For information

Legislative Council Panel on Food Safety and Environmental Hygiene

Safety and Labelling of Genetically Modified Food

Purpose

This paper sets out the latest situation regarding the safety and labelling of genetically modified (GM) food.

Background

2. GM food is any food that is, or is derived from, an organism in which its genetic material has been modified by modern biotechnology, such as herbicide-tolerant corns, soyabeans with improved nutritional value, etc. GM crops have been commercially produced since the 1990s. Over the past two decades, GM food has been growing in prevalence in different parts of the world, with the most adopted GM crops being soyabean, corn, cotton and canola. According to the information from the International Service for the Acquisition of Agri-biotech Applications, based on the growing area of individual crops as of 2019, 79% of cotton, 74% of soyabean, 31% of corn and 27% of canola were GM crops globally.

Safety of GM Food

3. Some countries and regions with more developed agricultural production and technology have been implementing pre-market safety assessment schemes (PMSAS) for GM foods to tie in with their development of relevant industries and confirm the safety of newly emerging GM events, i.e. specific combinations of deoxyribonucleic acid (DNA), of the relevant crops. To date, the World Health Organization (WHO) has stated that GM foods currently available on the international market have passed safety assessments and are not likely to present risks to human health. In addition,

there is no evidence showing that GM foods have resulted in any food safety issues in the countries where they are available for sale after assessment.

4. Although the operational details of the PMSAS in different places vary (see Annex I), they are all implemented in accordance with the same framework, i.e. the internationally-recognised scientific principles and guidelines formulated by the Codex Alimentarius Commission (Codex) jointly established by the WHO and the Food and Agriculture Organization of the United Nations, as well as the Organisation for Economic Co-operation and Development (OECD) (see Annex II). In recent years, some food safety authorities around the world have been improving the efficiency of GM food safety assessments by sharing the assessment results with each other, thus avoiding the need to duplicate the same safety assessments by different authorities.

5. In Hong Kong, the Government also proposed previously to implement a mandatory PMSAS for GM foods. According to the preliminary proposal of the Centre for Food Safety (CFS) of the Food and Environmental Hygiene Department, all GM foods consisting of, or derived from, GM microorganisms, plants and animals must pass the safety assessments by the CFS before they could be sold in Hong Kong. However, considering that most food in Hong Kong is imported, the CFS has been monitoring international studies on the safety of GM food when further developing the relevant proposal. It is noted that study reports of different places in recent years commonly pointed out that consumption of GM foods is as safe as their non-GM counterparts (see Annex III).

6. In this connection, the CFS has sought advice from the Expert Committee on Food Safety[1] (Expert Committee) recently regarding such scientific evidence on the safety of GM food and the latest international developments on conducting safety assessments. The Expert Committee agreed that the GM events of GM foods commercially produced and sold internationally have generally passed safety assessments in other countries and regions with a PMSAS in place for years, and that such GM foods are not likely to present risks to human health and there is no need for Hong

[1] The Expert Committee on Food Safety set up under the CFS is responsible for advising the Director of Food and Environmental Hygiene in the formulation of food safety measures, review of food safety standards in light of international practices, trends and developments, as well as risk communication strategies.

Kong to duplicate these efforts in pre-market safety assessment for GM foods. After considering the opinions of the Expert Committee, the CFS also believes that conducting another round of local pre-market safety assessment for GM foods will have little practical effect on improving the level of food safety in Hong Kong and may not be an effective use of resources.

7. The Public Health and Municipal Services Ordinance (Cap. 132) has laid down the legal framework for food safety regulation in Hong Kong. Section 54 of the said Ordinance provides that all food intended for sale for human consumption, no matter whether it is GM food or not, must be fit for human consumption. The CFS will continue to collect food samples on a risk-based approach for testing under its Food Surveillance Programme to ensure food safety in Hong Kong.

Labelling of GM Food

8. The Codex considers that governments of different places may make their own decisions on whether or not to label GM food. It also emphasises that such labelling arrangement, if made, should be in conformity with the provisions promulgated by the Codex to avoid potential trade issues. Meanwhile, insofar as highly processed food products are concerned, the DNA of crops or relevant ingredients can be destroyed during their manufacturing process, rendering the GM materials in the food products undetectable.

