soya sauce chicken, Other cooked chicken, Roasted duck/ goose, Lo-mei duck/ goose, Other cooked poultry; Chinese sausages; Dried pork (Chinese gammon); Dried duck; Chinese ham; Other meat, others	Yes	Sold primarily unpackaged. Some items, such as chilled bacon, luncheon meat, etc. will be sold packaged - these may contain glucose syrup or corn starch as a minor ingredient.
Group 15: Fresh vegetables		
White cabbage; Flowering cabbage; Chinese kale; Chinese lettuce; Cabbage lettuce; Leaf mustard; Water cress; Spinach; Water spinach; Chinese spinach; Tientsin cabbage; Matrimony vinc; Round cabbage; Celery; Chinese chives; Broccoli ; Cauliflower; Pea shoot; Other leaf vegetables; Wax gourd; Hairy gourd; Bitter gourd; Silky gourd; Green cucumber; Egg plant; Chinese radish; Green turnip; Carrots; String beans; Tomatoes; Lotus roots; Potatoes; Ginger; Bean sprouts; Spring onions; Sweet peppers; Onions; Fresh straw mushroom; Other fresh vegetables (excl leaf vegetables)	No	Fresh vegetables are mostly sold unpackaged. GM vegetable crops are generally not produced for un-processed consumption.
Group 16: Processed vegetables		
Canned sweet corn	Yes	Contains corn as major ingredient.
Canned vegetables, others	Yes	Mixed vegetables may have corn.
Frozen vegetables, others	Yes	Mixed vegetables may have corn.
Preserved cabbage; Preserved vegetable; Mustard vegetable; Pickled cabbage; Other preserved vegetables; Dried white cabbage; Other dried vegetables; Red beans; Green beans; Spotted beans; Other dried beans; Canned morel; Canned pickled lettuce; Canned braised bamboo-shoots; canned beans and peas; frozen green peas.	No	No GM ingredients.
Group 17: Fresh fruit		
Oranges; Apples; Pears; Grapes; Bananas; Water melons; Lychees; Mangoes; Mandarins; Longnans; Pomelos; Melons; Papayas; Plums; Durians; Carambolas; Persimmons; Grapefruit; Cherry; Kiwifruit; Strawberries; Peach/ nectarine; Pineapples; Fruit basket/ plate; Fresh fruit, others	No	No GM ingredients.

Commodity Subcategory	Sold Packaged & That May Have Detectable GM Ingredient	Discussion
Group 18: Processed fruit		
Canned fruit	Yes	Syrup used may include corn derivatives which, although highly processed, may include some GM DNA.
Sweetened dates; Dried and preserved red dates; Dried and preserved black dates; Dried and preserved figs; Dried and preserved fruit, others; Jam and marnalade; Other fruit preparations	No	No GM ingredients.
Group 19: Dairy products		
Butter / margarine	Yes	May contain lecithin as a minor ingredient.
Ice-cream / popsticks	Yes	May contain lecithin as a minor ingredient.
Fresh milk; Sterilized milk; Milk powder; Evaporated milk; Condensed milk; Flavoured milk; Yogurt; Cheese; Dairy products, others	Yes	Some dairy products, e.g. low fat yoghurt, may contain novel GM DNA (thickening agents).
Group 20: Eggs		
Hen eggs; Preserved eggs; Salted eggs; Other fresh eggs	No	No novel GM DNA.
Group 21: Edible oil		
Corn oil; Canola Oil	Yes	Can contain residual protein DNA after processing.
Peanut oil; Other edible oils	No	No residual protein DNA after processing.
Group 22: Beverages		
Soya bean milk	Yes	Major manufacturer has committed to be GM-free.
Carbonated drinks	Yes	Contains corn derivative - high fructose corn syrup, some residual GM DNA after processing possible.
Fresh fruit juice; Other fruit juices	Yes	Contains sugar, or possibly high fructose corn syrup, some residual GM DNA possible.
Flavoured drinks; Coffee; Cocoa; Tea, leaf; Tea-bags; Tea, others; Fruit juice and flavoured drinks in powder form; Herb-tea; Essence of chicken; Other meat extracts; Invigorating liquors; Isotonic drinks; Mineral water/ distilled water	Yes	Contains sugar, or possibly high fructose corn syrup, some residual GM DNA possible.
Group 23: Sugar		
Granulated white sugar; Sugar slab; Sugar candy; Honey; Other sugar and sugar preparations	No	Amylase (an enzyme) sometimes used in sugar production, but exempt under all options. Taikoo Sugar claims to be GM free.

Commodity Subcategory	Sold Packaged & That May Have Detectable GM Ingredient	Discussion
Group 24: Confectionary		
Chocolates	Yes	Contains lecithin as a minor ingredient. Most chocolates are imported and are major multi-national brands. It can be expected that the chocolate can be easily resourced from Europe or Australia.
Candies	Yes	Contains high fructose corn syrup (exempt) and some contain lecithin.
Chewing gum	No	No GM ingredients that are detectable. Dextrose is very unlikely to have any traces of detectable GM DNA.
Chinese confectionery	Yes	Contains undefined flour, possibly corn flour.
Other confectionery	Yes	Much of this will be sold unpackaged but some could contain traces of GM DNA.
Group 25: Flavourings and additives		
Soya sauce	Yes	Contains soya.
Chili sauce	Yes	Some varieties contain soya.
Yellow soya beans	Yes	Soya bean.
Fermented bean, dried	Yes	Bean curd is likely produced using high-grade Soya, which is a non-GM variety.
Preserved bean curd	Yes	Bean curd is likely produced using high-grade Soya, which is a non-GM variety.
Salad pastes	Yes	Salad dressing may contain soya oil, although this may be exempt. Given the variety of pastes available it is likely that some will be impacted by the options.
Oyster sauce; Tomato ketchup; Salt; Vinegar; Gourmet powder; Shrimp paste; Superior broth/ clear chicken broth; Other flavourings and additives	Yes	A few products could contain GM ingredients.
Group 26: Foods, others		
Soup in tin/ packet	Yes	May contain corn as a major ingredient or corn flour as a thickener.
Frozen instant food	Yes	Could contain corn derivatives as thickeners (corn flour).
Bean curd	Yes	Likely made from high grade (non-GM) soya beans.
Bean curd products	Yes	Likely made from high grade (non-GM) soya beans.
Potato chips	Yes	Flavours may use Soya derivative as a carrier.
Corn Snacks	Yes	Corn is a major ingredient. Most are produced by multinationals that can resource the product.
Other snacks; Other cooked snacks	Yes	Likely to contain corn starch as a minor ingredient.
Mushroom, dried; Dried fungus; Bean vermicelli; White nuts, raw; Ground nuts, raw; Cashew nuts, raw; Lotus nut, raw; Walnut, raw; Other nuts and seeds, raw; Fried shrimp paste; Dried pork, snacks; Dried beef, snacks; Dried chicken, snacks; Fried/ cooked nuts; Dried and preserved fruit; Jellies; Baby food; Sushi, handroll; Bird's nest; Hashima; Other food, others	Yes	The majority of these products will not contain GM ingredients. There may be some sensitivity to GM ingredients in baby food, however from a cost (rather than policy) standpoint total consumption of baby food is not significant compared to other products that might require reformulation, and therefore its contribution to costs as a result the various labelling options will be small compared to other categories (such as corn snacks).

