codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/FBT 06/6/6**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Sixth Session

Chiba, Japan, 27 November – 1 December 2006

DISCUSSION PAPER ON COMPARATIVE FOOD COMPOSITION ANALYSIS OF STAPLE FOODS

(Submitted by India)

Background[1]

1. At the Fifth Session of the Task Force, India proposed that the Task Force should start, in the future, new work on comprehensive analysis of nutrients, anti-nutrients as well as methods of toxicity studies because quantitative and qualitative analytical methods would be necessary tools to conduct safety assessment of recombinant-DNA plants.

2. The Task Force agreed to invite India to submit a discussion paper on this subject for further consideration by the Sixth Session of the Task Force.

3. The Paper submitted by India is in the Annex to this document.

[1] ALINORM 06/29/34, paras 43-44

ANNEX

Project Area: Composition analysis of Genetically Modified (GM) staple foods

Objective

(i) Generation of data on comprehensive compositional analysis of the major staple GM foods with regard to information on key nutrients, anti-nutrients, allergens and toxicants.

(ii) Development of standardised protocol and quality control for testing of relevant components of staple GM food including the risk analysis studies.

Rationale:

It is estimated that with the current population growth rate the world population will nearly double in 50 years and in most of the increase will be in developing countries. Feeding such an expanding world population would be one of the major challenges of the new millennium with limited availability of arable land and water resources for irrigation. With these problems, the development and use of genetically modified crops with enhanced nutrients and phenotypic characteristics (e.g. resistance to pests, adverse climates etc.) is considered by many as an important tool to help ensure global food security. Globalization interconnects raw material like staple food crops with consumers of all regions of the world, and thus ensuring that no unintended changes have taken place in the GM food is likely to be the major stepping stone towards acceptance of transgenic products.

It is logical to expect that while considering various thrust areas for evaluation of GM food, staple food would be ranked as top priority since any country, specially a developing one with limited resources would at least wish to ensure adequacy of availability of staple food for which the need could be met from either domestic or imported sources. At the same time since food regulations are important in protecting consumer health, it is essential that all national governments would like to ensure that such regulations keep pace with developing technology.

GM food technology should help in better understanding of the relationship between compositional characteristics and unintended effects of genetic modification with regard to known or unknown components like nutrients, anti- nutrients, allergens, toxins etc. in staple GM crop. In addition, substantial work is being carried out all over the world with promising results to develop methods for compositional analysis of GM food based on fingerprinting techniques, or on the detection of altered gene expression by amplification of specific subsets of mRNA.

Further work on compositional analysis of GM staple crops in terms of chemical or molecular analysis will help to build up knowledge base that could be helpful for developing countries to augment domestic production of staple crops through improved techniques as well as to adopt science based approach towards import of staple GM crops in order to ensure adequate availability of staple food in the country. Moreover, availability of information regarding GM food composition would help the consumers in rationalizing approach regarding choice of GM food for their food basket.

Background:

Long-term animal toxicity studies are generally applicable for safety assessment of many compounds in food including pesticides, pharmaceuticals, industrial chemicals and food additives that are well characterized, of known purity, of no nutritional value, and for which human exposure is generally low since such studies can be carried out utilizing a range of doses (amounts greatly above expected human exposure levels) in order to determine the safe level of exposure for humans. By contrast, traditional toxicological testing is not applicable to the assessment of whole foods that are complex mixtures of constituents, have wide variations in composition and nutritional value and due to its bulk can only be fed to laboratory animals at low multiples of the amounts that might be present in the human diet. In addition, a diet that consists entirely of a single category food can cause adverse effects on nutritional status in the animals, potentially masking any other smaller effect of a component or components of the food being tested. The

United Nations Food and Agriculture Organization (FAO) and World Health Organization (WHO), with reference to the work by Organization for Economic Development and Cooperation (OECD), recommended that the concept of 'substantial equivalence' could be a guiding principle to detect intended and unintended differences between a GM food crop and its non-GM control to address these limitations. It should be based on listing out the composition of macro-and micro-nutrients, anti-nutrients, inherent plant toxins, secondary metabolites and allergens that need to be analysed for each crop species. It should further foresee the validated techniques to establish the content of these compounds in the GM plants and common methods to statistically analyse the data. Differences detected could then be focused on further nutritional, toxicological and immunological evaluation. An operational definition of 'substantial equivalence' should also include detailed protocols on the design of the field trials for collecting compositional data of a GM food crop and its non-GM reference. The principle was set out that if a modified food or food component would be determined to be substantially equivalent to an existing food, it could be treated in the same manner. No additional safety concerns would be expected. However, when a food or food component would not be determined to be substantially equivalent, the identified differences should be the focus of further evaluations.

