



**International Dairy Foods Association**  
Milk Industry Foundation  
National Cheese Institute  
International Ice Cream Association

July 24, 2009

Docket No. FDA 2009-D-0260

Division of Dockets Management (HFA-305)  
Food and Drug Administration (FDA)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Dear Sir/Madam:

The International Dairy Foods Association (IDFA) represents the dairy manufacturing and marketing industries and their suppliers, with a membership of 530 companies representing a \$110-billion a year industry. IDFA is comprised of three constituent organizations, the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). IDFA's 220 dairy processing members run more than 600 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85% of the milk, cultured products, cheese and frozen desserts produced and marketed in the United States. IDFA can be found online at [www.idfa.org](http://www.idfa.org).

IDFA is pleased that FDA has issued *Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry* and, in particular, that FDA is seeking input from the regulated community. IDFA is, however, concerned about the short time frame with which FDA intends to finalize the guidance and effectuate the obligation to begin using the registry portal by September 8, 2009. Accordingly, we urge FDA to delay the effective date of the registry reporting obligation to 60 days from the release of a revised industry guidance document that reflects the comments that FDA receives during the comment period ending July 27, 2009.

With respect to the guidance document itself, IDFA would like to raise the following issues for FDA's consideration.

## ISSUE RELATING TO TRANSFER

I. IDFA is concerned about the use of the phrase *transfer to another person* in the answer to guidance question #15. Question #15 describes a circumstance where an adulterated food is not required to be reported. Question #15 and the answer as currently drafted are provided below.

### Question #15

#### **When is a responsible party not required to submit a reportable food report to FDA?**

A responsible party is not required to submit a reportable food report when all of the following criteria are met:

- i) the adulteration originated with the responsible party; AND
- ii) the responsible party detected the adulteration prior to any transfer to another person of such article of food; AND
- iii) The responsible party
  - corrected such adulteration; or
  - destroyed or caused the destruction of such article of food.

IDFA would like FDA to clarify that the *transfer to another person* phrase in this instance is limited to a transfer that involves a transfer that passes title or the right to exercise dominion and control over the food, not a transfer that only involves physical possession. Please note that many food processors do not have sufficient onsite warehousing capabilities to handle their entire production and storage needs. In many cases, food processors commonly utilize third party warehouses for this function. These third party warehouses do not have the right to release product without explicit instructions from the food manufacturer because they do not have the legal title or the legal right to exercise dominion and control over the products stored therein. By operation of law, the food manufacturer retains title or is at all times in constructive possession of the food products and only the food manufacturer controls the subsequent distribution from the warehouse. The warehouse in these circumstances is a custodian who operates at the sole discretion of the food manufacturer. Other similar or analogous situations exist as well which would call for the same determination.

IDFA urges FDA to expressly state that transfer to another person in the above answer does not apply to situations where the food manufacturer has not passed title or can still exercise dominion and control via constructive possession. Unless a food manufacturer has relinquished title or control over a product's subsequent distribution it is irrelevant whether the product has been physically transferred to another person. This is a well established legal notion. Black's Law Dictionary describes constructive possession as "control or dominion over a property without actual possession or custody of it." The critical issue that FDA should be concerned with in the context of Question #15 is who has title or control over the product, not who has possession. Where title has not passed or the product is under the control of the manufacturer there should be no need to report

when the other criteria are satisfied. IDFA believes the answer to Question #15 can be corrected by the insertion of the underlined text below.

Question #15

**When is a responsible party not required to submit a reportable food report to FDA?**

A responsible party is not required to submit a reportable food report when all of the following criteria are met:

- i) the adulteration originated with the responsible party; AND
- ii) the responsible party detected the adulteration prior to any transfer to another person where such transfer includes a transfer of title or of dominion and control over such article of food; AND
- iii) the responsible party
  - corrected such adulteration; or
  - destroyed or caused the destruction of such article of food.

ISSUES RELATING TO CONFIDENTIALITY, DATA QUALITY, AND MISUSE

II. IDFA is concerned about confidentiality issues that are raised by the fact that the information collected through the registry is publicly available via a Freedom of Information Act (FOIA) request. IDFA is aware of Exemption 4 under the Freedom of Information Act and would like to be sure that Trade Secret and Confidential Business Information that is collected by FDA is treated appropriately and is not inadvertently disclosed under a FOIA request. In particular, we note that in Question #20, FDA allows for the possibility of it collecting "contact information for the immediate previous source and/or immediate subsequent recipient of the article of food..." This sort of information has clearly been determined to be within the scope of FOIA Exemption 4 and FDA needs to have established procedures to protect and prevent inadvertent and unlawful disclosure of such information. While paper and electronic submissions to the government can be and are traditionally marked as Trade Secret or Confidential Business Information when such markings are warranted, IDFA urges FDA to provide an opportunity to declare certain hand keyed information submitted through the portal as such.

