# Development of Novel Anti-Cancer Combination Chemotherapy Targeting Warburg Effect

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#### <Summary>

Many cancer cells generate ATP mainly through glycolysis than oxidative phosphorylation via electron transport chain in TCA cycle, even in the presence of oxygen. This Metabolic Reprogramming is known as "Warburg effect". In such glycolysis-dependent energy metabolism, toxic methylglyoxal (MG) is produced as the side-product. Glyoxalase I (GLO I), is the rate-limiting enzyme for detoxification of MG, and is highly expressed specifically in many cancer cells. MG is known to be highly reactive with DNA/RNA and proteins, and thereby to induce apoptosis. Thus, the specific inhibitors of GLO I have been expected as possible effective anti-cancer drugs, which selectively kill GLO I-overexpressing tumors. We have found a novel GLO I inhibitor, TLSC702, which is more effective than already reported glutathione (GSH) analog inhibitors. Although TLSC702 has more potent inhibitory effect on GLO I than GSH analog inhibitor in vitro, it is required at higher concentrations to induce apoptosis. A reason for this is considered to be a possibility that cancer cells alter metabolic pathway to use more mitochondrial respiration (TCA cycle) than glycolysis (Metabolic Shift) to avoid the MG accumulation and apoptosis induction. So, we assumed the effective anti-proliferation and apoptosis mechanisms by combination of GLO I inhibition with suppression of mitochondrial respiratory function, focused on pyruvate kinase M2 (PKM2), which is specifically expressed in cancer cells. In this study, we examined the combined anti-cancer effect of GLO I inhibitor TLSC702 with a PKM2 specific inhibitor on a GLO I-overexpressing tumor cell line (NCI-H522 cells). As the results, this combination is revealed to be effective to induce apoptosis to cancer cells. Our studies are important to develop novel combination cancer chemotherapy targeting specific key molecules involved in Warburg effect.

International Conference on Infrastructure Needs for a Food Control System: Roadmap for Regional Harmonization

Rekha Sinha ILSI-India Hiroaki Hamano ILSI Japan

This report is an excerpt from the original version prepared by Ms. Rekha Sinha, Executive Director of ILSI-India. The full report is available on the Website of ILSI-India at <a href="http://www.ilsi-india.org">http://www.ilsi-india.org</a>.

ILSI-India and ILSI Japan organized the "International Conference on Infrastructure Needs for a Food Control System: Roadmap for Regional Harmonization" on December 9th -10th, 2014 in New Delhi, India. The Conference was organized with support from Ministry of Agriculture, Forestry and Fisheries, Japan, in association with Food Safety and Standards Authority of India (FSSAI), Ministry of Health and Family Welfare, Government of India (GOI), and was co-sponsored by Export Inspection Council, Ministry of Commerce and Industry, GOI. Over 100 delegates from 7 countries from Government, Industry, Academia, FAO and WHO and other national and international institutions participated in the Conference.

#### Agenda for the Conference

#### INAUGURAL SESSION:

- Welcome Remarks By Mr. D. H. Pai Panandiker, ILSI-India
- Introduction And Background By Mr. H. Hamano, ILSI Japan
- Address By Dr. A M Gondane, Ministry of External Affairs, India
- Opening Remarks By Mr. H. Yamada, Ministry of Agriculture, Forestry and Fisheries, Japan
- Inaugural Address By Mr. K. Chandramouli, Ministry of Health and Family Welfare, India
- Vote Of Thanks By Mr. N. M. Kejriwal, ILSI India

#### SESSION ONE: FOOD CONTROL SYSTEM IN SAARC COUNTRIES

- Food Control System In Bangladesh By Mr. Mohammed Ruhul Amin Talukder, Ministry of Food, Bangladesh
- Food Control System In Bhutan By Ms. Dechen Choki, Ministry of Agriculture and Forest, Bhutan
- Food Control System In India By Ms. Vinod Kotwal, Ministry of Health and Family Welfare, India
- Food Control System In Maldives By Mr. Satheesh Moosa, Ministry of Health, Maldives
- Food Control System In Nepal By Ms. Rita Pandey, Ministry of Agriculture Development, Nepal
- Food Control System In Sri Lanka By Dr. Ananda Jayalal, Ministry of Health, Sri Lanka