Results of Household Expenditure Analysis (HK$)

Description	Option II				Option III				Option IV				Option V			
	Minimum		Maximum		Minimum		Maximum		Minimum		Maximum		Minimum		Maximum	
	Reformulation (one-of)	Compliance (per yr)	Reformulation (one-of)	Compliance (per yr)	Reformulation (one-of)	Compliance (per yr)	Reformulation (one-of)	Compliance (per yr)	Reformulation (one-of)	Compliance (per yr)	Reformulation (one-of)	Compliance (per yr)	Reformulation (one-of)	Compliance (per yr)	Reformulation (one-of)	Compliance (per yr)
Rice																
Other cereals and cereal preparations	.66m	68.k	.66m	68.k	.97m	220.5k	.97m	220.5k	1.89m	79.4k	1.89m	79.4k	2.73m	249.8k	2.73m	249.8k
Bread, cakes, biscuits and puddings	.35m	2.9k	.35m	2.9k	.53m	9.5k	.53m	9.5k	4.97m	89.7k	4.97m	89.7k	7.35m	182.5k	7.35m	182.5k
Salt-water fish																
Fresh-water fish																
Other fresh sea products																
Processed sea products			.62m	23.4k			.88m	75.8k	.88m	.1k	1.5m	23.5k	1.32m	.2k	2.2m	76.1k
Pork, locally slaughtered																
Beef, locally slaughtered																
Live poultry																
Meat, frozen									.97m	2.9k	.97m	2.9k	1.41m	6.2k	1.41m	6.2k
Meat, canned									.84m	2.5k	.84m	2.5k	1.19m	5.3k	1.19m	5.3k
Meat, others									.44m	.3k	.44m	.3k	.66m	.6k	.66m	.6k
Fresh vegetables																
Processed vegetables	.7m	21.3k	.7m	21.3k	1.01m	69.k	1.01m	69.k	.7m	21.3k	.7m	21.3k	1.01m	69.k	1.01m	69.k
Fresh fruit																
Processed fruit	.26m	2.4k	.26m	2.4k	.26m	5.1k	.26m	5.1k	.26m	2.4k	.26m	2.4k	.26m	5.1k	.26m	5.1k
Dairy products	.18m	2.9k	.18m	2.9k	.22m	9.3k	.22m	9.3k	.75m	9.9k	.75m	9.9k	1.01m	23.7k	1.01m	23.7k
Eggs																
Edible oils			.44m	232.3k			.66m	753.k			.44m	232.3k			.66m	753.k
Beverages	.53m	147.9k	1.76m	353.5k	.79m	446.1k	2.55m	1.11m	.53m	147.9k	1.76m	353.5k	.79m	446.1k	2.55m	1,112.6k
Sugar																
Confectionary	.62m	11.8k	.62m	11.8k	.88m	38.1k	.88m	38.1k	2.02m	14.8k	2.02m	14.8k	2.9m	44.3k	2.9m	44.3k
Flavourings and additives	1.06m	68.5k	1.14m	68.7k	1.5m	206.7k	1.63m	207.2k	1.72m	70.5k	1.8m	70.6k	2.46m	210.6k	2.6m	211.1k
Food, Other	1.76m	39.6k	1.76m	39.6k	2.55m	127.4k	2.55m	127.4k	5.63m	62.k	5.63m	62.k	8.23m	175.1k	8.23m	175.1k
Total (HK$)	**6.12m**	**.37m**	**8.49m**	**.83m**	**8.71m**	**1.13m**	**12.14m**	**2.63m**	**21.6m**	**.5m**	**23.98m**	**.97m**	**31.33m**	**1.42m**	**34.76m**	**2.91m**

Notes: 'm' is million

'k' is thousand

Annex G

Economic and Financial Analysis

Table G1: Option II

Item	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Economic Impacts										
Economic costs										
Minimum Government Costs	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094
Minimum reformulation cost	6,116,000	305,800	305,800	1,053,800	343,200	343,200	343,200	343,200	343,200	343,200
Minimum ongoing cost	365,216	356,085	347,183	378,303	368,845	359,624	350,633	341,868	333,321	324,988
Minimum testing costs	889,600	467,040	467,040	575,840	524,160	524,160	524,160	524,160	524,160	524,160
Maximum Government Costs	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436
Maximum reformulation cost	8,492,000	424,600	424,600	1,172,600	462,000	462,000	462,000	462,000	462,000	462,000
Maximum ongoing cost	826,783	806,114	785,961	833,242	812,411	792,101	772,298	752,991	734,166	715,812
Maximum testing costs	1,235,200	648,480	648,480	757,280	705,600	705,600	705,600	705,600	705,600	705,600
Minimum Total Costs	*8,416,910*	*2,175,019*	*2,166,117*	*3,054,037*	*2,282,299*	*2,273,078*	*2,264,087*	*2,255,322*	*2,246,775*	*2,238,442*
Maximum Total Costs	*15,329,419*	*6,654,630*	*6,634,477*	*7,538,558*	*6,755,447*	*6,735,137*	*6,715,334*	*6,696,027*	*6,677,202*	*6,658,848*
Minimum Net Present Value of Costs		***24,771,941***								
Maximum Net Present Value of Costs		***63,295,400***								
Financial Impacts to the Food Trade										
Costs to the trade										
Minimum reformulation cost	6,116,000	305,800	305,800	1,053,800	343,200	343,200	343,200	343,200	343,200	343,200
Minimum ongoing cost	365,216	356,085	347,183	378,303	368,845	359,624	350,633	341,868	333,321	324,988
Minimum testing costs	889,600	467,040	467,040	575,840	524,160	524,160	524,160	524,160	524,160	524,160
Maximum reformulation cost	8,492,000	424,600	424,600	1,172,600	462,000	462,000	462,000	462,000	462,000	462,000
Maximum ongoing cost	826,783	806,114	785,961	833,242	812,411	792,101	772,298	752,991	734,166	715,812
Maximum testing costs	1,235,200	648,480	648,480	757,280	705,600	705,600	705,600	705,600	705,600	705,600
Minimum Total Costs	*7,370,816*	*1,128,925*	*1,120,023*	*2,007,943*	*1,236,205*	*1,226,984*	*1,217,993*	*1,209,228*	*1,200,681*	*1,192,348*
Maximum Total Costs	*10,553,983*	*1,879,194*	*1,859,041*	*2,763,122*	*1,980,011*	*1,959,701*	*1,939,898*	*1,920,591*	*1,901,766*	*1,883,412*
Minimum Net Present Value of Costs		***16,287,182***								
Maximum Net Present Value of Costs		***24,562,336***								

Key Data:		Maximum average ongoing cost (HK$/product)	4,284
Discount Rate	4%	*Year 3 onward*	
Government Costs		Minimum additional number of products at risk	17
Minimum enforcement cost (HK$)	1,046,094	Minimum average ongoing cost (HK$/product)	2,341
Maximum enforcement cost (HK$)	4,775,436	Maximum additional number of products at risk	17
Products		Maximum average ongoing cost (HK$/product)	3,937
Reformulation cost (HK$/product)	44,000	Annual percentage decrease in ongoing costs	2.5%
Year 1- 3		Turnover of products per annum	5%
Minimum number of products at risk	139	Testing Costs	
Minimum average ongoing cost (HK$/product)	2,627	Unit Cost (HK$/product)	3,200
Maximum number of products at risk	193		

