For discussion
on 12 March 2013

LegCo Panel on Food Safety and Environmental Hygiene

Proposed Regulation of Genetically Modified Food

Purpose

This paper briefs Members on the Administration's proposal to consider regulating genetically modified (GM) food by introducing a mandatory pre-market safety assessment scheme (PMSAS) in Hong Kong.

Background

2. GM food is any food that is, or is derived from, an organism in which genetic material has been modified using modern biotechnology. It has been available on the market for nearly two decades since its first commercialisation. According to the World Health Organisation (WHO), GM food currently traded on the international market are not likely, nor have been shown, to present risks for human health. This notwithstanding, there have been concerns among green groups, some members of the public and Members of the Legislative Council (LegCo) on the potential long-term impact of GM food on human health and the environment. In particular, there have been calls on the Government to consider strengthening regulation of GM food in Hong Kong, for example, by introducing a mandatory labelling system.

3. The approaches adopted for regulating GM food vary to a great extent among different countries and places. The main reason is that individual country or place formulates its policy and system based on its own situation. Apart from food safety and consumers' right to information, other factors are also taken into account, including protection of local agricultural market, economy and trade, as well as conservation of the ecological environment. Hong Kong is not a major agriculture producing area. We rely predominantly on imported food. In considering whether new food regulatory measures should be introduced, the Administration is primarily concerned with public health and food safety. The legislative framework for regulating food safety in Hong

Kong is laid down in the Public Health and Municipal Service Ordinance (Cap. 132). Section 54 of the Ordinance stipulates that all food for sale must be fit for human consumption. This applies equally to GM and conventional food.

4. In response to public concern on GM food, the Administration conducted a public consultation on GM Food labelling in 2001 and a regulatory impact assessment (RIA) in April 2002. The RIA revealed certain issues that need to be addressed when implementing a mandatory GM food labelling scheme in Hong Kong, e.g. increasing operational cost of the trade with a greater impact on the small and medium-sized enterprises and the lack of international consensus on GM food labelling. Taking into account the findings of the RIA and the lack of strong justification for the labelling of GM food on food safety grounds, the Administration considered that, in the circumstances then prevailing, encouraging the trade to adopt a voluntary labelling system would be a practical alternative to a mandatory labelling system. Subsequently in July 2006, the Centre for Food Safety (CFS) issued a set of "Guidelines on Voluntary Labelling of Genetically Modified Food" (the Guidelines), setting out the principles underlying the recommended labelling approaches for GM food, and providing reference for the trade to make truthful and informative labels in a consumer-friendly manner. In brief, the Guidelines recommend the trade to label food items with 5% or more GM materials in their food ingredients and to provide additional information on the label if the GM food concerned has undergone significant modifications in specific aspects. The trade is advised not to use negative labels in absolute terms and to use other forms of negative labels only when the declaration is substantiated by documentation. The Guidelines were the product of a Working Group set up by the Food and Environmental Hygiene Department, comprising representatives from the food trade, the Consumer Council and relevant government departments.

Voluntary GM Food Labelling

5. The Guidelines are advisory in nature. Members of the trade are encouraged to adopt the Guidelines on a voluntary basis. The trade's attention has also been drawn to the legal requirements of the relevant legislation, such as section 54 of Cap. 132 as quoted in paragraph 3 above and section 61 of the same Ordinance which outlaws false descriptions about a food product, as well as the labelling requirements set out in the Food and Drugs (Composition and Labelling) Regulations.

6. In 2008, CFS evaluated the effectiveness of the voluntary labelling scheme. The findings illustrated that there was no pressing need for mandatory labelling, as measured by the level of GM material used in the samples. Up till then, there was no major development at the international level in GM technology and GM food labelling standards. On the other hand, the new legislation in Hong Kong on nutrition labelling had been introduced and was set to commence with effect from July 2010. That was a major step forward in promoting consumers' access to food product information. The Administration therefore considered it prudent to continue its efforts in promoting the voluntary labelling regime for GM food before considering any further changes to the labelling law.

7. Since then, CFS has carried on with its efforts in promoting the Guidelines to the trade and enhancing consumer education on this front, as well as monitoring international developments in GM technology and GM food labelling standards. In the latter regard, after years of debate among regulators around the world, the Codex Alimentarius Commission[1] (Codex) came to a view in 2011 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.

8. On whether mandatory GM food labelling should be introduced in Hong Kong, many of the considerations derived from the RIA conducted in 2002 set out in paragraph 4 are still relevant. Most of the GM food available on the market in Hong Kong are imported. As shown in the table at Annex, not all food exporting economies require mandatory labelling of GM food, and even for the ones that do, the labelling requirements vary. It would be costly and difficult for Hong Kong food importers to come up with labels for all GM ingredients in respect of GM food coming from all over the world in order to comply with Hong Kong's labelling requirement if one were to be introduced on a mandatory basis. According to Codex, it is up to individual economy to decide whether to implement GM labelling. From the food safety

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[1] The Codex Alimentarius Commission was created in 1963 by the United Nations Food and Agriculture Organisation (FAO) and 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 include protecting the health of consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organisations.

perspective, we note that GM food currently available on the international market are not likely, nor have been shown, to present risks for human health. While a mandatory GM food labelling system could address consumers' demand for more product information and facilitate the making of informed choices by consumers, it may not necessarily be the most useful tool to ensure the safety of GM food.