### SESSION TWO: CODEX AND INTERNATIONAL STANDARDS FOR PROTECTING PUBLIC HEALTH AND ENSURING FAIR TRADE PRACTICES IN FOOD TRADE

• Importance Of Codex For Promoting Public Health And Ensuring Food Security By Dr. Shashi Sareen, FAO Regional Office for Asia and Pacific, Bangkok

- Understanding The Scientific Basis For Codex Food Safety Standards By Dr. Yukiko Yamada, International Consultant on Food Safety, Tokyo
- Codex Guideline Of Food Labelling And Claim By Dr. B K Nandi, Society for Nutrition, Education and Health Advancement, India
- Codex General Standards On Food Additives (GSFA) By Mr. Anil Mehta, Ministry of Health and Family Welfare, India
- CCFICS Guideline On National Food Control System By Mr. Parmod Siwach, Ministry of Commerce and Industry, India
- Food Safety Tools (GMP, HACCP, ISO 22000) By Ms. Vani Bhambri Arora, National Accreditation Board for Certification Bodies, India

### SESSION THREE: PROMOTING HARMONIZATION OF FOOD SAFETY STANDARDS AND FOOD CONTROL SYSTEM

- Practical Application Of Codex By Mr. S. Dave, Ministry of Health and Family Welfare, India
- Overview Of Food Safety Control System In Japan By Ms. Keiko Saito, Ministry of Health, Labour and Welfare, Japan
- Harmonization Of Food Control System In SAARC Region By Dr. S. K. Saxena, Ministry of Commerce and Industry, India
- Facilitating Food Safety Standards Harmonization In ASEAN-ILSI SEA Region's Scientific Initiatives By Ms. Pauline Chan, ILSI Southeast Asia Region, Singapore

#### SESSION FOUR: INFORMATION AND COMMUNICATION

- INFOSAN By Dr. Ritu Singh Chauhan, World Health Organization, India
- Risk Perception And Communication Associated With Food Safety By Dr. Sudarshan Rao, National Institute of Nutrition, India

### PANEL DISCUSSION ON: INFRASTRUCTURE NEEDS TO PROMOTE HARMONIZATION OF FOOD STANDARDS AND MODERN FOOD CONTROL SYSTEM FOR SAARC COUNTRIES

• Dr. Y. Yamada, Mr. S. Dave, Dr. S. K. Saxena, Dr. S. Rao, Mr. A. Jauli, Ms. R. Pandey and Mr. M. R. A. Talukder

#### CONCLUDING SESSION

- Valedictory Address By Mr. Y. S. Malik, Ministry of Health and Family Welfare, India
- Vote Of Thanks By Mr. Hiroaki Hamano, ILSI Japan

India and its neighboring countries, such as Afghanistan, Bangladesh, Bhutan, Maldives, Nepal, Pakistan and Sri Lanka are rapidly growing with more open economies. There is now greater attention to food safety standards and/or food safety control systems with the dual objective of promoting trade and ensuring better public health. The Conference, therefore, aimed to share information and to build capacity in the food safety control systems among the countries and further to identify needs for the future.

The Conference shared information about food control system in SAARC countries and also in other Asian countries. It created awareness about Codex standards, their scientific basis and use for protecting public health and ensuring fair trade practices. It identified the

infrastructure needs for modern food control system and discussed about possible future actions.

It is hoped that the Conference recommendations will promote and further strengthen the harmonization of food safety standards and/or food safety control systems in SAARC region. It has been instrumental in building the network among food safety authorities in the region. Steps will be initiated at regional level and country level for action on specific issues and considering needs of each country for future capacity building activities.