Table G2: Option III

Item	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Economic Impacts										
Economic costs										
Minimum Government Costs	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094
Minimum reformulation cost	8,712,000	435,600	435,600	1,535,600	490,600	490,600	490,600	490,600	490,600	490,600
Minimum ongoing cost	1,131,617	1,103,327	1,075,744	1,107,378	1,079,694	1,052,701	1,026,384	1,000,724	975,706	951,313
Minimum testing costs	1,267,200	665,280	665,280	825,280	749,280	749,280	749,280	749,280	749,280	749,280
Maximum Government Costs	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436
Maximum reformulation cost	12,144,000	607,200	607,200	1,707,200	662,200	662,200	662,200	662,200	662,200	662,200
Maximum ongoing cost	2,627,438	2,561,752	2,497,709	2,533,692	2,470,350	2,408,591	2,348,377	2,289,667	2,232,425	2,176,615
Maximum testing costs	1,766,400	927,360	927,360	1,087,360	1,011,360	1,011,360	1,011,360	1,011,360	1,011,360	1,011,360
Minimum Total Costs	*12,156,911*	*3,250,301*	*3,222,718*	*4,514,352*	*3,365,668*	*3,338,675*	*3,312,358*	*3,286,698*	*3,261,680*	*3,237,287*
Maximum Total Costs	*21,313,274*	*8,871,748*	*8,807,705*	*10,103,688*	*8,919,346*	*8,857,587*	*8,797,373*	*8,738,663*	*8,681,421*	*8,625,611*
Minimum Net Present Value of Costs		***36,220,518***								
Maximum Net Present Value of Costs		***84,491,129***								
Financial Impacts to the Food Trade										
Costs to the trade										
Minimum reformulation cost	8,712,000	435,600	435,600	1,535,600	490,600	490,600	490,600	490,600	490,600	490,600
Minimum ongoing cost	1,131,617	1,103,327	1,075,744	1,107,378	1,079,694	1,052,701	1,026,384	1,000,724	975,706	951,313
Minimum testing costs	1,267,200	665,280	665,280	825,280	749,280	749,280	749,280	749,280	749,280	749,280
Maximum reformulation cost	12,144,000	607,200	607,200	1,707,200	662,200	662,200	662,200	662,200	662,200	662,200
Maximum ongoing cost	2,627,438	2,561,752	2,497,709	2,533,692	2,470,350	2,408,591	2,348,377	2,289,667	2,232,425	2,176,615
Maximum testing costs	1,766,400	927,360	927,360	1,087,360	1,011,360	1,011,360	1,011,360	1,011,360	1,011,360	1,011,360
Minimum Total Costs	*11,110,817*	*2,204,207*	*2,176,624*	*3,468,258*	*2,319,574*	*2,292,581*	*2,266,264*	*2,240,604*	*2,215,586*	*2,191,193*
Maximum Total Costs	*16,537,838*	*4,096,312*	*4,032,269*	*5,328,252*	*4,143,910*	*4,082,151*	*4,021,937*	*3,963,227*	*3,905,985*	*3,850,175*
Minimum Net Present Value of Costs		***27,735,759***								
Maximum Net Present Value of Costs		***45,758,065***								

Key Data:		Maximum average ongoing cost (HK$/product)	9,520
Discount Rate	4%	*Year 3 onward*	
Government Costs		Minimum additional number of products at risk	25
Minimum enforcement cost (HK$)	1,046,094	Minimum average ongoing cost (HK$/product)	2,341
Maximum enforcement cost (HK$)	4,775,436	Maximum additional number of products at risk	25
Products		Maximum average ongoing cost (HK$/product)	3,937
Reformulation cost (HK$/product)	44,000	Annual percentage decrease in ongoing costs	2.5%
Year 1- 3		Turnover of products per annum	5%
Minimum number of products at risk	198	Testing Costs	
Minimum average ongoing cost (HK$/product)	5,715	Unit Cost (HK$/product)	3,200
Maximum number of products at risk	276		

Table G3: Option IV

Item	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Economic Impacts										
Economic costs										
Minimum Government Costs	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094
Maximum Government Costs	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436
Minimum reformulation cost	21,604,000	1,080,200	1,080,200	1,080,200	1,080,200	1,080,200	1,080,200	1,080,200	1,080,200	1,080,200
Minimum ongoing cost	503,647	491,056	478,780	466,810	455,140	443,761	432,667	421,851	411,304	401,022
Minimum testing costs	3,142,400	1,649,760	1,649,760	1,649,760	1,649,760	1,649,760	1,649,760	1,649,760	1,649,760	1,649,760
Maximum reformulation cost	23,980,000	1,199,000	1,199,000	1,199,000	1,199,000	1,199,000	1,199,000	1,199,000	1,199,000	1,199,000
Maximum ongoing cost	965,215	941,084	917,557	894,618	872,253	850,447	829,185	808,456	788,244	768,538
Maximum testing costs	3,488,000	1,831,200	1,831,200	1,831,200	1,831,200	1,831,200	1,831,200	1,831,200	1,831,200	1,831,200
Minimum Total Costs	*26,296,141*	*4,267,110*	*4,254,834*	*4,242,864*	*4,231,194*	*4,219,815*	*4,208,721*	*4,197,905*	*4,187,358*	*4,177,076*
Maximum Total Costs	*33,208,651*	*8,746,720*	*8,723,193*	*8,700,254*	*8,677,889*	*8,656,083*	*8,634,821*	*8,614,092*	*8,593,880*	*8,574,174*
Minimum Net Present Value of Costs		***55,481,513***								
Maximum Net Present Value of Costs		***93,870,089***								
Financial Impacts to the Food Trade										
Costs to the trade										
Minimum reformulation cost	21,604,000	1,080,200	1,080,200	1,080,200	1,080,200	1,080,200	1,080,200	1,080,200	1,080,200	1,080,200
Minimum ongoing cost	503,647	491,056	478,780	466,810	455,140	443,761	432,667	421,851	411,304	401,022
Minimum testing costs	3,142,400	1,649,760	1,649,760	1,649,760	1,649,760	1,649,760	1,649,760	1,649,760	1,649,760	1,649,760
Maximum reformulation cost	23,980,000	1,199,000	1,199,000	1,199,000	1,199,000	1,199,000	1,199,000	1,199,000	1,199,000	1,199,000
Maximum ongoing cost	965,215	941,084	917,557	894,618	872,253	850,447	829,185	808,456	788,244	768,538
Maximum testing costs	3,488,000	1,831,200	1,831,200	1,831,200	1,831,200	1,831,200	1,831,200	1,831,200	1,831,200	1,831,200
Minimum Total Costs	25,250,047	3,221,016	3,208,740	3,196,770	3,185,100	3,173,721	3,162,627	3,151,811	3,141,264	3,130,982
Maximum Total Costs	*28,433,215*	*3,971,284*	*3,947,757*	*3,924,818*	*3,902,453*	*3,880,647*	*3,859,385*	*3,838,656*	*3,818,444*	*3,798,738*
Minimum Net Present Value of Costs		***46,996,753***								
Maximum Net Present Value of Costs		***55,137,025***								

Key Data:			
Discount Rate	4%	Maximum number of products at risk	545
Government Costs		Maximum average reformulation cost (HK$/product)	44,000
Minimum enforcement cost (HK$)	1,046,094	Maximum average ongoing cost (HK$/product)	1,771
Maximum enforcement cost (HK$)	4,775,436	Annual percentage decrease in ongoing costs	2.5%
Products		Turnover of products per annum	5%
Minimum number of products at risk	491	Testing Costs	
Minimum average reformulation cost (HK$/product)	44,000	Unit Cost (HK$/product)	3,200
Minimum average ongoing cost (HK$/product)	1,026		