III. IDFA notes that federal, state and local public health officials may submit instances of reportable food to FDA via the portal. IDFA is concerned that one or more of these entities may at some point submit reports based upon testing of a product after it has been in a consumer's hands. In essence, we envision circumstances by which federal, state or local public health officials may have tested a food product that was supplied to them by a consumer for the presence of deleterious substances. Our concern in this situation is the reliability of a positive test result in this circumstance. A positive test result that stems from a product that has been opened by a consumer could occur for any number of reasons when in fact the food product left the food manufacturer or retailer in pristine form. False results in these instances could be the result of accidental at-home contamination, or as FDA's Office of Criminal Investigation is well aware, an intentional and nefarious attempt to manipulate the system for malicious reasons. IDFA suggests

that reports generated on the basis of post-consumer testing warrant a level of scrutiny that is not likely to occur prior to actions being initiated as a result of the filing of a report via the portal. For this reason, IDFA urges FDA exclude reports based upon test results that were performed after a consumer came into possession of the food product.

IV. As these comments indicate, IDFA is concerned with both the accuracy of the data and information collected via the portal and the subsequent disclosure of that information to third parties, including via FOIA requests. Information collected via the portal has the potential to severely and unnecessarily harm responsible parties and their companies when it is inaccurate, or even fraudulent. IDFA urges FDA to make sure that does not happen. Therefore, IDFA suggests FDA develop procedures by which erroneous filings and inaccurate information can be purged from the system before someone is harmed. The purging of inaccurate or erroneous reports should be done by FDA automatically where FDA detects the errors or upon request of a responsible party when FDA verifies the error.

IDFA also notes that the reasonable probability threshold will, by its very nature, result in reporting that ultimately turns out to be unnecessary because the SAHCODHA threat was never actually present. FDA stated in the July 23rd public meeting that in such a case, the report would be closed. As we suggested above, IDFA urges FDA to develop a process by which the reports in this case are deleted or purged. By doing so, FDA would encourage, rather than discourage, reporting when it is a close determination.

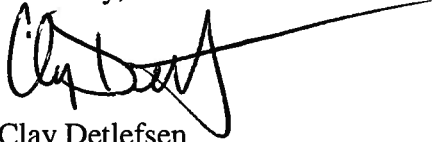
V. FDA's reportable food registry portal will likely contain a great deal of information that will assist FDA in its mission of protecting the food supply. Unfortunately, misuse of the information carries with it the risk of wrongfully imposing great harm. FDA must ensure that proper internet security protocols are followed that will ensure that the data collected is not breached, altered, or misused. In addition, it would be helpful for FDA to identify who will have access to the data contained in the reportable food registry database and under what circumstances that information may be accessed.

#### ISSUE OF EFFICIENT DATA SUBMISSIONS

VI. IDFA has been told that the portal will allow for the submission of data in a variety of forms and formats. We believe it is imperative that FDA allow for the uploading or submission of a number of electronic file formats to ensure the efficiency with which data collection occurs. For example, the guidance indicates that FDA may request contact information of immediate subsequent recipients of a reportable food product. While we understand that the portal allows for that information to be hand keyed into a data entry screen, FDA needs to also allow the system to accept information in the form of a Word document, a PDF file, an Excel spreadsheet, a text delimited file as well as other formats. This is important because at times the number of recipients could be hundreds or thousands and hand keying that volume of information is unworkable.

IDFA appreciates the opportunity FDA has provided with this comment period and commends FDA for scheduling three public workshops where the food registry portal will be demonstrated to the public and end users. That said, this powerful tool has the potential to create many problems if it is not carefully implemented. As these comments indicate, the guidance document alone has raised a number of issues that demand resolution prior to FDA making the portal use mandatory on September 8, 2009. IDFA therefore urges FDA to delay the mandatory use of the portal until FDA can resolve the issues we have raised in these comments and those that are likely being raised by other associations, companies and groups. As stated above, we believe a 60-day implementation period from the date of publication of the revised guidance would be appropriate. IDFA would not oppose the voluntary use of the portal by responsible parties from September 8, 2009 until the lapse of the 60-day implementation period at which point it would be mandatory for all responsible parties and voluntary for federal, state and local public health officials.

Sincerely,

A handwritten signature in black ink, appearing to read "Clay Detlefsen", with a long horizontal line extending to the right.

Clay Detlefsen  
Vice President & Counsel