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
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ERM

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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

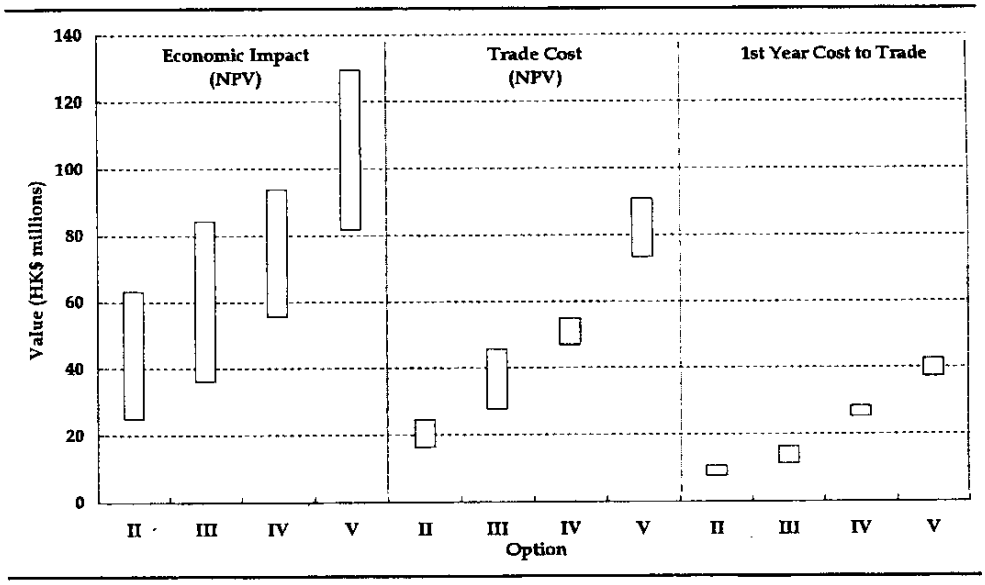
Table 1 and *Figure 1* present the results of the economic and financial analysis.

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.

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

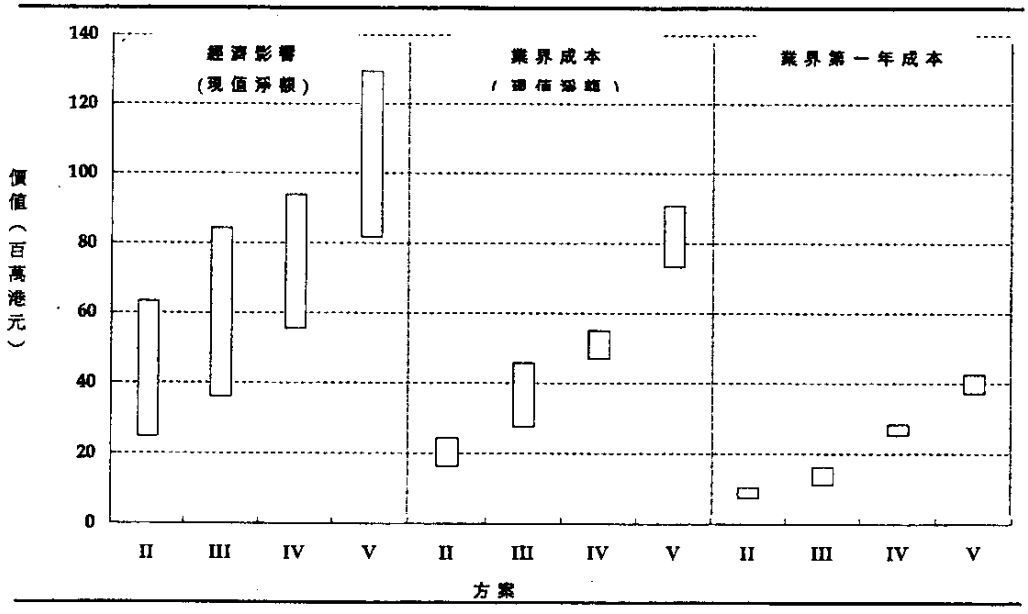
表 1 和圖 1 列載經濟及財務分析的結果。

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。