Table G4: Option V

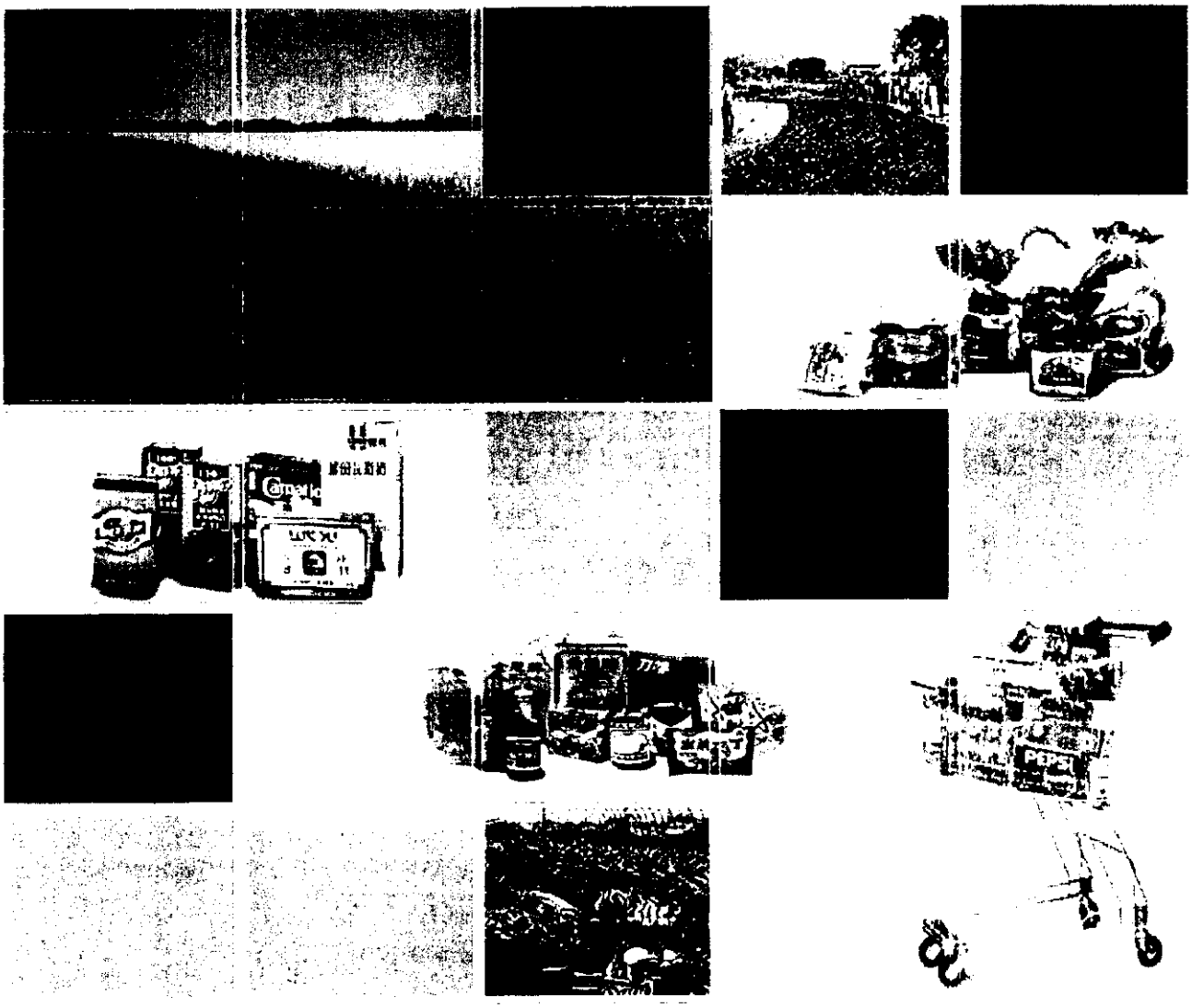
Item	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Economic Impacts										
Economic costs										
Minimum Government Costs	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094	1,046,094
Maximum Government Costs	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436	4,775,436
Minimum reformulation cost	31,328,000	1,566,400	1,566,400	1,566,400	1,566,400	1,566,400	1,566,400	1,566,400	1,566,400	1,566,400
Minimum ongoing cost	1,418,626	1,383,161	1,348,582	1,314,867	1,281,996	1,249,946	1,218,697	1,188,230	1,158,524	1,129,561
Minimum testing costs	4,556,800	2,392,320	2,392,320	2,392,320	2,392,320	2,392,320	2,392,320	2,392,320	2,392,320	2,392,320
Maximum reformulation cost	34,760,000	1,738,000	1,738,000	1,738,000	1,738,000	1,738,000	1,738,000	1,738,000	1,738,000	1,738,000
Maximum ongoing cost	2,914,448	2,841,586	2,770,547	2,701,283	2,633,751	2,567,907	2,503,710	2,441,117	2,380,089	2,320,587
Maximum testing costs	5,056,000	2,654,400	2,654,400	2,654,400	2,654,400	2,654,400	2,654,400	2,654,400	2,654,400	2,654,400
Minimum Total Costs	*38,349,520*	*6,387,975*	*6,353,396*	*6,319,681*	*6,286,810*	*6,254,760*	*6,223,511*	*6,193,044*	*6,163,338*	*6,134,375*
Maximum Total Costs	*47,505,884*	*12,009,422*	*11,938,383*	*11,869,119*	*11,801,587*	*11,735,743*	*11,671,546*	*11,608,953*	*11,547,925*	*11,488,423*
Minimum Net Present Value of Costs		***81,670,339***								
Maximum Net Present Value of Costs		***129,742,593***								
Financial Impacts to the Food Trade										
Costs to the trade										
Minimum reformulation cost	31,328,000	1,566,400	1,566,400	1,566,400	1,566,400	1,566,400	1,566,400	1,566,400	1,566,400	1,566,400
Minimum ongoing cost	1,418,626	1,383,161	1,348,582	1,314,867	1,281,996	1,249,946	1,218,697	1,188,230	1,158,524	1,129,561
Minimum testing costs	4,556,800	2,392,320	2,392,320	2,392,320	2,392,320	2,392,320	2,392,320	2,392,320	2,392,320	2,392,320
Maximum reformulation cost	34,760,000	1,738,000	1,738,000	1,738,000	1,738,000	1,738,000	1,738,000	1,738,000	1,738,000	1,738,000
Maximum ongoing cost	2,914,448	2,841,586	2,770,547	2,701,283	2,633,751	2,567,907	2,503,710	2,441,117	2,380,089	2,320,587
Maximum testing costs	5,056,000	2,654,400	2,654,400	2,654,400	2,654,400	2,654,400	2,654,400	2,654,400	2,654,400	2,654,400
Minimum Total Costs	37,303,426	5,341,881	5,307,302	5,273,587	5,240,716	5,208,666	5,177,417	5,146,950	5,117,244	5,088,281
Maximum Total Costs	*42,730,448*	*7,233,986*	*7,162,947*	*7,093,683*	*7,026,151*	*6,960,307*	*6,896,110*	*6,833,517*	*6,772,489*	*6,712,987*
Minimum Net Present Value of Costs		***73,185,580***								
Maximum Net Present Value of Costs		***91,009,529***								

Key Data:

Discount Rate	4%	Maximum number of products at risk	790
<u>Government Costs</u>		Maximum average reformulation cost (HK$/product)	44,000
Minimum enforcement cost (HK$)	1,046,094	Maximum average ongoing cost (HK$/product)	3,689
Maximum enforcement cost (HK$)	4,775,436	Annual percentage decrease in ongoing costs	2.5%
<u>Products</u>		Turnover of products per annum	5%
Minimum number of products at risk	712	<u>Testing Costs</u>	
Minimum average reformulation cost (HK$/product)	44,000	Unit Cost (HK$/product)	3,200
Minimum average ongoing cost (HK$/product)	1,992		

FSEH Panel
20/3/2003

EXECUTIVE SUMMARY
研究報告摘要



Food and Environmental Hygiene Department
食物環境衞生署

Regulatory Impact Assessment on Labelling of Genetically Modified (GM) Food
基因改造食物標籤規管影響評估

March 2003
二零零三年三月

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EXECUTIVE SUMMARY
研究報告摘要

Food and Environmental Hygiene Department
食物環境衛生署

Regulatory Impact Assessment on Labelling of Genetically Modified (GM) Food
基因改造食物標籤規管影響評估

March 2003

Reference C2363

For and on behalf of
Environmental Resources Management

Approved by: Dr Andrew Jackson

Signed:

