



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

July 16, 2010

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.

IDFA is pleased that FDA has issued revised draft guidance for industry, *Questions and Answers Regarding the Reportable Food Registry* and, in particular, that FDA is continuing to seek input from the regulated community. IDFA is also impressed with the improvements to the reportable food registry portal itself and, specifically, the option to create an account which allows users to pre-populate reports as well as save, view and modify reports. These features greatly enhance the user experience and will serve FDA and the regulated community well.

In the May 25, 2010, Federal Register notice announcing the revised guidance, FDA requested comments on whether the interpretation of the term "transfer" should be dependent upon possession of the food, whether the interpretation should be dependent on ownership of the food, or whether there are other interpretations that FDA should

consider, such as a combination of possession and/or ownership. IDFA is pleased to offer its viewpoint on this important issue that affects the dairy processing industry in the following pages, but in a nutshell we believe the issue is all about control over the product.

INDUSTRY USE OF THIRD PARTY WAREHOUSES

Many food processors do not have sufficient onsite warehousing capabilities to handle their entire production and storage needs. For example, the ice cream industry is reliant on third party warehouses for inventory storage during the peak build up period that occurs each year from February to May in preparation for heavy demand during the hot summer months. The cheese industry on the other hand relies on third party warehouses for storage due the extended warehousing time required for the aging process that applies to most cheeses.

Despite the fact that these third party warehouses have physical possession, they 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 and 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. In some respects this is analogous to leaving one's valuables in a bank safe deposit box. The bank is in physical possession but it has very limited rights to the disposition of the contents of the box.

IDFA's HISTORICAL VIEWPOINT ON TRANSFERS

IDFA expressed concern in July 2009 comments about how FDA would interpret *transfer to another person* in the answer to the then guidance question #15. Question #15 describes a circumstance where an adulterated food is not required to be reported. Question #15 and the answer as it was originally 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.

In the comments we filed in July 2009, IDFA requested that FDA 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. IDFA urged FDA to expressly state that transfer to another person in the above answer does not include situations where the food manufacturer has not passed title or where it is still exercising dominion and control via constructive possession. 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 proposed and believes the answer to Question #15 should have been changed 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.

Unfortunately, FDA focused its interpretation of transfer on physical possession which we do not believe is the appropriate approach. As a result, we believe that this interpretation is creating an obligation to report that serves neither FDA nor the regulated community in an efficient manner. The current interpretation is expressed in revised guidance questions E.3, E.4 and E.5 below.

THE CURRENT REVISED GUIDANCE EXCERPTS RELATING TO TRANSFER

The following text has been excerpted from FDA's *Questions and Answers Regarding the Reportable Food Registry (Edition 2)*

E.3 When is a responsible party not required to submit a reportable food report to FDA for food that would otherwise be reportable?

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

- The adulteration originated with the responsible party; AND
- The responsible party detected the adulteration prior to any transfer to another person of such article of food; AND
- The responsible party

- o corrected such adulteration; or
- o destroyed or caused the destruction of such article of food.

E.4 When does a “transfer to another person” occur under section 417(d)(2)(B) of the FD&C Act?

A transfer to another person occurs when the responsible person releases the food to another person. “Person” is defined in section 201(e) of the FD&C Act as including individuals, partnerships, corporations and associations.

FDA does not consider an intra-company transfer in a vertically integrated company to be a “transfer to another person,” where the company maintains continuous possession of the article of food. For example, if Company A owns a processing plant, warehouse facility, and distribution facility, the intra-company transfer from the processing plant to the warehouse facility and/or the warehouse facility to the distribution facility would not be considered a transfer to another person.

E.5 If a reportable food is shipped to a third-party warehouse, but the responsible party maintains ownership and direct control over distribution, must the responsible party submit the reportable food report?

Yes. Transfer to another person occurs when the responsible person releases the food to another person. “Person” is defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)) as including individuals, partnerships, corporations and associations. In this situation, the warehouse operator is a distinct legal person.

PROPOSED REVISION

We do not believe FDA's current interpretation is consistent with the definition of reportable food that Congress established in the *Food and Drug Administration Amendments Act of 2007 Public Law 110-85 (September 27, 2007)*. In the Amendments Act, Congress set forth the following definition.

Reportable food.--The term 'reportable food' means an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.

IDFA urges FDA to consider the *reasonable probability* phrase in the Congressional definition of reportable food and to consider the totality of circumstances when an interpretation is applied to third party warehouses that are mere custodians of food. IDFA asserts that 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. In essence, where a food manufacturer exercises

dominion and control over the food products in question, a food that presents a reasonable probability that it could cause serious adverse health consequences or death to humans or animals will not be allowed into the stream of commerce and will be brought back to the manufacturer for reprocessing or destruction. Therefore the allegedly reportable food should not be a reportable food because there is no probability that it will be used or that anyone will be exposed to it.

FDA's current interpretation of transfer focuses solely on physical possession. This is inefficient because it requires the regulated community to potentially report foods that present no risk to the public and it requires FDA to review and analyze those same reports. FDA, the regulated community and the general public are not served by reports relating to no-risk scenarios. Arguably, given finite government and private sector resources, these no-risk reports take time and resources away from situations that do require attention and therefore it is counterproductive and actually diminishes the public benefit. We believe that Congress understood that where a problem originated with a food manufacturer and that food manufacturer can still control the destiny of the implicated product, nothing is to be gained by requiring reporting. This is the essence of the *no report required* clause in the Amendments Act. IDFA asserts that when the affected product is in a food manufacturer's facility or under their control in a third party warehouse, the ultimate disposition is the same, the food will not present any risk to the public.

The appropriate and efficient way to handle the transfer issue is to focus on transfers where a food manufacturer does not control the food's entry into commerce and that strategy can be accomplished by revising E.3 and E.5 as indicated below.

PROPOSED REVISED E.3 When is a responsible party not required to submit a reportable food report to FDA for food that would otherwise be reportable?

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

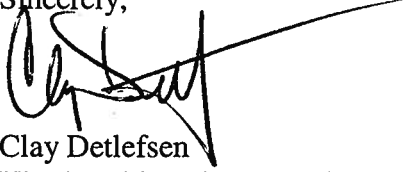
- The adulteration originated with the responsible party; AND
- The responsible party detected the adulteration prior to any transfer to another person of such article of food where such transfer includes a transfer of title to, or of dominion and control over the food; AND
- The responsible party
 -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

PROPOSED REVISED E.5 If a reportable food is shipped to a third-party warehouse, but the responsible party maintains ownership and direct control over distribution, must the responsible party submit the reportable food report?

No. Transfer does not occur until such time as dominion and control over the food has been relinquished from the responsible party to another party. In this example, transfer has not occurred, there is merely a change in physical custody.

At this time, given the facts in FDA's possession through this commenting process and from other sources, we believe FDA can make an adjustment to eliminate some unnecessary reports for the benefit of all. IDFA appreciates the opportunity FDA has provided with this comment period and looks forward to seeing a favorable and efficient resolution of the transfer issue.

Sincerely,

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

Clay Detlefsen
Vice President & Counsel