



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



November 14, 2013

Division of Dockets Management  
U.S. Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Docket No. FDA-2011-N-0920, Food Safety Modernization Act: Current Good Manufacturing Practice and Risk-Based Preventive Controls Human Food

Dear Sir/Madam:

The International Dairy Foods Association (IDFA), Washington, D.C., represents the nation's dairy manufacturing and marketing industries and their suppliers, with a membership of 550 companies within a \$125-billion a year industry. IDFA is composed of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). IDFA's 180 dairy processing members run nearly 600 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85 percent of the milk, cultured products, cheese, ice cream and frozen desserts produced and marketed in the United States.

The National Milk Producers Federation, based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies. Visit [www.nmpf.org](http://www.nmpf.org) for more information.

IDFA and NMPF supported passage of the Food Safety Modernization Act (FSMA) and recognize that a robust food safety system is crucial for both public health and the success of our member companies. We appreciate the need for enhanced preventive controls and support the Food and Drug Administration's (FDA) efforts as it promulgates rules to implement the FSMA. In these comments, we respond specifically to FDA's request for information on the interplay between the Pasteurized Milk Ordinance (PMO) and the FSMA Preventive Control Rule.

Grade "A" milk and milk products have been subject to regulation by the states under the PMO for decades. The PMO is administered by the National Conference on Interstate Milk Shipments (NCIMS), which in turn is overseen by the U.S. Food and Drug Administration (FDA). The PMO provides a comprehensive set of requirements for ensuring the safety of Grade "A" milk and milk products. Inspections of Grade "A" dairy processors are required to be conducted

every three months by the states under an agreement with the FDA, and the FDA maintains numerous regional milk specialists to lend guidance to the states to ensure consistent, nationwide application. As noted, the PMO has been in place for decades, in actuality since 1924, and stands as a model for food safety protection. This fact was recognized by FDA in 1977 when the FDA Commissioner of Food and Drugs signed a Memorandum of Understanding (Memorandum) between the FDA and NCIMS. The Memorandum is still in effect today and is attached to these comments.

FSMA was signed into law in January 2011 and provides a comprehensive regime for food safety to be applied to all food products, except for meat, poultry and liquid egg products that are regulated by the U.S. Department of Agriculture (USDA). The central focus of FSMA is prevention, by providing that food products have a scientifically validated system of controls to assure safety of the finished product. FSMA also provides that FDA (or the states on FDA's behalf) must inspect food companies on a regular schedule, based on risk. Importantly, FSMA exempts from preventive controls a number of product categories--namely, seafood, juice, low acid canned foods, and dietary supplements—where adequate FDA regulatory programs were already in place. For the reasons stated below, FDA should do the same for Grade “A” milk and milk products, based on existing adequate *state* regulation of these products under the PMO.

### **Compliance with the PMO should also be compliance with FSMA**

There are a number of reasons why FDA should consider dairy processors which are compliant with the PMO to also be compliant with FSMA. These include:

- FSMA and the PMO are both based on prevention: The cornerstone of both FSMA and the PMO is prevention. FSMA requires a validated set of preventive controls that assure the safety of the finished product, and the PMO requires pasteurization of all Grade “A” milk products – with pasteurization being the ‘gold standard’ for control of foodborne pathogens. So the central feature of FSMA is also at the core of the PMO.
- Congress cited the PMO in FSMA as a model of food safety: In directing FDA to prepare implementing regulations, Congress pointed the agency to the PMO – by name – as a model that FDA should consider in preparing food industry-wide regulations. Indeed, the PMO is the only domestic food safety standard specially called out in FSMA. Accordingly, Congress essentially deemed the PMO as being an authoritative food safety regime.
- The PMO is specific to dairy products: FDA has the enormous task of developing regulations that apply across an incredibly broad array of food products – including beverages, cereals, snack foods, spices, and many more – so that any set of regulations will have only general application. In contrast, the PMO has been developed and implemented expressly for Grade “A” milk and milk products, and therefore provides a far greater degree of specificity for this sector than could any possible general set of FSMA regulations.