The Conference Statement of Recommendations and Roadmap for Regional Harmonization are summarized below.

# STATEMENT OF RECOMMENDATIONS & ROADMAP FOR REGIONAL HARMONIUZATION

ILSI-India and ILSI Japan organized the "International Conference on Infrastructure Needs For A Food Control System: Roadmap For Regional Harmonization" on December 9th -10th, 2014 in New Delhi, India. The Conference was organized with support from Ministry of Agriculture, Forestry and Fisheries, Japan, in association with Food Safety and Standards Authority of India (FSSAI), Ministry of Health and Family Welfare, GOI, and was co-sponsored by Export Inspection Council, Ministry of Commerce and Industry, GOI.

The Conference was inaugurated by Mr. K. Chandramouli, Chairman, FSSAI. Discussions on some of the key subjects were led by: Dr. S. K. Saxena, Director, EIC; Mr. S. Dave, Advisor, FSSAI; Dr. Ryuji Yamaguchi, Executive Director, ILSI Japan; Dr. B. K. Nandi, Former Senior Food and Nutrition Officer, FAO RAP; Dr. V. Prakash; FRSC, Distinguished Scientist of CSIR INDIA, Director, Innovation Research and Development at JSS MVP, Mysore. The Valedictory Address was delivered by Mr. Y. S. Malik, Chief Executive Officer, FSSAI. Presentations were made by 28 eminent speakers on different related subjects, apart from the panel discussion which focused on infrastructure requirements of the region, the gaps that exist and the way they could be made up. Over 100 delegates from 7 countries from Government, Industry, Academia, FAO and WHO and other national and international institutions participated in the Conference.

#### <u>Preamble</u>

The objective of the two-day conference was to develop a road map for harmonization of food control systems in the South Asian region. This road map may be relevant to other regional groupings as well.

The action points that emerged from the presentations and discussions and are essential components of the roadmap for harmonization with the dual objectives of ensuring safe and nutritious food and facilitating food trade within the region and the rest of the world.

It is essential for each country to have a food control system with legal provisions for levels of safety, infrastructure, surveillance mechanism, food labeling, to make harmonization possible.

Harmonization of food regulations would be beneficial keeping in view Codex as the reference point since Codex standards have WTO acceptance and are based on the best available science.

#### Regulatory Authorities In SAARC Region

The food control system varies a good deal among countries in the South Asian region. The Bangladesh Parliament enacted the Food Safety Act 2013 which is under implementation including the establishment of Bangladesh Food Safety Authority.

The food control system is governed by the Food Act of Bhutan 2005 and Regulations 2007. The National Food Quality and Safety Commission is the highest decision making body in food matters.

In India the food control is governed by Food Standards and Safety Authority of India set up under the 2006 Act by Parliament.

The food control system is regulated in Maldives by Food and Drug Authority and the Health Protection Agency. The Department of Food Technology and Quality Control is the implementing authority for food legislation in Government of Nepal has provisioned Department of Food Technology and Quality Control as the implementing agency for food legislation.

The Ministry of Food Security and Research is working on a national strategy on implementing food safety which will provide a sound regulatory foundation for domestic and international food trade of Pakistan.

Food control activities are mainly carried out in Sri Lanka by the Ministry of Health through its Food Control Administrative Unit.

The food control systems in different countries have evolved in response to need. In spite of the differences in the systems and regulations it should be possible to harmonize the systems with the central objective of bringing them in line with Codex standards.

#### **Action Points**

#### 1 - Areas For Harmonization

The best option for the region is to complete the process of harmonization which was started by ILSI-India in 1999 with the regulatory regime under Codex. This process has to be transparent and open with consistency and practicality and subject to preference indicators. ASEAN is a good example. The areas identified in this Conference are:

- a. Legal provisions about safety
- b. Surveillance mechanism
- c. Safety tools including GMP,GAP,GLP,ISO, HACCP and risk assessment
- d. Food labeling including nutrient declarations which should be mandatory and supplementary nutrition information
- e. Food categorization systems
- f. Food additives
- g. Contaminants and biological hazards

#### 2 - Process of Harmonization

The regulations should be implementable, provide room for innovation and introduction of new products. This mechanism essentially involves all stakeholders including regulators, consumer organizations and industry.