9. At present, policies on GM food labelling vary in different countries and regions (see Annex I). For example, Singapore has no specific requirements on GM food labelling; Canada implements voluntary GM food labelling on the consideration that safety assessments have found GM foods to be as safe and nutritious as non-GM foods, thus GM foods are only required to be labelled like any other foods. While mandatory GM food labelling is implemented in the United States, the European Union, Australia and Mainland China etc., details of their implementation such as the scope of food products covered, the format of labelling and the threshold level of labelling required vary in different places. The exemption arrangements for food products with GM materials undetectable (e.g. refined foods) are generally different as well.

10. In Hong Kong, the CFS issued the "Guidelines on Voluntary Labelling of Genetically Modified Food" (Guidelines) in 2006 to set out the basic principles and reference materials of the recommended GM food labelling approaches for the trade. The Guidelines recommend that the trade label any food items with 5% or more GM materials in their respective food ingredients. To avoid misleading consumers, labels which indicate that the food or ingredient comes from a non-GM source are not recommended for foods without any GM counterparts. "GM free" and similar labels are also not recommended as a truly GM free status is very difficult to attain due to the possibility of unintentional mixing of GM and non-GM crops. However, the trade can apply negative labelling to indicate that any food ingredients with GM counterparts are "derived from non-GM sources", provided that there should be documentation to substantiate such declaration.

11. The CFS communicates with the trade from time to time on issues relating to the safety and labelling of GM food, and encourages the trade to label GM foods with reference to the Guidelines. Major local food manufacturers, importers and retailers generally attach great importance to the truthfulness of GM food labels and make reference to the recommendations in the Guidelines when applying such labels. For example, considering the possibility of unintentional mixing of GM and non-GM crops, they generally do not apply "GM free" and similar labels. For foods with corresponding GM counterparts (e.g. soyabean and corn products), they keep the relevant documentation, such as certification from suppliers, laboratory testing reports or Identity Preservation Certificates, etc., to substantiate the declaration of "derived from non-GM sources" before applying such labels to the relevant food ingredients.

12. Mandatory GM food labelling, if implemented in Hong Kong, would result in cost increases to the trade. The impact of such costs to small enterprises would be particularly significant. They would encounter a range of difficulties including the need to secure contractual agreements with product manufacturers as to whether their products contain GM ingredients, possibly resulting in some products being dropped from the market. In fact, there is wide international consensus that GM foods on the market are safe, but views on the issue of labelling remain mixed. The CFS has recently sought advice on GM food labelling from the Expert Committee, which recommended the CFS to continue the voluntary labelling scheme and keep

in view the situation regularly. We will continue to monitor relevant developments and the continued implementation of the Guidelines by the local trade.

Food and Health Bureau
Food and Environmental Hygiene Department
Centre for Food Safety
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Annex I

Measures on Safety Assessment and Labelling of GM Food in Mainland China and Other Places

Mainland China

The Regulations on Safety of Agricultural Genetically Modified Organisms require agricultural GM organisms used for production, further processing and other purposes to be subjected to safety assessments and issued with biosafety certificates before a production licence can be obtained.

The Implementation Regulations on the Safety of Import of Agricultural Genetically Modified Organisms require foreign companies exporting agricultural GM organisms used for production, raw materials for further processing and other purposes to apply to the Ministry of Agriculture for biosafety certificates after safety assessments. The application must contain information and certifications to prove that the place of origin allows the subject agricultural GM organism to be used for the corresponding purposes and sold in the domestic market, and that the organism has undergone scientific testing to prove that it is harmless to human, animals, plants, microorganisms and the environment, etc.

The Implementation Regulations on the Inspection and Quarantine of Imported and Exported Genetically Modified Products provide for a declaration system administered by the General Administration of Customs on imported GM animals, plants, microorganisms and their products as well as food products. Upon filing of an import declaration, the consignor or his agent must indicate whether the subject commodity is genetically modified and, if so, ensure that it is issued with a biosafety certificate for agricultural GM organism or relevant approval documents.

