GUIDELINES FOR THE SAFETY ASSESSMENT OF NOVEL FOODS

VOLUME I

Preamble and Guidance Scheme for Notification

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1. INTRODUCTION

Developments in food science and biotechnology are resulting in the introduction into the Canadian marketplace of novel foods and foods developed using novel processes. While such developments may add to the economic well-being of Canadians and provide a greater choice to the consumer, the safety of some of these foods has yet to be established. Concern has been expressed particularly with respect to the possible introduction of harmful substances into the food supply, including: the introduction of new toxicants; increased levels of existing toxicants; and, the reduction of nutritional value.

Existing regulations under the Food and Drugs Act use premarket notification and assessment to address food safety issues in several areas. These areas include the safety assessment of food additives; the establishment of maximum residue limits (MRL) for pesticides; the safety assessment of foods treated with ionizing radiation; and, the notification process for infant formulae. Such activities will not be affected by the approaches expressed in this document. However, premarket notification requirements do not presently exist for many novel foods, including the products of biotechnology.

Not all "new" food products will require notification or assessment. However, certain novel foods that have not been previously available in the Canadian marketplace, or foods produced by novel processes may require notification prior to sale. The Branch has proposed new regulations intended to ensure that these novel products receive oversight. A notification does not mean that a safety assessment of a novel food by the Branch will be required in all cases. However, information demonstrating the safety of the product may be requested. In support of these proposed Novel Food Regulations, guidelines have been developed which identify the safety assessment criteria for genetically modified microorganisms and genetically modified plants (*Guidelines for the Safety Assessment of Novel Foods, Volume II: Genetically Modified Microorganisms and Plants*).

2. PURPOSE

This preamble will provide assistance to producers and processors respecting pre-market notification in regard to novel products and products from novel processes.

3. RELEVANT PRODUCTS AND PROCESSES

Annex I of this guideline contains a number of definitions that are relevant to the concept of novel foods. The proposed definition of novel food is presented there, **but may be subject to revision as development of the regulation continues**. However, the current proposal requires further clarification to ensure that only those products for which notification is required receive the necessary evaluation, without requiring notification for all new products.

Novel foods may include:

- products and processes that have previously not been used before as food or to process food in Canada[1]

- food containing microorganisms that have not previously been used as food or to process food,

- foods that result from genetic modification and exhibit new or modified characteristics that have previously not been identified in those foods, or that result from production by organisms exhibiting such new or modified characteristics, or

- food that is modified from the traditional product or is produced by a process that has been modified from the traditional process.

These principles are further clarified in a series of charts that appear in Annex II. These charts are presented for guidance only and should not be considered a rigid checklist. The questions that are embodied in these charts lead to endpoints that in some cases require notification to the Food Directorate. The information requirements for a notification include:

- the name under which the novel food will be sold,

- the name and address of the principle place of business of the manufacturer and the importer if applicable,

- a statement of the nature of the novel food, its process of manufacture, its intended uses and history of consumption if used as food in another country.

- the name and nature of the novel food process used to produce a food that would not in or of itself be considered a novel food,

- as applicable, information about the possible displacement of existing foods and the nutritional impact thereof,

- the written text of all labels to be used in connection with the novel food, and

- the name and title of the person who signed the notification and date of signature.

In addition, information demonstrating the safety of such products as food may be requested by the Director.

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[1] Newness of the product in the Canadian marketplace is of importance. However, use of the novel product in a jurisdiction with a similar food safety system would become an important consideration with respect to the evaluation of the product or process.

Additional guidance was viewed as necessary for the safety assessment of certain novel foods. As a first step, Volume II of this guideline has been prepared to provide guidance for the safety assessment of genetically modified plants and microorganisms. Other guidelines may be developed as necessary to address similar issues.