Position: Managing Director

Date: 6th March 2003

研究報告摘要

引言

政府現正就預先包裝的基因改造食物考慮多個標籤方案。為此，政府委託香港環境資源管理顧問有限公司進行規管影響評估，以便了解各個方案所帶來的影響。

進行規管影響評估的目的，是研究香港特別行政區為預先包裝的基因改造食物訂定標籤計劃，對經濟可能帶來的影響。

考慮方案

這項研究考慮了下列五個方案：

方案 I：自願為基因改造食物加上標籤

根據這個方案，業界是否為基因改造食物加上標籤，純屬自願。這亦是現時的情況，因為香港並沒有特定法例，規管屬於基因改造類別的產品。

方案 II：分階段為指定產品實施強制性標籤制度 — 容許量為 5%

這個方案規定，食品的主要成分如果包括指定的基因改造農作物，就必須加上標籤。主要成分是指按食品的重量計算居於首五位者，並佔最終製成品重量至少 5%。這些基因改造食品的容許量為 5%(即任何主要成分的基因改造物質含量如超過 5%便須加上標籤)。此外，基因改造食物的特質與原來品種如有很大的差別，例如產生致敏原、成分或營養價值有所改變等，都必須在標籤內註明。不過，精製食品、食物添加劑、香料和加工助劑，則可獲豁免。在第一階段，基因改造黃豆和玉米產品(以及含基因改造黃豆和玉米的加工食品)必須加上標籤；到了第二階段，菜籽、馬鈴薯和棉籽，也須加上標籤說明成分。

方案 III：分階段為指定產品實施強制性標籤制度 — 容許量為 1%

這個方案與方案 II 基本上一樣，只是主要成分的基因改造物質含量的容許量定為 1%。

方案 IV：實施強制性標籤制度，所有基因改造食物須加上標籤 — 容許量為 5%，多重加工食物獲得豁免

根據這個方案，任何食品如含有超過 5%的基因改造物質，均須加上標籤。此外，基因改造食物的特質與原來品種如有很大的差別，例如產生致敏原，成分或營養價值有所改變等，都必須在標籤內註明。不過，精製食品、食物添加劑、香料和加工助劑，則可獲豁免。

方案 V：實施強制性標籤制度，所有基因改造食物須加上標籤 — 容許量為 1%，多重加工食物獲得豁免

這個方案與方案 IV 基本上一樣，只是容許量為 1%。

標明不含基因改造成分的副方案

這項研究也就標明不含基因改造成分及作出類似聲稱的標籤，考慮了三個副方案：

- *維持現狀* — 即對不含基因改造成分及類似聲稱的標籤，不作特別的規管；

- *提交證明文件* — 即聲稱其產品不含基因改造成分或作類似聲稱的人士，必須提供文件，證明產品如何“保存本質”或出示類似的支持文件，以證明該產品不含基因改造成分；以及

- *禁止作出不含基因改造成分的聲稱* — 即禁止作出不含基因改造成分和其他類似聲稱。

評估結果及有關實施標籤制度的問題

在成本方面對食物業的影響

財務分析結果顯示，方案 II 至方案 V 都會影響食物業的經營成本，方案 I(即維持現狀)則不會令業界的成本增加。

影響主要會在第一年出現，因為公司為確保產品符合法例規定，會在第一年檢驗、重新配製和測試產品。

業界在成本方面的增加幅度，將介乎港幣 1,600 萬元(方案 II 的最低成本)至 9,100 萬元(方案 V 的最高成本)之間。

方案 IV 和方案 V 的成本明顯高於方案 II 和方案 III(前兩項為港幣 4,700 萬元至 9,100 萬元，後兩項則為港幣 1,600 萬元至 4,600 萬元)。主要原因是方案 IV 和方案 V 的涵蓋範圍較廣，包括食品的所有成分，而方案 II 和方案 III 只包括食品的首五項主要成分。

此外，分析結果亦顯示：

- 如有更多基因改造的農作物推出市場，無論政府採用哪個方案，業界承擔的成本都會大幅增加。方案 V 會使成本增加高達 64%；方案 IV 34%；方案 III 51%；而方案 II 也會導致成本增加 28%。當中以方案 III 和方案 V 的估計成本增幅較大，因為這兩個方案都把容許量定為較嚴謹的 1%。

- 假如公司選擇為含有基因改造成分的產品加上標籤，而不是為了避免加上標籤而重新配製產品，業界受到的整體影響可能較小。但是業界多數不會這樣做，因為反對基因改造食物的聲音，通常比支持者或科學安全評估所提出的支持論點，更為人知曉，公司不會冒失去市場佔有率的風險。一名製造商曾指出，即使失去市場佔有率 5%亦不能接受。因此，他們會重新配製產品，改為屬於非基因改造類別。

- 業界的成本受多大影響，要視乎重新配製產品及維持該產品的基因改造類別所涉及的開支。雖然顧問公司已盡量準確地預計所需開支，但實在難以預測個別食品公司對新法例的回應，因此，標籤制度對業界在成本方面的整體影響還有未知之數，會因應個別產品和公司的特殊情況而有所分別。

- 建議的方案可能會對進口某些系列產品的小型進口商影響很大，特別是當他們無法就產品的基因改造類別，與產品製造商達成合約性的協議。部分產品可能因而不能在市面出售，特別是那些進口的數量不多，以及沒有在已執行基因改造標籤法例的司法管轄區(例如歐洲、澳洲、新西蘭、日本和韓國)出售的產品。

- 無論採用哪個方案，部分小型本地食品製造商在實施方案的第一年受到的影響最大。但值得注意的是，對大部分製造商來說，因而增加的成本不會很高。假如這些成本可在一段較長的時間(超過一年)攤分，對公司的收入和利潤的實際影響應該不會太大。在現時的經濟情況下，增加的成本應不會轉嫁給零售商。

對經濟成本的影響

與財務分析結果一樣，方案 II 至方案 V 對香港的經濟成本都會有一定的影響。方案 I(即維持現狀)則不會令香港的經濟成本增加。

*經濟成本與業界成本*唯一不同的地方，是經濟成本包括執法成本。執法成本每年約為港幣 100 萬至 500 萬(視乎所採用的執法措施)。

就如在成本方面對業界的影響一樣，實施標籤制度對經濟成本的影響，主要也會在第一年出現，因為公司為了確保產品符合法例規定，也會在第一年檢驗、重新配製和測試產品。

經濟成本將介乎港幣 2,500 萬元(方案 II 的下限)至 1.3 億元(方案 V 的上限)之間。一如財務分析的結果，方案 IV 和方案 V 的成本，較方案 II 和方案 III 為高(前兩項為港幣 5,500 萬至 1.3 億元，後兩項則為港幣

2,500 萬至 8,400 萬元)。

對消費者的影響

顧問公司與食品製造商和零售商討論後發現，為證明其產品屬於某基因改造類別所涉及的成本，多數不會轉嫁給消費者。已重新配製產品的香港食品製造商和零售商表示，其產品的零售價格並沒有因而改變。其實，產品的零售價格隨着市場需求而變動，有部分產品的價格甚至向下調整。

為了評估萬一成本轉嫁給消費者時可能造成的最大影響，顧問公司計算了這些額外成本佔家庭在食物方面總開支所佔的百分比，以反映消費者可能受到的影響。分析結果顯示，整體食品價格可能受到的最大影響，或會介乎家庭食物總開支 0.03%(方案 II)與 0.10%(方案 V)之間。

標明不含基因改造成分的情況

由於不含基因改造成分的產品有潛在的市場，業界亦希望把其產品的"非基因改造"特質告知顧客，因此或會自行在產品的標籤上，加上不含基因改造成分或類似的聲稱。這項研究探討了如果規管標明不含基因改造成分或作出同等聲稱的產品，對現正這樣做的產品有甚麼影響。顧問公司研究了兩個方案，第一是規定作出不含基因改造成分或類似聲稱者，提供文件證明有關產品屬於非基因改造的類別；第二是禁止標明不含基因改造成分及作出類似的聲稱。

結果顯示，禁止標明不含基因改造成分及作出類似聲稱所涉及的成本，會比要求有關人士提供"保存本質"證明文件的成本為少，但這樣做或會限制了消費者的選擇權利。另一方面，提交"保存本質"證明文件的額外成本，可能會由海外製造商負責，而重新加上標籤的成本，則多半會由香港的公司(例如進口商和零售商)承擔。