Pre-market Safety Assessment Scheme (PMSAS)

9. 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. Despite this, changes to such a situation in the future could not be ruled out. In this regard, 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.

10. As a regulatory measure, many developed economies have put in place a PMSAS (see Annex) to evaluate the safety of GM food derived from GM organisms, whether on a voluntary or mandatory basis. In 2003, the Administration had proposed to introduce a mandatory PMSAS for GM food, supplemented by a voluntary labelling scheme. The voluntary labelling scheme was introduced in 2006. The introduction of a mandatory PMSAS, on the other hand, was held up due to other competing and more pressing priorities on the food safety front, including the legislation on nutrition labelling and pesticide residues in food, as well as the overarching Food Safety Ordinance. We consider it timely at this juncture to re-consider the introduction of a mandatory PMSAS underpinned by law to further enhance the system for regulating food safety in Hong Kong.

11. At present, it is estimated that more than 70 types of GM plants (such as soyabean, corn, tomato and potato) are commercialised in the international market for food use. Most of these GM plants are developed by five biotechnology companies[2] and have been assessed by other regulatory authorities with PMSAS in place before they (and food

[2] The five biotechnology companies are: 1) Bayer CropScience; 2) Dow AgroSciencs LLC; 3) Monsanto Company; 4) Pioneer Hi-Bred International Inc. A DuPont Company; and 5) Syngenta Seeds Inc.

with these plants as ingredients) are put to the market. It is conceivable that more varieties of GM food from different places of origin will enter the international market in the future. The introduction of a mandatory PMSAS in Hong Kong would provide a further mechanism to enhance the food safety control over GM food and provide the legal basis for preventing unauthorised GM products from entering the local market.

The Proposed Scheme

12. According to the preliminary thinking of CFS, it is envisaged that under the scheme, a GM food developer who intends to place a GM food on the local market would be required to submit an application together with the necessary supporting documentation to CFS for evaluation. CFS will determine 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.

13. 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. Besides, as mentioned above, most of the GM plants currently available in the international market for food use are developed by five biotechnology companies and have already been assessed by overseas authorities. 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, provided that the approach and principles adopted by the relevant regulatory authorities are similar to those of Codex. The applicants (i.e. biotechnology companies) would be required to submit approval certificates from other food safety regulatory authorities (including the country of origin of the GM food), if any, and the detailed findings of their evaluation to facilitate the processing and consideration of their applications. CFS would evaluate the application by making reference to the safety assessment conducted by other regulatory authorities. CFS would also devise suitable transitional arrangement for GM food that is already on the market at the time when the new PMSAS comes into operation.

14. 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.

15. 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 plants, 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.

16. 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. The Government Laboratory will need to be better equipped to further develop its capacity in testing GM-related products and enforce the future law on PMSAS, if this proposed legislative amendment is approved.

Advice Sought

17. Members are invited to note the latest development in relation to GM food labelling and comment on the Administration's plan to consider introducing a mandatory PMSAS. The Administration intends to launch a public consultation on the subject in the second half of this year.

Food and Health Bureau
Centre for Food Safety
Food and Environmental Hygiene Department
March 2013

Annex

International Practice on Regulation of GM Food

Places	Pre-market Safety Assessment Scheme		Labelling System	
	Approach	**Effective Date**	**Approach**	**Effective Date**
The US	Voluntary	1992	Voluntary (for foods without significant changes)*	1992
Canada	Voluntary	1994	Voluntary at 5% threshold (for foods without significant changes)*	1994
	Mandatory	1999		
EU	Mandatory	1997	Mandatory pan-labelling at 0.9% threshold	1997
Australia / New Zealand	Mandatory	1999	Mandatory pan-labelling at 1% threshold	2001
Japan	Voluntary	1991	Mandatory labelling of designated GM products at 5% threshold	2001
	Mandatory	2001		
Republic of Korea	Mandatory	2004	Mandatory labelling of approved GM products at 3% threshold	2001
Mainland China	Mandatory	2003	Mandatory labelling of designated GM products; no threshold specified	2003

Places	Pre-market Safety Assessment Scheme		Labelling System	
	Approach	**Effective Date**	**Approach**	**Effective Date**
Taiwan	Mandatory	2003	Mandatory labelling of designated GM products at 5% threshold -- Promulgated in 3 stages	1st stage (raw agricultural products): 2003 2nd stage (primary processed products): 2004 3rd stage (other processed products): 2005
Singapore	Issued guidelines for safety assessment of GM organisms. Biotechnology company may submit documents for registration.	1999	No specific requirement	--

* Mandatory labelling for foods is required, where the foods have significant changes, e.g. presence of allergen, nutritional changes, or compositional changes, etc.