#### 3 - Prerequisites of Harmonization

In order to get the full advantage of harmonization it is essential to:

- **a.** Understand and in appropriate manner incorporate the Codex standards, guidelines and recommendations, as also the best international practices and the science on which these are based
- **b.** Strengthen cooperation among regional countries to promote sharing of data, knowledge base, best practices, laboratory infrastructure training of manpower
- c. Use the SAARC organization to implement the road map for harmonization

#### 4 - National Food Control System

The national food control system should:

- a. ensure that only safe and wholesome foods are marketed
- b. take decisions based on science and risk assessment
- c. empower authorities to detect sources of contamination and take necessary action to prevent contaminated foods from reaching the consumer
- d. enforce compliance by farmers, manufacturers, distributors, importers and other stakeholders
- e. be transparent and promote public confidence
- f. utilize capacity building programs by FAO/WHO

#### 5 - Food Regulators

Agreement among food regulators will ensure common standards for food safety, contaminants, labeling requirements, streamlined procedures, methods of analysis, accreditation of laboratories, conducting surveys, maintaining data base and organizing training programs at all levels.

#### 6 - Surveillance And Monitoring

Post-marketing surveillance and monitoring based on information from different sources, analysis of such information and their use in decision making would ensure efficient and effective implementation of the food control system and minimize risk of biological and chemical hazards.

#### 7 - Self-Regulation

Self-regulation by industry is the best way of control if their product is demonstrated to be safe.

#### 8 - Consumer Education

Education of the consumer has to be a shared responsibility of industry, regulators and consumer organizations. Consumer perceptions about food safety, standards and risks can greatly impact on their choice of food. It is therefore important to develop effective risk communication strategies.

#### 9 - Strengthening of Infrastructure

The panel discussion focused on the infrastructure needs of the region to enable efficient implementation of food control systems. Infrastructure would primarily include laboratories for sample analysis and research, trained personnel, etc. and would require huge investment. Hence it would be desirable to have common infrastructure facilities with shared secondary requirements. To achieve this objective it is necessary to:

- a. Establish accredited laboratories.
- **b.** Set up cold chains to avoid food wastage
- c. Organize programs for capacity building
- d. Ensure good laboratory practices
- e. Adopt internationally accepted methods of sampling and analysis
- f. Maintain proper documentation

#### 10 - The Way Forward

- a. Networking of NFCS at SAARC
- b. Develop SAARC as a block
- c. Notify referral laboratories
- d. Counselling and Training of NFCS staff
- e. Create a data base for the region

Harmonization is a complex and extensive exercise and will take time if a beginning is made with the mapping of NFCS in different counties the goal can be achieved to ensure safe and nutritious food to the consumer and facilitate and enhance trade within the region and with the rest of the world.

#### Globalization of Food Industry

Investigation of Food Regulations in Asia and Their Database

Hiroaki Hamano Advisor ILSI Japan

#### <Summary>

For the purpose of supporting Japanese food industry to expand overseas businesses in the fast-growing markets of emerging countries, the Ministry of Agriculture, Forestry and Fisheries (MAFF) has been offering funding projects since FY 2009: FY 2009-2012 for Overseas Business Support, 2013 for Global Innovation Support and 2014 for Globalization of Food Industry.

Having been authorized by the MAFF, ILSI Japan, in collaboration with ILSI Asian branches, has been conducting investigation of legal framework on foods, product standards/specifications of specific food categories and food additives in Asian countries, and further developing a Database of all the information investigated for public use in 2015.

