LABELLING OF GENETICALLY MODIFIED (GM) FOOD AND THE PROPOSED PRE-MARKET SAFETY ASSESSMENT SCHEME (PMSAS)

Trade Consultation Forum

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食物環境衞生署
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Background

- Genetically modified (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

- According to the World Health Organization, GM foods currently available on the international market have passed safety assessments and are not likely to present risks for human health

International scenario of GM food labelling

- In 2011, the Codex Alimentarius Commission stated that governments are free to decide on whether to label foods derived from modern biotechnology, including foods containing GM organisms

- However, it has emphasised that labelling, if pursued, should be carried out in conformity with the texts approved by Codex to avoid potential trade issues

GM food labelling systems

- The approaches adopted for regulating GM food vary among different countries and places

- "Voluntary" labelling approach
  - Only GM foods that are significantly different from their conventional counterpart, in terms of composition, nutritional value and allergenicity, need to be labelled

- Mandatory labelling approach
  - "Pan-labelling"- Any food contain GM materials exceeding a threshold value or have significantly different characteristics as a result of genetic modification
  - "Labelling for designated products only"- Only the designated products which are genetically modified need to be labelled

Practices on GM food labelling

Voluntary	Mandatory	
	Pan-labelling	Designated products
• USA • Canada	• European Union (0.9%) • Australia (1%) • New Zealand (1%) • Korea (3%)	• Japan • Taiwan • Mainland

GM food labelling in Hong Kong

- Regulatory impact assessment on implementation of mandatory GM food labelling scheme in 2002
  - Significant cost implications to small and medium enterprises
  - Withdrawal of products from market

- "Guidelines on Voluntary Labelling of Genetically Modified (GM) Food" in 2006
  - Enhance consumers' knowledge and right to make an informed choice of GM food
  - Support the local trade's initiative in setting up a voluntary labelling system for GM food

Guidelines on Voluntary Labelling of Genetically Modified (GM) Food

- Purposes
  - Set out principles underlying the recommended labelling approaches for GM food
  - Provide reference for the trade to make truthful and informative labels in a consumer-friendly manner

- Scope
  - Applicable to **prepackaged food** that contains food or food ingredients known to have a GM counterpart

Relevant regulations

Section 54 of the Public Health and Municipal Services Ordinance (Part V and VA of Cap. 132) stipulates that all food for sale must be fit for human consumption. This applies equally to GM and conventional food

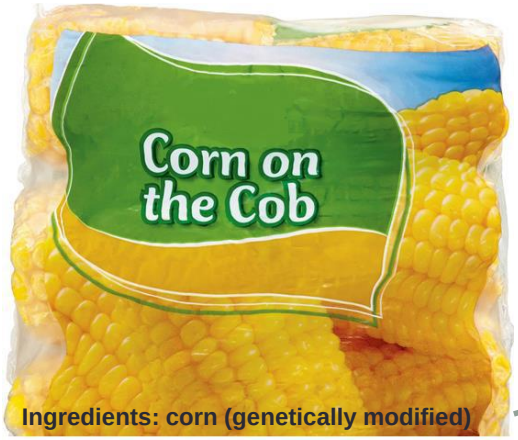
Section 61 of the Public Health and Municipal Services Ordinance (Part V and VA of Cap. 132) stipulated that no person shall give any food sold by him or display with any food exposed for sale by him, a label, which falsely describes the food

The Food and Drugs (Composition and Labelling) Regulations (Cap. 132) require that any prepackaged food shall be marked and labelled in the prescribed manner

Recommended practice for voluntary GM food labelling - Positive labelling

- Positive GM food labelling
  - Food items with 5% or more GM materials in their respective ingredient(s) should be labelled as “genetically modified”
  - With significant modifications

- Example 1 (For whole food or food with single ingredient)



List of Ingredients:
Corn (genetically modified)