研究結果摘要

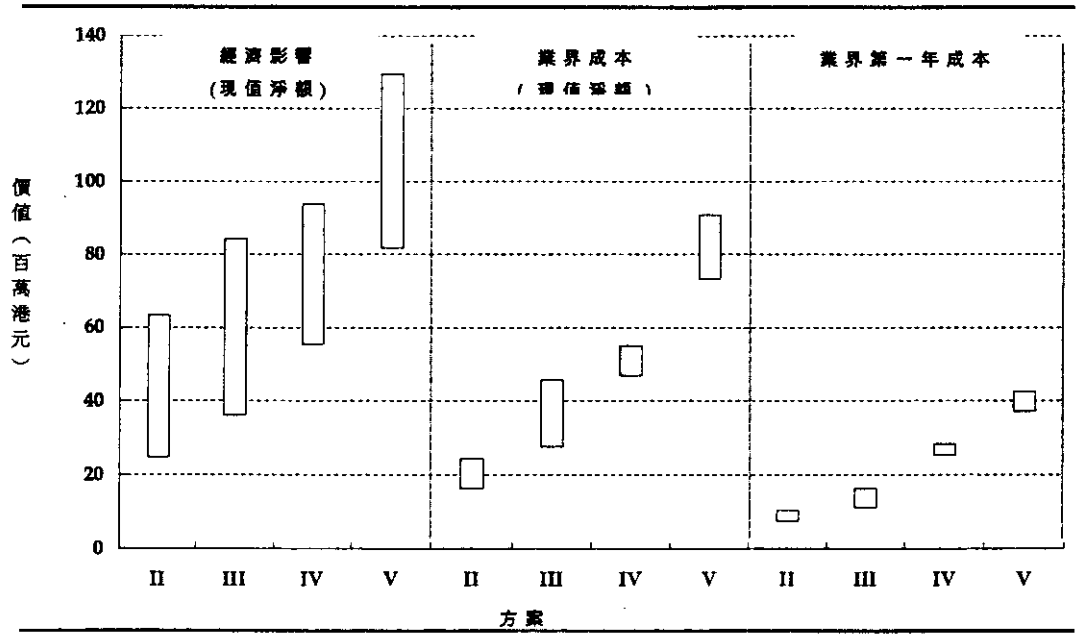
表 1 和圖 1 列載經濟及財務分析的結果。

表 1 成本影響(港幣百萬元)

方案	經濟成本 (現值淨額)		業界成本 (現值淨額)		第一年成本	
	最低	*最高*	*最低*	*最高*	*最低*	*最高*
I	-	-	-	-	-	-
II	25	63	16	25	7	11
III	36	84	28	46	11	17
IV	55	94	47	55	25	28
V	82	130	73	91	37	43

附註：“最低”的情況是假設精製產品，例如油和高果糖糖漿無需重新配製(因為可能獲豁免遵守標籤規定)。“最高”的情況則假設這些產品(油和高果糖糖漿)需要重新配製，以確保被檢出的脫氧核糖核酸(DNA)，不屬於基因改造類別。

圖 1 成本影響(港幣百萬元)



實施標籤制度的障礙

政府如選用方案II至方案V其中任何一個方案，實施時可能會受到下列問題影響：

- *基因改造食物的標籤工作未有國際共識。* 世界各地的規管機構對於如何為含有和沒有基因改造成分的食物加上標籤、使用的術語和字眼等，各有不同的規定。此外，聯合國食品法典委員會現時仍就基因改造食物的標籤問題，商討一套國際可以接受的政策，但在二零零四年前多數未能取得共識。由於香港在制訂食物標籤法規時經常參考食品法典委員會的決定，如採用的標籤制度與食品法典委員會最後達成的協議和其他地區的制度有所不同，有關法例日後或須修訂，香港的食品業因而可能須承擔額外成本，消費者又會感到困惑。

- *未來的基因改造農作物。* 由於不斷會有新的基因改造農作物研究成功和推出市場出售，實在難以準確預計基因改造食物標籤計劃對業界和香港經濟將會帶來的影響。如有很多基因改造農作物推出市場，而各國又未能就相關的標籤協議達成共識，香港食品業受到的影響將會比這項研究所預測的更大。

- *基因改造食物的測試欠缺國際共識。* 各國現時仍未能就基因改造食物的檢出率、量化的界限和方法等達成共識。因此，香港特別行政區政府應該採用何種量化的界限和方法，以及應否強制食品業採用這些方法，還須深思熟慮。此外，如未能在實施基因改造標籤規管制度前，就這些量化的界限和方法達成協議，而國際上又沒有已被接受的標準可以遵循，要有效地推行規管制度並不容易。

- *獨立實驗室的技術水平認證。* 與標籤有利益關係的人士會問，進行基因改造食物測試的實驗室是否可靠和獨立。食品製造商會希望有一套認證制度，證明進行測試的實驗室的測試水平，並確保實驗室可以證明製造商的產品符合出口市場的規

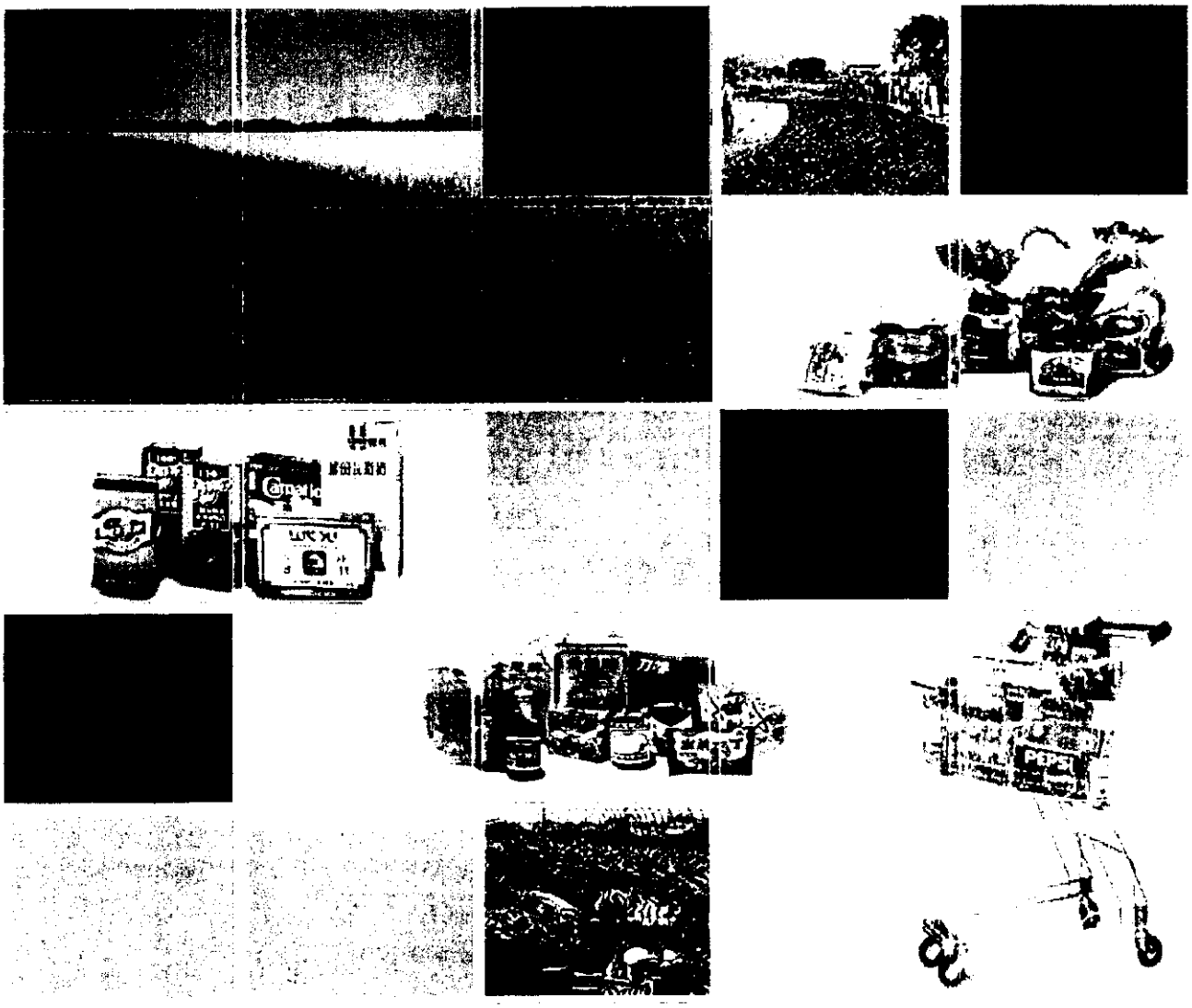
定，以及合乎香港特別行政區政府將會實施的標籤規定。這樣便帶出另一個問題，就是香港特別行政區政府在實施強制性基因改造食物標籤制度前，應否先提供實驗室的認可計劃；然而，認可私營實驗室的工作，需要很多時間和人力資源。

