



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

February 13, 2009

EPA Docket
Environmental Protection Agency
Mail Code 2822T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

**Re: Docket ID No. EPA-HQ-OPA-2008-0821
Oil Pollution Prevention; Spill Prevention, Control and Countermeasures Rule
Requirements -- Amendments. Milk Exemption Proposed Rule**

The International Dairy Foods Association (IDFA) submits these comments in response to the Notice of Proposed Rulemaking (NPR) which proposes to amend the Spill Prevention, Control and Countermeasures (SPCC) rule to exempt milk containers and associated piping and appurtenances from the SPCC requirements provided they are constructed according to the current applicable 3-A Sanitary Standards and are subject to the current applicable Grade "A" Pasteurized Milk Ordinance (PMO) or state dairy regulatory requirement equivalent to the current applicable PMO. We wholeheartedly support the concept of the exemption.

The International Dairy Foods Association 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 urges EPA to finalize an exemption from the SPCC rule for all milk and milk product containers, associated piping and appurtenances. The term *milk products* includes, but is not limited to, such items as cheese, cream, yogurt and ice cream mix. Ice cream itself does not need to be included because ice cream is not ice cream until such time as it is frozen and that only occurs when it is in its final retail or food service package which is well below the threshold quantity exemption. IDFA opines that these products and the containers, associated piping and appurtenances in which they are made or stored, do not present a requisite risk or potential of

spilling into navigable waters of the United States. In addition, they should be exempt because these products are not oil.

Milk and milk product operations and the SPCC Rule

Some milk, ice cream and cheese processing facilities are covered by the SPCC rule because they use and have onsite: 1) traditional vegetable oil which is used in product formulations such as non-dairy creamer, 2) fuel oil, or 3) oil in transformers, refrigeration systems or other equipment. In the summer of 2008, an EPA contractor contacted IDFA to inquire how the dairy industry was impacted by EPA's SPCC rule. During the course of conversations and exchanges with EPA's contractor and IDFA's members, we determined that approximately 50% to 60% of the aforementioned 600 processing plants within our membership did not have enough traditional oil onsite to trigger inclusion under the rule. Of the 40% to 50% that did have enough traditional oil to include their operations within the rule, no one that we are aware of has extended their SPCC plan to include milk containers, associated piping and appurtenances associated with fluid milk because no one considers fluid milk to be oil -- a view that has been historically shared by most personnel at EPA.

In addition, while most cheese is made, stored, or otherwise managed and sold in container sizes less than 55 gallons -- the SPCC container exemption threshold -- considerable amounts of cheese are made and stored in larger containers such as, but not limited to, 640-pound blocks. These blocks of cheese are contained in boxes that are constructed of wood, plastic or stainless steel, and the cheese therein contains various amounts of milkfat (an animal fat). For example, cheddar cheese is required to contain a minimum of 32% milkfat. To the best of our knowledge, no one has included those blocks in an SPCC plan, and no one has installed secondary containment around the blocks, nor do we think it would be appropriate to do so.

During the course of various meetings with EPA staff on SPCC issues over the years, EPA officials have inquired about the fate of cheese should a cheese production or storage facility catch fire. In essence, EPA officials were asking whether or not a fire in a cheese facility would cause the solid cheese to liquefy and run out of the facility and potentially pollute or endanger navigable waters of the United States. In each case, IDFA assured EPA that under no circumstances would cheese liquefy and flow as EPA had suggested. EPA officials seemed satisfied with that response.

Over the years, IDFA has also had many conversations with many EPA officials about what is or what is not subject to the rule. In particular, IDFA expressed concern to EPA about the wrongful potential inclusion of milk and milk products within the scope of the SPCC rule given the arguably ambiguous language and interpretations that are used under the rule to determine whether a product is oil. This issue usually surfaced when the discussion turned to how EPA treats "mixtures" under the rule. The issue was discussed with EPA at numerous meetings over the years including meetings arranged by the Food Industry Environmental Coalition (FIEC) and meetings hosted by the Small Business Administration (SBA). In every instance where fluid milk was raised as possibly being included or otherwise subject to the SPCC rule, EPA officials assured us that fluid milk would not be subject to the rule.

Many years ago, IDFA and EPA personnel discussed the dairy industry's reliance on stainless steel, the 3-A standards and how the rigorous cleaning and frequent inspection of dairy vats, vessels, tanks, pipes and appurtenances, weighed heavily against the inclusion of milk and milk products within the scope of SPCC. Unfortunately, the EPA staff person who so clearly understood our situation became ill and left EPA's employment and with that occurrence we all lost considerable expertise and understanding. Thankfully this proposal resurrects the underpinnings and provides us with an opportunity to act and resolve a situation that has languished for too long.

Why the rule should not apply to milk and milk products:

The fundamental reason the SPCC rule exists is to prevent leaks and spills of oil from reaching navigable waters of the United States. According to EPA, leaks typically occur when equipment containing oil deteriorates or corrodes up to the point where the integrity of the equipment is compromised. The fundamental reason this will not occur in the dairy industry is that the equipment must be constructed in a manner to preclude deterioration and it must be maintained in a manner to keep it clean and free of defects.

With exception of some containers for 640-pound blocks of cheese, all dairy processing equipment, storage containers, piping and appurtenances are made of high grade stainless steel and are designed and typically constructed in accordance with 3-A and/or FDA's Current Good Manufacturing Practices (CGMP) or equivalents. Cleanliness is provided for by scientifically validated processes which include frequent and thorough inspections by company personnel.