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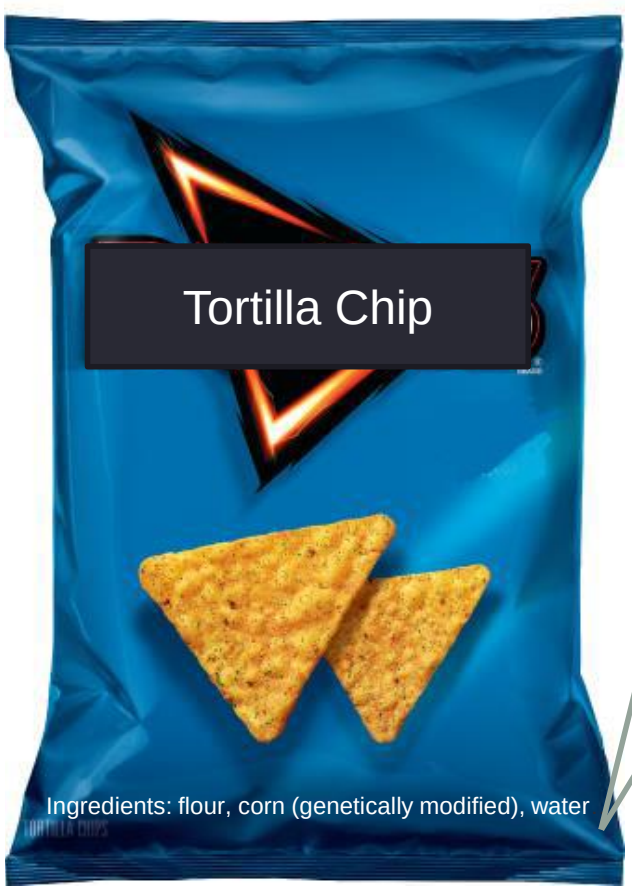
Recommended practice for voluntary GM food labelling - Positive labelling

- Example 2 (For processed food)



List of Ingredients:
flour, **corn (genetically modified)**, water…

OR

List of Ingredients:
flour, **corn***, water…
***genetically modified**

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Recommended practice for voluntary GM food labelling - Exemption

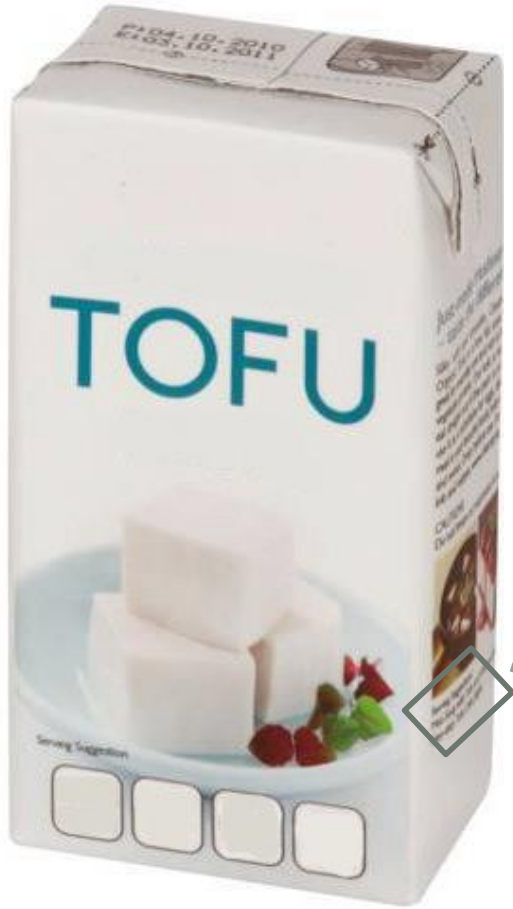
- Exemption
  - Food products that do not contain detectable DNA or protein
  - Highly refined food e.g. sugar, oil
  - Highly processed food

Recommended practice for voluntary GM food labelling - Additional declaration

- Additional declaration on label when –
  - Compositional or nutritional value significantly different from conventional counterpart
  - Level of anti-nutritional factors or natural toxicants significantly different from conventional counterpart
  - Presence of new allergen
  - Change in intended use of the food
  - An animal gene has been introduced

Recommended practice for voluntary GM food labelling - Additional declaration

- Example (For processed food)



List of Ingredients:
water, **soya bean (genetically modified to contain high oleic acid)**…

OR

List of Ingredients:
water, **soya bean***….
***genetically modified to contain high oleic acid**