In order to disseminate and share the information, this meeting "Globalization of Food Industry -Investigation of Food Regulation in Asia and their Database-" was organized on February 19, 2015 in Tokyo. In the meeting, information about "Database on ASEAN Food Additives and ILSI Activities Supporting ASEAN Food Standards Harmonization" and "Progress of ASEAN Food Standards Harmonization", as well as the details of ILSI Japan's activities were introduced.

### Report of the 19th Session of the FAO/WHO Coordinating Committee for ASIA

Shuji Iwata Director ILSI Japan

#### <Summary>

The 19th session of the FAO/WHO Coordinating Committee for ASIA (CCASIA) was held from 3 to 7, November, 2014 in Tokyo, Japan. The session was attended by 119 delegates from 21 member countries, 4 observer countries and 8 international organizations.

The summary and conclusions of the main agendas are as follows;

- the Coordinating Committee agreed to forward the amendments to the Regional Standard for Tempe to the 38th Commission for adaption
- the Coordinating Committee agreed to forward the Draft Regional Standard for non-Fermented Soybean Products to the 38th Commission for adaption at step 8
- provided replies regarding the status of implementation of selected activities of the Codex Strategic Plan 2014-2019 relevant to the work
- agreed on the need for revitalization of RCCs and made comments on several proposals
- returned the proposed draft Regional Standard for Laver Products and the proposed draft Regional Code of Hygienic Practice for the Street-vended Foods to step 2/3
- agreed to discontinue work on development of the Strategic Plan for CCASIA 2015-2020, and to replace it with the list of Activities of Interest to CCASIA
- unanimously agreed to recommend that India be appointed as Coordinator for ASIA

<Summary Report>
Pre-CCNFSDU Event:
ILSI SEA Region Seminar on Scientific Substantiation of Claims

Pauline Chan
Director of Scientific Programs
ILSI SEAR

Health claims are important tools used to communicate the health benefits of a food product to consumers, providing point-of-sale information to assist them in making informed choices. Globally, there is wide disparity between permitted claims across countries, and the process and requirements used to substantiate these claims. This presents a number of challenges for key stakeholders including regulatory bodies, industry and researchers.

The half-day seminar 'Scientific Substantiation of Claims', held in Bali, Indonesia prior to the 36th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), reviewed the current status and substantiation process for nutrition and health claims as well as challenges faced in Australia, Europe, Japan and Southeast Asia. It also provided an update on new biomarkers and parameters for evaluating health benefits, such as weight control. Attended by 90 regional and international participants including government and food industry regulatory personnel, the seminar commenced with a welcome address from ILSI Southeast Asia Region Executive Director Mrs. Boon Yee Yeong.

Key learnings and considerations in the scientific substantiation of claims in the EU was then presented by Dr. Ariane Titz from the Nutrition Unit, EFSA. She

reviewed the scientific assessment of health claims performed by the Panel on Dietetic Products, Nutrition and Allergies (NDA) of EFSA, explaining the principles of assessment. All relevant studies with sufficient quality are weighed with respect to their strength, consistency and specificity, and additional consideration is given to dose-response and biological plausibility. She noted that selecting relevant human studies for scientific substantiation of the claim, studies should be carried out with the food/constituent for claim, and using the appropriate outcome measure(s) for the claimed effect. Conditions for the studies should be comparable to conditions of use for the claim (e.g. dose tested vs. dose proposed) and study groups should be representative of the target group or able to be extrapolated to the target population. She went on to cite examples of the most common pitfalls encountered by the Panel in the evaluation of health claims, concluding by encouraging industry to use the EFSA website applications 'help desk' to assist in the preparation of claims applications.