Limitations of existing knowledge on Compositional assessment of GM food:

However, an operational definition of substantial equivalence is still lacking. There is for example no minimum list of macro-and micro-nutrients, inherent plant toxins, anti-nutrients, secondary plant metabolites and allergens known to be associated with a crop species, which should be analysed, for the determination of a GM food crop as substantially equivalent. Further, discussions on valid methods to generate compositional data of a GM food crop and its 'control' from field trials as well as on statistical analysis have not yet been completed e.g. by EC scientific committees and competent authorities of EU member states. There has been a lack of consistency in compositional data submitted by trials on the content of macro-and micro-nutrients, minerals, vitamins, inherent plant toxins and anti-nutrients. For example, the content of trypsin inhibitor, an anti-nutrient in maize, has not been determined in all cases. In addition, the design of the field trails, the number of locations and seasons, and the choice of the 'comparator' have considerably differed from case to case. The degree of difference between a natural food and its GM alternative before its 'substance' ceases to be acceptably 'equivalent' had not been defined, nor had an exact definition been agreed by legislators. The vagueness of this concept might make the concept useful to industry but unacceptable to the consumer. In some cases the analytical methods used to generate the crop data are not known and/or their performance parameters are not available. As a result, there was a clear need for a single, easily accessible and up-to-date source of crop composition information. It should also be noted that in cases where one part of the plant is eaten by humans (for example, grain) and other parts are eaten by animals (for example, forage) compositional analysis of both will need to be examined separately (for example, seeds vs. seeds and forage vs. forage) and may lead to different results.

Future Scope:

Genetically modified crop technology has revolutionized agriculture by solving many of the current problems in agriculture worldwide. The types of GM crops that may become available in the future could boost crop yields while enhancing the nutritional value of staple foods and eliminating the need for inputs that could be harmful to the environment. A consistent approach to the establishment of substantial equivalence might be improved through consensus on the appropriate components (e.g., critical nutrients, toxicants and anti-nutritional compounds) on a crop-by crop basis which should be considered in a comparison. It is recognized that the components may differ from crop to crop and this development of crop specific documents could detail the relevant components of a particular crop and this would be a requirement for establishing substantial equivalence. Data bases on nutrients, toxicants and allergens in food crops as well as the gene/protein sequence provide potentially valuable resource to facilitate the determination of substantial equivalence between a new food and a traditional counterpart. They may also be useful in addressing specific safety issues such as allergenicity. It is important to note that since establishment of substantial equivalence is a dynamic concept, information need to be regularly updated. OECD has published a series of Consensus Documents summarizing the existing data on the composition of crops such as soybean, maize, and canola. These documents are an excellent resource, but are limited by the availability of published composition data which are not easily updated to reflect current information or technologies. Targeted compositional analyses using validated quantitative methods will continue to be the core method to assess whether unintended changes have occurred. Using this approach in the evaluation of more than 50 GM crops that have been approved worldwide, the conclusion has been reached that foods and feeds derived from GM crops are as safe and nutritious as those derived from traditional crops.

Expected benefits:

According to FAO estimate for 2003-04, 82.4% of world cereal consumption is by developing countries. Review of global dietary patterns indicates cereals forming major part of diet in developing countries. Wheat is the primary staple food for almost one-third of the world's population. Among the developing countries, wheat ranks first in dietary shares in countries in Near East and North Africa, in many localities in Latin America, Pakistan, and India. It is also the staple food for over 3.3 billion people in developing regions, consumed as unleavened bread (Near East and North Africa, and parts of South Asia e.g. India and Pakistan), as noodles (East and South East Asia),as 'couscous' (North Africa) etc. Rice is the major cereal for roughly 3.4 billion people in developing countries and is grown in many regions, under a wider variety of climatic and soil conditions than any other crop. It is nearly always eaten in boiled form, without further processing other than milling, in contrast with most other cereals. However, in some countries in the Far East, manufactured rice products appear in diets, mainly in the form of rice noodles, which compete to some extent with wheat noodles. Maize represents either the major staple or main supplementary staple for 1 billion people in developing regions, mostly in Sub-Saharan Africa. Latin America, white and yellow maize is extensively used to make unleavened bread ('tortilla') and also eaten 'on the cob', while in Sub-Saharan Africa white maize is processed into various products, but popular forms include starchy pastes such as porridge. In the Near East, maize flour is commonly used to make bread, while in South and South East Asia (notably Indonesia and the Philippines) it is consumed in a number of diverse ways. These grains also appear in diets in large parts of India and Pakistan, where they are consumed predominantly as unleavened bread.

The proposal is likely to meet the following strategic objectives of Codex

(i) Promoting sound regulatory framework in various countries.

(ii) Promoting widest and consistent scientific principles of risk analysis.

(iii) Promoting linkages between Codex and other regulatory bodies.

(iv) Promoting maximum application of Codex standards.

Expected benefits likely to be gained by India:

While India has been so far supportive of transgenic plant research, the regulatory bodies in India would like that the benefits of GM food outweigh the risk.

In January 2000, as a result of establishment of an international trade agreement for labelling GM foods more than 130 countries, including the US, the world's largest producer of GM foods an agreement was considered which stated that exporters must be required to label all GM foods and that importing countries have the right to judge for themselves the potential risks and reject GM foods, if they so choose.

Following implementation of mandatory labelling of GM foods in India it is expected that compositional analysis of GM foods whether labelled or unlabelled will be an absolute requirement to complement. A definite guideline on the compositional analysis will help to frame a legislative guideline in the country for misbranding a GM food with nonpermissible composition, take care of the consumer protection and will help to establish our own standards which, when applied in the background of the International standards, will promote harmonization.