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Recommended practice for voluntary GM food labelling - Negative labelling

- Negative GM food labelling
  - Not recommended for food without GM counterparts e.g. orange, water, salt
  - Not recommended to indicate or imply food as a whole is from non-GM source
  - Absolute terms e.g. “GM free” is not recommended
  - Negative GM food labelling should be supported by documentations

Effectiveness of voluntary GM food labelling

- Study in 2008
  - Among the 46 samples tested, 1 sample was found to contain more than 5% GM material but with no GM food label

- Study in 2013
  - Among the 49 corn-based sample tested, 5 samples were found to contain more than 5% GM materials but with no GM food label
  - GM corn varieties used in these products have already passed the safety assessment of a number of countries and have been approved for human consumption
  - The CFS issued letters to these traders reminding them to label GM food in accordance with the " Guidelines on Voluntary Labelling of GM Food"

Proposed Pre-market Safety Assessment Scheme (PMSAS)

Proposed Pre-market Safety Assessment Scheme (PMSAS)

- Most of the GM food currently available on the international market have passed risk assessments of the food safety regulatory bodies of other economies and are not likely to be harmful to human health

- Codex has formulated different sets of guidance on the risk assessment of food derived from biotechnology. In addition, WHO is of the view that different GM organisms are developed in different ways and thus the safety of individual GM food should be assessed on a case-by-case basis

- Codex also recommends member countries to set up a regulatory framework for safety assessment of GM food and establish relevant guidelines for the assessment

Purposes of the proposed scheme

- Provide a further mechanism to enhance the food safety control over GM food

- Provide the legal basis for preventing unauthorised GM products from entering the local market

Proposed scheme

- GM food developer (e.g. Biotechnology companies)
  - Intends to place a GM food on the local market would be required to submit an application together with the necessary supporting documentation to Centre for Food Safety (CFS) for evaluation

- Centre for Food Safety (CFS)
  - Determines whether the GM food developer has adequately addressed the safety issues based on Codex principles and guidelines. GM food which consists of, or is derived from, GM microorganisms, plants and animals, must pass the safety assessment before it may be sold in Hong Kong

Proposed GM food approval process

- Product details
- Safety assessment
- Detection methods

Manufacturers e.g. corn chips

Biotech company (Developer)

Pre-market safety assessment

GM corn

Approved

Local traders

List of Approved GM Food

Ensure!

Consumers

Proposed assessment procedures (I)

- For GM food that has already been approved for food use by other food safety regulatory authorities, the proposed assessment procedures that would be carried out in Hong Kong would be much simplified
  - The applicants (i.e. biotechnology companies) would be required to submit approval certificates from other food safety regulatory authorities (including the place of origin of the GM food), if any, and the detailed findings of their evaluation to facilitate the processing and consideration of their applications

Proposed assessment procedures (II)

- For GM plants/animals/microorganisms that have not been approved for food use by other food safety authorities, it is expected that it will take CFS longer time for evaluation as CFS will need to conduct a complete assessment of the safety of the GM organisms
  - In such cases, CFS will have to go through the detailed information, including raw data, in accordance with the principles laid down by Codex
  - This said, we believe it is not likely that the biotechnology companies or manufacturers would choose Hong Kong as the first place for approval of many GM food, and hence the need for a detailed evaluation will be minimal and it is not likely to cause any significant impact on the trade and food supply

Responsibilities of traders

- If the PMSAS is put in place by law, the onus of making available to CFS the transgenic information and certified reference materials for the GM plants concerned lies with the applicant

- CFS will draw up a list of approved GM food and upload the list on its homepage for the reference of the public and the trade. It will be the responsibilities of food manufacturers and importers of GM food to ensure that their products contain only approved GM food

Potential impacts to traders

- It is envisaged that the application for PMSAS would normally be submitted by biotechnology companies which develop the GM organisms for food production. As such, the expected impact on traders, importers, distributors and retailers should be minimal

Conclusion

- CFS has carried on with its efforts in promoting the "Guidelines on Voluntary Labelling of Genetically Modified (GM) Food", as well as monitoring international developments in GM technology and GM food labelling standards with a view to coming up with a proposal for public consultation

Thank you