- *採用"首五項成分"方法的困難。* 食品公司的產品成分和所採用的供應商都會不斷改變。例如標籤上註明含有"乳化劑"，而其中可能已包含了三種不同的乳化劑。食品公司不願意公開其產品某種成分的組成細節，因為這些都是其品牌獨有的資料，亦是商業上高度敏感的資料。此外，一家提供基因改造食物測試服務的實驗室指出，要確定食物產品中被檢出的基因改造脫氧核糖核酸(DNA)屬於哪一種食物成分十分困難。例如在首五項的食物成分中，其中一種含有3%的基因改造物質，而另一種成分(不屬首五項成分)則含有5%或以上的基因改造物質，該項食物產品在測試時可能被檢出超過容許量的基因改造DNA含量。為了證明該項產品的標籤符合法例的規定，生產商須向規管機構提供各種成分細節，並須進一步測試該產品。但有關公司可能不願意披露這些敏感的商業資料。

- *文件證明。* 國際間現時還未有標準，規定如何以文件證明食品"保存本質"，也沒有確立制度，以文件證明產品的基因改造物質含量。因此，如果採用的標籤制度是依靠文件來證明食品含有或沒有基因改造成分，便會出現問題。

FSEH Panel
20/3/2003

EXECUTIVE SUMMARY
研究報告摘要



Food and Environmental Hygiene Department
食物環境衞生署

Regulatory Impact Assessment on Labelling of Genetically Modified (GM) Food
基因改造食物標籤規管影響評估

March 2003
二零零三年三月

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EXECUTIVE SUMMARY
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March 2003

Reference C2363

For and on behalf of
Environmental Resources Management

Approved by: Dr Andrew Jackson

Signed:

Position: Managing Director

Date: 6th March 2003

EXECUTIVE SUMMARY

INTRODUCTION

The Government is currently considering options for labelling packaged genetically modified (GM) food. To this end, ERM was commissioned to undertake a Regulatory Impact Assessment (RIA) and to advise the Government on the findings.

The objective of the RIA was to assess the economic impact of introducing a labelling scheme on pre-packaged GM food in the Hong Kong Special Administrative Region (HKSAR).

OPTIONS UNDER CONSIDERATION

The Study considered five options, as described below.

Option I: Voluntary labelling of GM food.

Under this option the trade can label GM food on a voluntary basis. Effectively this represents the status quo situation, where presently there are no specific regulations regarding GM-status of products.

Option II: Mandatory labelling of designated products by phases - at 5% threshold.

This option requires food products containing designated GM crops as major ingredients to be labelled. A major ingredient would be defined as one that is amongst the top five constituents of the food product by weight and as well as comprising at least 5% of the end product by weight. A 5% threshold would be allowed for these GM food products (i.e. any major ingredients with a GM content greater than 5% would have to be labelled). In addition, significantly different characteristics, such as the emergence of an allergen and changes in composition or nutritional value must also be labelled. However, highly refined food items, food additives, flavourings and processing aids are exempted from labelling requirement. The first phase would designate GM soya bean and corn (and processed food containing GM soya bean and corn) be labelled, while a second phase would add canola, potato and cotton seed to the list of designated products.

Option III: Mandatory labelling of designated products by phases – at 1% threshold.

This option is essentially the same as Option II, although with a 1% threshold for GM content in major ingredients.

Option IV: Mandatory labelling of all GM foods at 5% threshold with the exemption of highly processed food.

Under this option, GM ingredients exceeding 5% threshold in any food product would need to be labelled. In addition, significantly different characteristics, such as the emergence of an allergen and changes in composition or nutritional value must also be labelled. However, highly

refined food items, food additives, flavourings and processing aids are exempted from labelling requirement.

Option V: Mandatory labelling of all GM foods at 1% threshold with the exemption of highly processed food.

This option is essentially the same as Option IV except that the threshold is set at 1 %.

GM-free sub option

In addition, the Study also considered three sub options for GM-free and equivalent negative labelling:

- *The status quo,* where there is no specific requirement for GM-free and equivalent claims;
- *Require documentation,* where anyone making a GM-free or similar negative claim must be able to provide Identity Preserved (IP) or similar documentation to verify the status of the product; and
- *Prohibit GM-free Claims,* where GM-free and equivalent negative claims are prohibited.

FINDINGS AND BARRIERS TO IMPLEMENTATION

Cost Implications to the Food Trade

The financial analysis suggests that there will be cost implications for the food trade under Options II to V. Under Option I (status quo) there are no increases in costs to the trade.

The majority of these cost impacts are likely to be in the first year when companies examine, potentially reformulate and test their products to ensure compliance with the legislation.

These financial costs to the trade range between HK$ 16 million (lower bound for Option II) to HK$ 91 million (upper bound for Option V).

Options IV and V are significantly more costly than Options II and III (HK$ 47 million to HK$ 91 million vs HK$ 16 million to HK$ 46 million). This difference is principally attributable to the more inclusive nature of Option IV and V, which cover all food ingredients rather than the top 5 ingredients (as is the case for Options II and III).

Furthermore, analysis suggests:

- Under all options, the costs to the trade could increase significantly when, and if, more GM crops are commercialised. For Option V the costs could increase by up to 64%, for Option IV the costs could increase by up to 34%, for Option III the costs could increase by up to 51% while under Option II the costs could increase by up to 28%. The

relatively higher potential increases under Options III and V reflect the more stringent 1% threshold under these options.

- If companies choose to label their products as containing GM ingredients instead of reformulating (to avoid labelling) then the overall impacts on the trade are likely to be lower. However, this approach is unlikely given that objections to GM foods are often more widely publicized than advantages advanced by proponents of GM food or scientific safety assessment. Thus companies would not want to risk losing market share. One manufacturer stated that even a loss of 5% of market share would not be acceptable and therefore it would convert to non-GM.

- The magnitude of the cost implications to the trade is understandably sensitive to assumptions made about the costs associated with reformulating and maintaining GM-status. While the Consultant has sought to make these assumptions as accurate as possible, it should be recognised that considerable uncertainty exists as to how individual food companies will react to the legislation, and hence there is uncertainty in the value of the overall impact on the trade. Costs will be product and company specific.

- Small importers of some product lines may be significantly impacted by the proposed options. This will be the case if they are unable to secure contractual agreements with the product manufacturer as to the product's GM-status. This could result in some products being dropped from the market, especially those products that are not imported in significant quantities and that are not sold in jurisdictions with existing GM labelling requirements (such as Europe, Australia, New Zealand, Japan and Korea).

- Some smaller local manufacturers could be significantly impacted during the first year of implementation of any of the options. It is noted, however, that for most manufacturers these costs are unlikely to be significant and if the costs could be diluted over a longer period of time (more than one year), then the actual impact on the company's revenues and profits might not be significant. In the current economic climate it is unlikely that the costs incurred will be recoverable from retailers.

Costs to the Economy

As is the case for the financial analysis, Options II to V will have significant economic costs to Hong Kong. Under Option I (status quo) there are no increases in costs to the economy.