Dr. E Siong Tee, ILSI Southeast Asia Region, Malaysia described the process and key learnings in scientific substantiation of health claims in Southeast Asia. Dr. Tee began by noting that health claims are currently permitted in some countries in Southeast Asia, mostly arising from applications from food industry for other function claims and disease risk-reduction claims. Dr. Tee presented a summary of the permitted claims in the region, noting that regulatory systems related to claims approval varied from country to country in the region. He reviewed the claims application process, with each claim submitted in a prescribed format, and accompanied by scientific substantiation to be reviewed by a panel of experts appointed by the relevant regulatory agency. Two critical components of the application are the minimum level that the nutrient must be present for the claim, and sound scientific evidence for the claim, based on randomized, placebo-controlled double blind clinical trials and

other appropriate scientific data. Dr. Tee highlighted examples of some errors or inappropriate submissions for health claim applications in Malaysia. Some applications were rejected due to inadequately prepared dossiers, with sections of the application poorly explained, particularly the section on scientific substantiation. Other examples include wording of the proposed claim not matching the findings of the studies or extrapolated beyond the findings; the compound used in the study not matching the compound that is the subject of the claim; the food vehicle for the compound not matching the intended claim; studies were carried out using the 'pure' compound, rather than in food vehicles; or the study findings were not appropriate for the general population.

The nutrition labelling system in Japan was then discussed by Dr. Toshitaka Masuda, Food Labelling Division, Consumer Affairs Agency (CAA), Government of Japan. In order to ensure consumers' safety and their ability to choose foods offered for sale independently and rationally, the Food Labelling Bill was passed in Japan on 21 June 2013, followed by the Food Labelling Act, gazetted on 28 June 2013, moving the existing voluntary Nutrition Labelling System to a mandatory framework. Dr. Masuda noted that considerable time was spent investigating the issue of mandatory nutrition labelling, with the CAA firmly believing that such labels are necessary for the improvement of consumers' health, enabling them to manage their nutritional status and dietary habits. The CAA encourages food manufacturers to use nutrition labelling on a wide range of food products, and educates consumers on how to put healthy dietary habits into practice by helping them understand nutrition labelling and how to make practical use of its information. In Japan, function claims are only permitted for two food categories under the Food Sanitation Act and the Health Promotion Act: Food for Specified Health Uses and Food with Nutrient Function Claims. The government of Japan is developing a new system enabling manufacturers to make function claims on processed and fresh food using scientific evidence-based substantiation, using the U.S. dietary supplements regulatory system as a reference.

Dr. Pichet Itkor, Food Industry Club, Federation of Thai Industries, then outlined the industry challenges in the preparation of scientific dossiers for claims. He noted that food industries are now implementing nutrition labelling and displaying nutrition/health claims not only to provide information about the product to enable consumers to make an informed choice of purchase, but also to increase their competitiveness in the market place. 'Recommendations on the Scientific Substantiation of Health Claims', an Annex to 'Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)', have been established to assist regulatory authorities in their evaluation of health claims in order to determine The nutrition labelling system in Japan was then discussed by Dr. Toshitaka Masuda, Food Labelling Division, Consumer Affairs Agency (CAA), Government of Japan. In order to ensure consumers' safety and their ability to choose foods offered for sale independently and rationally, the Food Labelling Bill was passed in Japan on 21 June 2013, followed by the Food Labelling Act, gazetted on 28 June 2013, moving the existing voluntary Nutrition Labelling System to a mandatory framework. Dr. Masuda noted that considerable time was spent investigating the issue of mandatory nutrition labelling, with the CAA firmly believing that such labels are necessary for the improvement of consumers ' health, enabling them to manage their nutritional status and dietary habits. The CAA encourages food manufacturers to use nutrition labelling on a wide range of food products, and educates consumers on how to put healthy dietary habits into practice by helping them understand nutrition labelling and how to make practical use of its information. In Japan, function claims are only permitted for two food categories under the Food Sanitation Act and the Health Promotion Act: Food for Specified Health Uses and Food with Nutrient Function Claims. The government of Japan is developing a new system enabling manufacturers to make function claims on processed and fresh food using scientific evidence-based substantiation, using the U.S. dietary supplements regulatory system as a reference.