The Food Safety Law stipulates that GM foods produced commercially should be clearly labelled in accordance with the relevant regulations. The Implementation Regulations on Labelling of Agricultural Genetically Modified Organisms require the labelling of any agricultural GM organisms listed in the labelling catalogue, which covers the seeds and specified

products of five types of crops (namely soyabean, corn, canola, cotton and tomato). There is no threshold level for this labelling requirement.

Australia / New Zealand

GM foods intended for sale in Australia and New Zealand must undergo safety assessments by the Food Standards Australia New Zealand for approval to ensure that any approved GM foods are as safe and nutritious as comparable conventional foods already in the Australian and New Zealand food supply.

GM foods and ingredients which contain novel DNA or novel protein must be labelled with the words "genetically modified". If the food is unpackaged, the information must accompany or be displayed with the food. Labelling is also required for GM foods that have altered characteristics (e.g. altered nutritional profile) when compared to their counterpart non-GM foods. However, these labelling requirements do not apply to GM foods that do not contain any novel DNA or novel protein (e.g. removed during processing) and do not have any altered characteristic (usually refined foods such as sugars and oils). Labelling is also not required when there is no more than 1% (per ingredient) of an approved GM food unintentionally present in a non-GM food.

Canada

Pre-market safety assessment is mandatory before GM foods are sold in Canada. Manufacturers or importers are required to submit information of the food products to Health Canada for determining if they are safe prior to sale.

There are no specific legislative requirements in Canada about labelling of GM foods. Special labelling is required for all foods (including GM foods) where there are health and safety concerns such as allergenicity. Labelling is voluntary for any other GM foods with GM ingredients above a threshold level of 5%.

European Union (EU)

The EU requires authorisation of GM foods before being placed on the market. The authorisation requires submission of a dossier with experimental data and risk assessment for assessment by the European Food Safety Authority.

GM foods have to be labelled in EU countries. For prepackaged food, the list of ingredients must indicate that the relevant food is genetically modified or produced from GM organism. For unpackaged food, the GM food label must be clearly displayed in close proximity to the product. These labelling requirements do not apply to GM food products with no more than 0.9% of GM materials in proportion (considering each food ingredient individually), provided that such presence is unintended or technically unavoidable.

Japan

GM foods have to undergo safety assessments in Japan. Upon receiving an application, the Ministry of Health, Labour, and Welfare of Japan will request a food safety review by the relevant commission, which will provide its conclusions to the Ministry for completing the review.

GM food labelling is required for foods derived from GM crops and processed foods produced from such foods. The labelling requirements apply specifically to eight approved crops (i.e. soyabean, corn, potato, canola, cottonseed, alfalfa, sugar beet and papaya) and their specified processed food items, as long as the GM ingredient is among the top three ingredients (by weight) in a product and accounts for more than 5% of the total product. These labelling requirements do not apply to any vegetable oils and soy sauce as their original GM materials can no longer be detected.

Korea

Business operators who import, develop or manufacture GM foods are subject to safety evaluation on the relevant foods by the Korean Ministry of Food and Drug Safety. To this end, the Ministry has established the Safety

Evaluation Data Examination Committee to perform the relevant safety evaluation.

GM agricultural, fishery and livestock products with safety approval, or GM foods using these products as ingredients, are required to be labelled as GM foods. The relevant labelling requirements do not apply to food products which do not contain modified DNA or protein after production or processing, e.g. refined foods such as sugars, fats and oils, etc. They also do not apply to agricultural products with the unintended presence of GM agricultural ingredients of 3% or less, or foods or food additives manufactured and processed using such agricultural ingredients.

Singapore

According to the Singapore Guidelines on the Release of Agriculture-Related Genetically Modified Organisms, GM crop developers who wish to apply for the import of GM crops as food or food ingredients must submit a proposal to the Genetic Modification Advisory Committee for safety evaluation before importing. The Singapore Food Agency will consider the recommendations of the Advisory Committee and conduct further safety assessment on the GM crop before approving its import to Singapore for use as food for direct consumption and food ingredients, or for further processing to become ingredients for other foods.