The Guidelines are flexible due to the broad range of products being developed. A determination of the need for notification and the safety assessment of novel products will be conducted on a case-by-case basis, and will be based on the comparison of the novel substance to an analogous traditional food, where such exists. Notification may not be required if the modification to the product or process is not significant, or if a high degree of similarity to a traditional product exists. This concept of **substantial equivalence** is similar to the policy developed by the Organization for Economic Cooperation and Development (OECD).[2] Furthermore, not all information requirements outlined in the Guidelines may be appropriate for all products. Therefore, developers are encouraged to consult the Food Directorate in the early stages of product development in order to reach agreement on whether notification is required, and what information is appropriate to the evaluation of the safety of the particular product.

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[2] OECD, 1993. Safety Evaluation of Foods Derived By Modern Biotechnology. Concepts and Principles. Organization For Economic Cooperation and Development. Paris. 79 pages.

ANNEX I

DEFINITIONS

Biotechnology

is the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms. (*Canadian Environmental Protection Act*)

Food

includes any article manufactured, sold or represented for use as food or drink for man, chewing gum, and any ingredient that may be mixed with food for any purpose whatever. (*Section 2, Food and Drugs Act*)

Ingredient

is an individual unit of food that is combined as an individual unit of food with one or more individual units of food to form an integral unit of food that is sold as a prepackaged product. (*Section B.01.001, Food and Drug Regulations*)

Food Additive

is any substance the use of which results, or may be reasonably expected to result in it or its by-product becoming a part or affecting the characteristics of a food, but does not include

a) any nutritive material that is used, recognized or commonly sold as an article or ingredient of food,
b) vitamins, mineral nutrients and amino acids other than those listed in the tables to Division 16,
c) spices, seasonings, flavouring preparations, essential oils, oleoresins and natural extractives,
d) agricultural chemicals, other than those listed in the tables to Division 16,
e) food packaging materials and components thereof, and
f) drugs recommended for administration to animals that may be consumed as food.
(*Section B.01.001, Food and Drug Regulations*)

Genetic Modification

is any change to the heritable traits of an organism achieved by intentional manipulation. This includes, but is not limited to: recombinant nucleic acid techniques, somaclonal variation, electroporation, artificially induced mutagenesis, and the like.

Genetically Modified Organism

an organism which is constructed or intentionally changed, in its genetic make-up.

Recombinant Nucleic Acid Technology

is the precise transfer of spliced genes between different organisms of the same or different species. This can include the transfer of synthetic genes.

Substantial Equivalence

as described in *Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles* (OECD, 1993) substantial equivalence embodies the idea that existing organisms used as food or as a source of food can be used as the basis of comparison when assessing the safety of the human consumption of a food or food component that has been modified or is new.

If one considers a modified traditional food about which there is extensive knowledge on the range of possible toxicants, critical nutrients or other relevant characteristics, the new product can be compared with the old in simple ways. These ways can include, *inter alia*, appropriate traditionally performed analytical measurements or crop-specific markers, for comparative purposes. The situation becomes more complex as the origins/composition/exposure experience decreases, or if the new products lack similarity to old established products or, in fact, have no conventional counterpart. (Organization for Economic Cooperation and Development)

Safety Assessment

refers to the concepts described in the document *Risk Management in the Health Protection Branch* (Health Canada, 1990) and encompasses hazard identification, risk estimation, and risk evaluation and management.

Novel Food

is a food that has not previously been used as food, results from a process that has not previously been used for food in Canada, or has been used as food, but has been modified such that:

(a) the food results from genetic manipulation and exhibits one or more characteristics that were not previously identified in that food, or the food results from production by a genetically manipulated organism exhibiting such new characteristics,

(b) the food contains microorganisms that have not previously been used as a food or to process food, or

(c) the food is modified from the traditional product or is produced by a process that has been modified from the traditional process.

Organism

any unicellular or multicellular biological entity capable of reproduction or replication and viruses.

Microorganism

is any bacteria, mycoplasma, chlamydia, rickettsia, protozoa, fungi, algae, viruses, parts of these microorganisms and any combination thereof. (*Canadian Environmental Protection Act*)