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The presentations from this seminar are now available through the ILSI SEA Region website www.ilsi.org/sea region

# Report of the 36th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses

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#### <Summary>

The 36th of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was held in Bali, Indonesia from 24 to 28 November 2014. The Committee was attended by 299 delegates representing 54 Member Countries, 1 Member Organization and 29 International Organizations.

The Session reached the following conclusions:

- The Committee advanced to Step8 the Draft Revision of the General Principles for the Addition of Essential Nutrients to Foods, and to Step 5/8 the Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Guidelines on Nutrition Labelling NRV-R for Vitamin C, zinc, selenium, molybdenum and manganese and the Proposed Draft Nutrient Reference Value for Potassium in relation to the risk of non-communicable diseases.
- The Committee forwarded other texts for adoption:
  - Amendments to the Annex of the Guidelines on Nutrition Labelling;
  - Amendments to the Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten to add the term "khorasan wheat";
  - Amendments to the Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children to include zinc citrates; and
  - Proposed Draft Revision of the list of food additives in CODEX STAN 72-1981 to include INS 472c and INS 1450.
- The Committee agreed to submit proposals for new work on the Definition for biofortification or biofortified foods and the NRV-NCD for eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) long chain omega-3 fatty acids.
- The Committee:
  - provided replies regarding the status of implementation of selected activities of the Codex Strategic Plan 2014 2019 relevant to its work;
  - agreed to discontinue consideration of amendment to the Standard for Processed Cereal-based Foods for Infants and Young Children to include a New Part B for Underweight Children;
  - returned the revision of the Standard for Follow-up Formula to Step 2 for redrafting, circulation for comments at Step 3 and consideration at its next session;
  - agreed to keep the amended working list of additives (wish-list) up to the next session when a decision would be made on its future status;
  - agreed to defer discussions on conditions for claims for trans fatty acids to its next session pending the outcome of the NUGAG review and the advice from CCMAS on methodological issues; and

- agreed to request UNICEF, with support of Senegal, to prepare a revised discussion paper and project document on a standard for ready-to-use food (RUF) to be presented at the next session.

# Workshop on the Recent Progress in the Risk Assessment of Allergenicity for Genetically Modified Crops

Akane Matsushita Biotechnology Affairs and Regulatory, Dupont KK.

#### <Summary>

Since genetically modified (GM) crops often generate new protein within, it is necessary to demonstrate in the food safety assessment of GM crops that those introduced proteins have low allergenicity. Recently, lots of reports were published regarding the standard or appropriateness of current or new methods to evaluate allergenicity of proteins and much information has been accumulated.

In order to share and discuss those progress and some related topics, a workshop was held where internal and external experts gave update. New criteria based on the recent knowledge were proposed regarding heat stability of the protein, structural/sequence homology between the protein and known allergen and the search of unintended open reading frame which are required to be scrutinized for evaluating allergenicity of GM crops as food usage under the regulation in Japan. In addition, the mechanism of allergenic reaction and the various ways of diagnosis were introduced and the effectiveness of proteomics approach to measure the expression level of endogenous allergen was discussed as well.

It is ten years since the standards for the safety assessment of genetically modified foods (seed plants) was established. Consideration and incorporation of technical progress and accumulated information, including those for allergenicity discussed in the meeting, in the risk assessment of GM crops will be beneficial.

# Report on Workshop on International Trends regarding New plant Breeding Techniques

Shoei Hashimoto Chairman, Biotechnology Research Committee, ILSI Japan

#### <Summary>

Plant breeding plays a significant role to accomplish sustainable agriculture and increase productivity in agriculture. Last year, ILSI Japan held a workshop on NBT for Regulatory Considerations. After that workshop, OECD held workshop on NPBT in Paris on Feb. 2014, and ILSI-India held International Conference on NPBT in Jaipur, India on Oct. 2014. Japan started the Cross-ministerial Strategic Innovation Promotion Program (SIP), "Technologies for creating next-generation agriculture, forestry and fisheries". For sharing these information, ILSI Japan held workshop on International Trend regarding New plant Breeding Techniques.