Under the prevailing food regulations in Singapore, GM foods and foods that contain GM ingredients are not required to be specifically labelled. Food products for sale in Singapore can be voluntarily labelled as "GM" or "non-GM", as long as it is factual and not misleading.

The United States (US)

The US Food and Drug Administration (FDA) established the voluntary Plant Biotechnology Consultation Program in the 1990s, working with developers of new plant varieties to help them ensure GM foods made from the new varieties are safe and lawful prior to marketing. Developers of new plant varieties usually participate in the Program before bringing foods derived from a new GM plant to market. This includes the completion of

safety assessments by the developers and submission of the assessment summary to the FDA for further evaluation.

The US has established the National Bioengineered Food Disclosure Standard regarding the labelling of GM foods for full implementation from 1 January 2022. The Standard requires relevant food manufacturers, importers and certain retailers to ensure GM foods are appropriately disclosed through various means such as text, symbol, electronic or digital link, etc. It does not apply to ingredients or products in which the modified genetic material is not detectable (e.g. refined foods such as sugars and oils). It also allows for unintended or technically unavoidable presence of a GM substance of 5% or less in each ingredient.

Annex II

Summary of the Scientific Principles and Guidelines on Safety Assessment of GM Food formulated by Codex and OCED

The approach of the safety assessment is based on the principle that the safety of the GM food is assessed relative to its conventional counterpart having a history of safe use, taking into account both intended and unintended effects.

The safety assessment of GM food generally investigates the direct health effects (toxicity); tendencies to provoke allergic reaction (allergenicity); specific components thought to have nutritional or toxic properties; the stability of the inserted gene; nutritional effects associated with genetic modification; and any unintended effects which could result from the genetic modification. It follows a stepwise process of addressing relevant factors which include –

(a) Description of the GM organism;
(b) Description of the host organism and its use as food;
(c) Description of the donor organism(s);
(d) Description of the genetic modification(s);
(e) Characterisation of the genetic modification(s);
(f) Safety assessment:
    i. expressed substances (non-nucleic acid substances);
    ii. compositional analyses of key components;
    iii. evaluation of metabolites (applicable to GM plants and microorganisms) / health status of the recombinant-DNA animals (applicable to GM animals);
    iv. food processing;
    v. nutritional modification; and
(g) Other considerations (e.g. use of antibiotic resistance marker genes).

The above factors illustrate the process for assessing the safety of GM food in general and factors for consideration will vary case-by-case. For example, safety assessment of food derived from GM microorganism(s) may also take into account other factors, such as antibiotic resistance and gene

transfer, immunological effects, as well as the viability and residence of microorganisms in the human gastrointestinal tract. In certain circumstances, the characteristics of the GM food may necessitate development of additional data and information to address issues that are unique to the product under review.

Annex III

Study Results on the Safety of GM Food in the International Scene

- In 2016, the Institute of Genetics and Developmental Biology of the Chinese Academy of Sciences stated that all GM crops which have passed the safety assessment for GM organisms are safe.

- In the same year, a study conducted by the US National Academy of Sciences on the chemical composition of GM foods on the market revealed that there are no differences, in terms of safety to human health, between consumption of GM foods and their non-GM counterparts; and that there is no persuasive evidence of adverse health effects attributable to consumption of foods derived from GM crops after having carefully searched all available research studies.

- In the same year, the Royal Society of the United Kingdom also concluded that it is safe to eat GM crops, and that there has been no evidence of ill effects linked to the consumption of any approved GM crops since the widespread commercialisation of GM produce in the 1990s.

- In 2017, the US Society of Toxicology concluded that, based on data from scientific studies, food obtained from GM crops are as safe and nutritious as food obtained from non-GM crops.

- In 2019, the Australian Academy of Science expressed that GM foods are safe and no ill effects to human from consuming them have been identified; and that the GM foods approved are no different to unmodified foods in terms of their safety and are digested normally.

- In 2020, the American Cancer Society held the view that there is no evidence that foods containing GM ingredients that are now on the market or the substances found in them are harmful to human health, or that they may either increase or decrease cancer risk.