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The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

අංක 1456/22 - 2006 අගෝස්තු 03 වැනි මහස්පතින්දා - 2006.08.03

No. 1456/22 - THURSDAY, AUGUST 03, 2006

(Published by Authority)

PART I : SECTION (I) — GENERAL

Food Act No. 26 of 1980

L.D.B. 11/89 (ii).

REGULATIONS made by the Minister of Healthcare and Nutrition in consultation with the Food Advisory Committee under section 32 of the Food Act No. 26 of 1980.

NIMAL SIRIPALA DE SILVA,
Minister of Healthcare and Nutrition.

Colombo,
02nd August, 2006.

Regulations

1. These regulations may be cited as the Food (Control of Import, Labelling and Sale of Genetically Modified Foods) Regulations 2006 and shall come into operation on 1st January 2007.
2. No person shall, import, store, transport, distribute, sell or offer for sale -
 - (a) any genetically modified organism as food for human consumption;
 - (b) any food containing or consisting of genetically modified organisms;
 - (c) any food produced from or containing ingredients produced from genetically modified organisms;without the approval of the Chief Food Authority (hereinafter referred to as the "Authority").
3. Any food or ingredients used in the preparation of food as is referred to in regulation 2, shall not -
 - (a) be injurious to the health of the consumer;
 - (b) differ nutritionally to the disadvantage of the consumer as opposed to the nutritional value of food or food ingredients consumed normally by such consumer.
4. Any person (hereinafter referred to as the 'applicant' who intends to import store, sell or offer for sale the food or the ingredients used in the preparation of food as is referred to in regulation 2 shall submit an application to the Authority in the form specified in the Schedule hereto.
5. (1) The application referred to in regulation 4 shall -
 - (a) contain the necessary information, including copies of the studies which have been carried out;
 - (b) contain the modification done on the Deoxyribonucleic acid (DNA) and protein, the process, the countries where these products are sold and any other materials which are available to demonstrate that the food or ingredients used in the preparation of food, complies with the criteria laid down in regulation 3;
 - (c) indicate the manner of presentation and labelling in accordance with the requirements under regulation 11.

(2) The application referred to in regulation 4 shall be accompanied by such information relating to the food or ingredient used in the preparation of food, compiled in a readily comprehensive manner.

6. The Authority shall acknowledge receipt of the application in writing, within fifteen days of receiving. The acknowledgement shall include the date of receipt of the application. The Authority shall forthwith submit the application for a scientific risk assessment report to a Technical Evaluation Committee (hereinafter referred to as the "TEC"), appointed by the Authority on the recommendation of the Food Advisory Committee (hereinafter referred to as the "FAC").
7. Where the TEC is satisfied with the information furnished in the application, a scientific risk assessment report shall be issued by TEC within a period of three months from the date on which the application was received by it. The TEC may request the applicant to provide supplementary information in support of the application. This information shall be provided within a period of three months from the date of receipt of the request. The time period of three months for the preparation of the report shall not apply until the information is provided by the applicant by way of oral or written explanation.
8. The Authority shall charge a processing and assessment fee which shall be determined by the Authority in consultation in the FAC from time to time to be a non-refundable deposit be paid by the applicant.
9. The Authority shall forward the report of the TEC to the FAC and shall communicate the decision on the recommendations of the FAC to the applicant.
10. Where the application has been approved and permission granted in accordance with these regulation the applicant shall be permitted to place the product in the market subject to appropriate labelling of the product.
11. The label on or attached to a package of genetically modified food or food ingredients used in the preparation of good must include the statement 'genetically modified' in conjunction with the name of that food or ingredients used in the preparation of food, or processing aid irrespective of the size of the label or package.
Example 1: for single ingredient genetically modified foods "Soy flour - Genetically Modified" or "Soy flour - from genetically modified soya beans"
Example 2: for genetically modified ingredients: "Ingredients; Soy Protein Isolate (genetically modified), Maltodextrin, Vegetable Oil, Emulsifier (INS 471)"
12. Where genetically modified food is displayed for retail sale other than in a package, any information that would have been required under regulation 11, shall, where it is attached to the food, be considered sufficiently labelled.
13. Food which contains or has genetically modified organisms less than nought decimal five per centum (0.5%), are exempted from the provisions of these regulations:

Provided that the presence of such genetically modified organisms are considered technically unavoidable and the organisms have been subjected to a scientific risk assessment and considered to be safe.
14. (i) Where new information or a reassessment of the existing information reveals that the use of food or genetically modified food approved by these regulations endangers human health, the Authority shall immediately suspend the sale of such food.
(ii) The Authority shall require the person who submitted the application for approval to import, store, transport, distribute or sell such food, as the case may be, to withdraw the product from the market and such person shall immediately comply with the requirement.
15. In the event of refusal of an application, the applicant may appeal within one month of such refusal to the Authority, along with any further information in support of the application.
16. Any Appeal received under regulation 15 shall be referred by the Authority to the TEC. The TEC shall within thirty working days from the receipt of such appeal prepare a report which shall be forwarded to the FAC for further consideration of the application.

17. There shall be only one appeal made in respect of a food or ingredients used in the preparation of food. The Authority shall not accept more than one appeal in respect of the same food or ingredient.
18. The FAC shall communicate its response to the Authority within one month of receiving the decision from the TEC, and the Authority shall communicate the decision of the FAC to the applicant, stating reasons for the decision. The decision of the FAC shall be final.
19. Notwithstanding the provisions of regulation 17, any applicant may make a fresh application in respect of the same food or ingredients used in the preparation of food in accordance with regulation 4.

SCHEDULE

Director General of Health Services,
 (Chief Food Authority)

APPLICATION FOR A PERMIT TO IMPORT GENETICALLY MODIFIED FOOD/FOOD INGREDIENTS OR MATERIALS CONNECTED THERERTO

I/We wish to import genetically modified food/import and sell genetically modified food/ import genetically modified substances to be used as food ingredients/ prepare/process / manufacture and sell genetically modified food, the details of which are furnished below as required in terms of regulation 4.¹

| | |
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| 1. Name and address of the applicant/s and other relevant information of the organization/trade; | |
| 2. Description of the food or food ingredient intended for import and specifications: | |
| 3. Detailed description of method or production/manufacturing of the food: | |
| 4. Detailed description of the host organism or the food: | |
| 5. Description of donor organism: | |
| 6. Information of changes such as nutrients, toxicants or allergic reaction etc in the product. | |
| 7. Copies of the studies which have been carried out and any other material that is available to demonstrate the safety of the food: | |
| 8. Support by anlysis report as data determining the fact that the food is not different from conventional food: | |
| 9. Where appropriate, the conditions for placing in the market, foods produced from it, including specific conditions for use and handling: | |
| 10. Method for detection, including sampling and identification of the transformation event. Where applicable method for detection and identification of transformation event in the food and / or in the food produced from it: | |
| 11. Samples provided of modified food and their controls; | |
| 12. Documents relating to the approvals and marketing of the same/identical food in any other country or countries: | |
| 13. Proposed scheme for post-marketing monitoring | |
| 14. Any other material relevant to the application to facilitate and expedite the process of assessment | |

1. Strike off inapplicable words

I/We hereby confirm that the information furnished by me/us are true and accurate to the best of my/our knowledge and that I/We would promptly notify the Chief Food Authority in the event of any information furnished are subsequently found to be inaccurate or requires revision in the light of new information provided by scientific research. I/we also undertake to provide any further information relating to the application and the relevant product whenever required by the Chief Food Authority. I/We further undertake to abide by all the conditions stipulated by the Chief Food Authority in respect of import, manufacturing/processing, packaging, labelling, storing, transport and sale of the products in the event of approval being granted.

Signature/s of Applicant/s

Date:.....

Note: Applicants are expected to provide all the information requested above in detail. Reference should be made in the respective columns to documents or materials attached to the application. If, for any special reasons, they are unable to provide the information in respect of certain issues, they should explain why they are unable to do so:

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