DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

IMPLEMENTATION PLAN ON THE SHARING OF CONFIDENTIAL INFORMATION BETWEEN THE EUROPEAN COMMISSION'S HEALTH AND CONSUMER PROTECTION DIRECTORATE GENERAL AND THE UNITED STATES FOOD AND DRUG ADMINISTRATION OF THE DEPARTMENT OF HEALTH AND HUMAN SEVICES

The European Commission's Health and Consumer Protection Directorate General (DG SANCO) and the United States Food and Drug Administration of the Department of Health and Human Services (HHS/FDA) (collectively "the Participants") recognise the need to further improve their relationship and in particular, in the Transatlantic Economic Partnership Action Plan, the need for increased co-operation as a means of promoting public health protection and addressing technical barriers to trade in food.

Such cooperation shall not compromise each Participant's ability to carry out its responsibilities and shall not create any kind of legal obligation on the part of HHS/FDA and the European Commission.

Therefore the Participants are pleased to cooperate to facilitate the sharing of documents and/or information related to ensuring food safety.

This cooperation activity will strengthen communication between public authorities involved in food safety activities and reinforce public health protection.

The type of information that may be shared includes, but is not limited to:

1. All legislation and guidance documents available under the rules and regulation governing food safety and public health protection in the EU and in the US in particular concerning nutrition labelling, compositional criteria for specific categories of foods, label claims relevant to health promotion and/or protection, added ingredients including nutrients, transgenic animals and animal cloning, use of animal drugs used in food-producing animals, emergency response and preparedness, and food and feed alerts associated with specific incidents. This also includes relevant position papers, notes for guidance and any other guidance documents developed by one Participant that may be made available for review by the other Participant either in draft, finalised or released for consultation.

2. Documents relating to controls carried out by HHS/FDA or DG SANCO and necessary for the preparation and effective execution of the verifications foreseen in Art. 9 of the Agreement between the United States of America and the European Community on Sanitary Measures to Protect Public and Animal Health in Trade in Live Animals and Animal Products.

3. In relation to DG SANCO's Rapid Alert System for Food and Feed and HHS/FDA's corresponding notification system relevant to food safety emerging situations the information to be exchanged may include, but is not limited to, the following:

- Product details: brand name, common name, size, codes (Universal Product Code (UP), best before, lot), photo (if available), package description;
- Copy of press release if released, name of foreign manufacturer, name of foreign exporter, name of establishment, registration number of establishment, and distribution to other countries;
- Reason for recall or for notification: identified hazard, links to illnesses or allergic reactions, whether the illness has been linked to food through epidemiological evidence or a match, through biological means (e.g. Pulse Field Gel Electrophoresis (PFGE) pattern);
- Other microbiological information, PFGE pattern, stereotypes, etc;
- Any conclusions on the cause of problem that led to the recall;
- Lab results, with methodology used; open or closed samples; and
- Any additional information on clients in the USA/the EU.

The Participants reserve the right to limit the scope of the above information should its dissemination or exchange undermine specific interests of either Participant, including national security; commercial, industrial or professional secrecy; the protection of the individual and of privacy; or the Participants' interests in the confidentiality of their proceedings. Any exchange of non-public information will be made in accordance with the Participants' laws and regulations and, in particular, with the letters exchanged by the Participants on June 6, 2005. In some cases, under this plan, exchange of proprietary or other similar company-specific information in the possession of one of the Participants may be subject to prior approval and authorisation from the private sector companies concerned.

We look forward to implementing this plan for the sharing of information and to continuing cooperative activities to further enhance the relationship between the HHS/FDA and the European Commission in the best interest of public and animal health.

Signed this the 23rd day of September, 2005.

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