In addition to company inspections, federal and state inspectors enforcing the PMO and acting under other authorities, frequently inspect dairy operations to ensure that the facilities are being operated in a safe and suitable manner so as to avoid any potential human health issues. In particular, the inspections carried out by company and governmental personnel look specifically for defects in the equipment. Defects in the form of pits or minor surface imperfections could harbor bacteria and give them a niche in which to grow. The possibility of these defects going unnoticed to the point where the integrity of the equipment is compromised is unfathomable.

To exemplify the robust frequency of inspections at dairy facilities, please see the attached Michigan Food and Dairy Annual Report 2002. Michigan inspects both farms and processing locations. In 2002, Michigan conducted 8551 inspections at the 2972 dairy farms in that state. In addition, Michigan conducted another 204 dairy plant inspections of the 83 plants within the state at that time. Michigan, has formally adopted the PMO. Michigan's protocol and frequency is typical of what would occur in other states and U.S. territories. In fact, the PMO requires a plant to be inspected at least once every three months. See PMO Section 5 for the schedule. For facilities that are not regulated under the PMO, the inspection schedule is only slightly less rigorous and most dairy facilities are inspected more or less on a three month interval basis.

To further support the underlying rationale of why dairy is treated differently, IDFA offers the following statement taken from FDA's website (and attached in the Appendix) on Food CGMP Modernization: "For certain high risk products, such as ready-to-eat foods that support the growth of *Listeria monocytogenes*, there is a need for microbiological monitoring of the plant

environment in order to verify the adequacy of cleaning and sanitizing procedures and to identify potential environmental sources of product contamination." Milk and milk products are ready-to-eat products and can support the growth of *Listeria monocytogenes*, as such; their production and storage warrant a need for enhanced monitoring that may not be appropriate for other food products. Microbiological monitoring of the plant environment requires visual inspections and swabs of any suspect as well as non-suspect areas. Further, the CGMP's state at 21 CFR § 110.40:

Equipment and utensils.

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms...

The design, construction, cleaning and inspection process, as outlined here and as further described in the appendix, negates and eliminates the risk that dairy equipment will leak or spill, let alone reach navigable waters of the United States.

Specifically, IDFA believes that the EPA exemption should state that **"the SPCC rule does not apply to storage containers and associated piping and appurtenances that contain milk or milk products that are: a) subject to the construction requirements of 3-A Sanitary Standards or the equivalent standards approved by a federal, state or local regulatory authority, and b) are subject to 21 CFR Part 110, the PMO, or a state or local equivalent."**

IDFA cautions EPA that the rigorous regulatory scheme that applies to milk and milk products is both unique and complex. The PMO, for example, has a lengthy list of milk products in its definitional section. Towards the end of the definition, the PMO states that it is not intended to include dietary products, infant formula, ice cream, or other frozen desserts, butter or cheese. That said, a cheese plant would not normally be subject to the PMO, but if that cheese plant wanted to sell Grade A whey (whey is a byproduct of cheesemaking), the plant would have to comply with the PMO. Further, an ice cream plant would generally not be required to be a PMO-compliant facility, except in certain states, like Florida, Texas and others, where they must be. Finally, the PMO is not applied on a partial basis; it either applies to the facility or it does not. So, for example, there is no such thing as having it apply to the milk silo at a cheese or ice cream plant but not the rest of the plant.

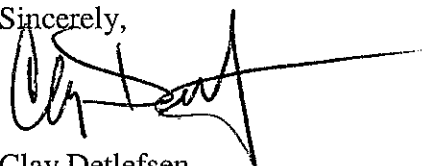
IDFA also cautions EPA that the current version of the PMO is the 2007 edition which is not available online at FDA's website, however, IDFA and many other sources do make the current version available online as a PDF file. EPA should also note that FDA's CGMPs are not limited to the products covered by the PMO, but rather the CGMPs apply to all foods under FDA's jurisdiction, so the CGMP references above would cover cheese and ice cream equipment.

Related Issues that Warrant EPA Efforts:

In addition to finalizing the milk and milk product exemption for the overall benefit of the integrity and defensibility of the rule, EPA needs to clarify the mixture rule and the boundaries of the mixture rule concept. We, and other food industry organizations, have frequently proposed sensible fixes for EPA to consider, such as exempting liquid mixtures containing less than 50% oil and mixtures that are solid at room temperature. While EPA has expressed a willingness to seek out improvements in these areas, compliance dates are beginning to loom before the potentially regulated community. Unless the scope of the SPCC rule is clearly understandable and understood, the concept of due process, and the doctrines of void for vagueness and fair notice demand that EPA not initiate any enforcement actions against operations where there is substantial doubt regarding whether substances at those facilities are within the scope of the SPCC rule and therefore trigger rule compliance.

IDFA is very pleased that EPA has proposed action on our long standing concern about the unnecessary inclusion of milk and milk products in the SPCC rule and we are impressed with the clear understanding of this issue demonstrated in the Federal Register notice. We appreciate EPA's efforts in addressing the milk and milk products issue and EPA's expressed willingness to fix other areas of the SPCC rule. To assist EPA in its efforts, we are attaching a number of documents which may provide some further insight into the rigors of fabrication, cleaning and inspection of milk and milk product equipment and the long history of SPCC issues that have been raised by the dairy and food industries. The foregoing aside, IDFA wants to reiterate that we do not now, nor have we ever believed that milk or milk products can be legitimately construed as *oil* under the SPCC rule, and nothing in these comments should be construed to the contrary.

Sincerely,



Clay Detlefsen
Vice President, Regulatory Affairs and Counsel