The only difference between the *economic* and *financial* costs are the enforcement costs which range between HK$ 1 million and HK$ 5 million per annum (depending on the enforcement strategy adopted).

However, as for costs to the trade, the majority of economic cost implications are likely to be in the first year when companies examine, potentially reformulate and test their products to ensure compliance with the legislation.

These economic costs range from HK$ 25 million (lower bound for Option II) to HK$ 130 million (upper bound for Option V). As for the financial analysis, Options IV and V are significantly more expensive than Options II and III (HK$ 55 million to HK$ 130 million vs HK$ 25 million to HK$ 84 million).

Cost to Consumers

Discussions with food manufacturers and retailers suggest that the costs associated with achieving a certain GM-status are unlikely to be passed onto consumers. Indeed, Hong Kong based food manufacturers and retailers who have already undergone reformulation note that it has not changed their retail price – in reality their retail prices are a response to market pressures and have, in some cases, been decreasing.

However, in order to illustrate the maximum possible impact in the unlikely event that any costs are passed onto the consumer, the financial impact as a percentage of household expenditure on food was calculated. This analysis suggests that the maximum possible impact on overall food prices could be between 0.03% (for Option II) and 0.10% (for Option V) in terms of household expenditure.

GM-Free Scenarios

The trade may label their products with GM-free or similar negative claims on a voluntary basis because of the potential market niche for these products and they would like to inform their customers of the "non-GM" nature of their products. The Study examined the impact of regulating GM-free or equivalent claims on those products that already carry such claims. Two GM-free scenarios were compared against the status quo. The first requires those making GM-free or similar negative claims to provide sufficient documentation to verify the status of the product. The second prohibits the use of GM-free and equivalent negative claims.

The analysis suggested that prohibiting GM-free and equivalent labelling is likely to incur less costs than requiring them to produce IP documentation. However, prohibiting GM-free and equivalent negative labelling might limit consumer choice. On the other hand, the additional cost for producing IP documentation would likely be borne by overseas manufacturers while the costs of re-labelling are more likely to fall on Hong Kong companies (e.g. importers and retailers).

Summary of Findings

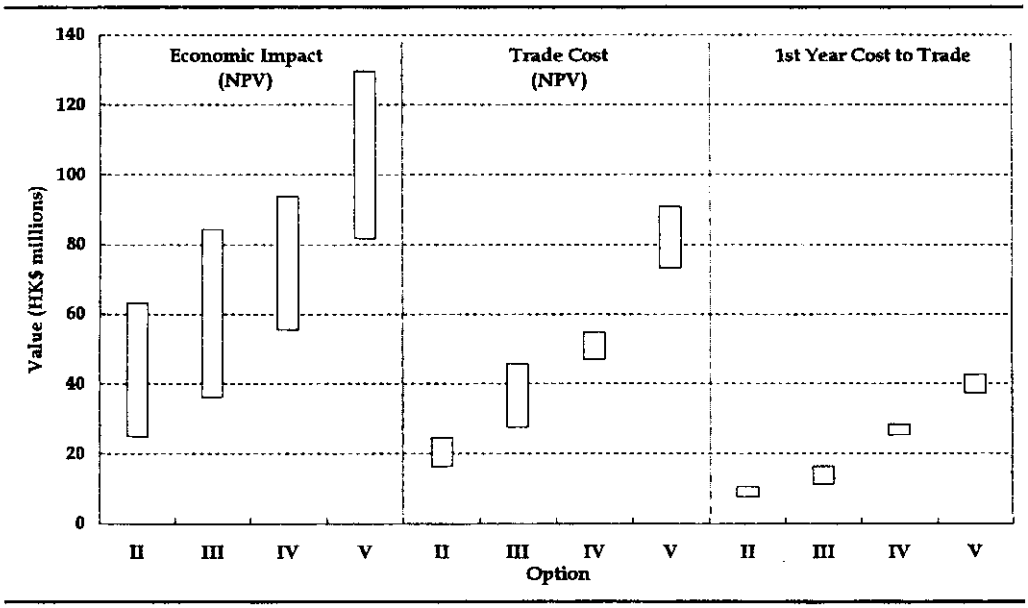
Table 1 and *Figure 1* present the results of the economic and financial analysis.

Table 1 ***Cost Implications (HK$ millions)***

Option	Economic Costs (Net Present Value)		Trade Costs (Net Present Value)		1st Year Costs	
	Min	*Max*	*Min*	*Max*	*Min*	*Max*
I	-	-	-	-	-	-
II	25	63	16	25	7	11
III	36	84	28	46	11	17
IV	55	94	47	55	25	28
V	82	130	73	91	37	43

Note: The min scenario assumes that highly refined products such as oil and high-fructose corn syrup (HFCS) are not reformulated (as they would be exempted). The max scenario assumes that these products (oil and HFCS) are reformulated to ensure that any DNA that might be detected is not of a GM type.

Figure 1 ***Cost Implications (HK$ millions)***



Barriers to Implementation

If the Administration chooses to proceed with any of Options II to V the following issues are likely to impact on the implementation of the selected option:

- *Lack of International Consensus on GM Labelling.* Different jurisdictions in the Asia Pacific region, and beyond, have adopted different approaches, terminology and wording requirements for GM and GM-free labelling of food. In addition, the international community, in the form of the Codex Alimentarius Commission of the United Nations, is still working towards a consensual policy on GM food labelling. Agreement is unlikely before 2004. Since Hong Kong has always taken Codex as reference in formulating its food labelling regime, the introduction of a scheme in Hong Kong that does not align with any eventual agreement by Codex and

regional schemes would mean further legislative change and would place additional costs on the Hong Kong's food trade as well as confuse consumers.

- *The Future of GM Crops.* New GM crops are continually being developed and commercialised. As such there remains considerable uncertainty over the extent of the financial and economic impact of any GM labelling scheme. If a lot more GM crops are commercialised, and in the absence of any international agreement on their labelling, the impact on the Hong Kong food trade could be higher than that predicted by this Study.

- *Lack of International Consensus on GM Testing.* International consensus on GM detectability and quantification limits and methodologies has not yet been reached. The lack of international consensus raises the issues of which limits and methods the HKSAR Government should adopt and whether these should be mandated to the food trade. In addition, if these limits and methods were not agreed prior to the implementation of GM labelling regulations, the lack of internationally accepted standards might preclude effective enforcement by the Administration.

- *Proficiency Certification of Independent Laboratories.* A query raised by stakeholders was the reliability and independence of laboratories. Some manufacturers would like to see a certification scheme for testing laboratories, to verify the quality of the services that they would receive and to ensure that their products meet the requirements of export markets and any labelling requirement that the HKSAR Government is to implement. This raises the issue as to whether the HKSAR Government should provide such an accreditation scheme prior to the implementation of any regulations mandating GM labelling. It should be noted, however, that accrediting private laboratories would require much time and human resources.

- *Difficulties with Top 5 Ingredients Approach.* Companies change ingredients and suppliers on a continual basis. A label may state emulsifier but this might be comprised of three different emulsifiers. Companies would be reluctant to give compositional analysis by particular ingredient, as this is proprietary brand-specific information and commercially highly sensitive. Further, it was suggested by one of the testing laboratories that it can be difficult to establish which ingredient within the food product is responsible for the novel GM-DNA detected. For example, if one of the top 5 ingredients had GM content of 3%, whilst another had a GM content of 5% or above (but is not one of the top 5 ingredients), the food product when tested may register novel GM-DNA content over the threshold. In order to prove the product met the requirement of the standard, the food producer would need to provide details of the ingredients to the regulatory agency and further testing would be required. Again, the company may be reluctant to share this commercially sensitive information.

- *Documentation.* There are currently no international standards on IP and similar documentation systems for certifying the GM content of products.

As such, the introduction of any labelling scheme, whether negative or positive labelling, that relied on such documentation could be problematic.