- The States inspect dairy processors more frequently than is required by FSMA: The states inspect all processors of Grade “A” milk and milk products every three months – i.e., four times per year. This is far more frequent than what FSMA requires for even the highest risk products – which is at least once every three years. Thus, the PMO provides inspection at a frequency twelve times that of FSMA. This provides for far stronger oversight of dairy processors than FDA can do for the food industry as a whole. FDA should take advantage of that and devote its limited resources to other product sectors where inspectional oversight is far more limited.
- The FDA still exerts considerable control and can assure standards are kept high: Even apart from FSMA, FDA plays a significant role in the management of and implementation of the PMO. FDA works closely with the NCIMS on any amendments to the PMO, and in fact FDA has veto authority over any amendments that the agency believes would not advance food safety. As referenced earlier, the Memorandum under which the state regulatory agencies operate requires them to conduct inspections and carry out enforcement activities with FDA’s regional milk specialists helping to assure consistency of application across the country. Thus, FDA does not need to apply FSMA regulations in order to assure the adequacy of food safety regulation under the PMO.
- The PMO has a long track record of food safety: Due largely to the stringency of the PMO and the scientific validity of the pasteurization process, the PMO has a long track record of assuring food safety – a track record stretching back for decades. Under the principle of “If it ain’t broke, don’t fix it,” FDA should rely on the PMO as providing a strong regime for milk safety and devote its attention to more needy product areas.

The FDA has an arduous task under FSMA of developing food safety regulations that cover the entire spectrum of the food supply. In implementing FSMA, FDA should recognize there is one area that is already covered: Grade “A” Milk and Milk Products under the PMO, a regulatory regime that is based on high standards, frequent state inspections, and oversight by the FDA and NCIMS.

### **NCIMS History and Composition**

The National Conference on Interstate Milk Shipments had its inception in 1946 when the Conference of State and Territorial Health Officers requested the U. S. Public Health Service to develop a plan for the certification of interstate milk shippers. In 1949, representatives of several Midwestern states met in Indianapolis, Indiana for the purpose of determining whether some plan could be developed to address a more effective and efficient system of regulating the interstate shipment of milk products. As a result, representatives of eleven Midwestern states met in Chicago, Illinois in February 1950 to investigate the problems and to arrange for a national conference.

The first Conference was held in St. Louis, Missouri on June 1, 1950, with representatives from 22 state Departments of Health or Agriculture and the District of Columbia in attendance. Also attending the Conference were representatives of the dairy industry.

The Procedures accepted by the first Conference in 1950 have been used by states in developing sound and more uniform milk sanitation programs. They have led to the development of a greater degree of reciprocity between states on acceptance of inspection and laboratory results. The Procedures have been revised from Conference to Conference in order to best serve the needs of the parties involved.

The NCIMS has served as a model cooperative program between the U. S. Public Health Service/Food and Drug Administration, the states, and the dairy industry. It is a shining example of esprit de corps, and reflects the cooperative spirit of all those committed to ensuring a safe and wholesome supply of milk and milk products.

The main thrust of the Conference is to deliberate proposals submitted by various individuals from state or local regulatory agencies, FDA, USDA, producers, processors, consumers, etc., who have an interest in ensuring that the dairy products we consume are safe. The proposals are assigned to one of three councils, who then discuss the merits of each proposal with a resulting recommendation to the delegate body. The proposals typically involve modifications to the PMO which if passed by the delegates, are then reviewed by FDA and if they are ultimately accepted by FDA, the PMO is modified.

The delegate body is composed of representatives from each state and U. S. territory that chooses to send such a representative. Each state/territory has one vote. There were 50 states and 1 territory represented by delegates at the 2013 Conference held in Indianapolis, Indiana.

The NCIMS is governed by an Executive Board comprised of representatives from state and local regulatory agencies from three different geographical regions, FDA, USDA, industry, and laboratories and academia. The Board also includes, in a non-voting capacity, chairpersons from each of the three councils, chairperson of the NCIMS/FDA Liaison Committee, the NCIMS Past Chairperson, the Program Committee Chairperson, a representative from the National Milk Producers Federation, a representative from the International Dairy Foods Association, a consumer representative, and the NCIMS Executive Secretary. The Executive Board meets as necessary between Conference meetings to carry on the business of NCIMS.

In addition to the Executive Board, committees have been established to study various proposals and report their findings to the following Conference. These studies and reports aid the council members and delegates in making informed decisions as they deliberate and vote on the proposals.

As noted above, while compliance and enforcement of the then current PMO is primarily a function of state agencies due to the state adoption of the PMO as part of state law, FDA's role and involvement with the PMO and the process by which the PMO is revisited and revised through the NCIMS process is paramount and cannot be understated. As previously stated, FDA personnel are an integral part of the re-evaluation and modification process and no modification can be made without FDA's express consent. In essence, even under the PMO, with inspections and compliance conducted by the states, FDA has maintains its authority and responsibility to ensure Grade "A" dairy product safety.

## **Exemption or “Otherwise Deemed Compliant” for Pasteurized Milk Ordinance (PMO) Regulated Facilities**

At the March 1, 2013 public meeting on preventive controls, in response to a question from the audience regarding whether FDA would consider exempting PMO-regulated facilities from the preventive controls rule for food, FDA stated that a two-fold test would need to be met in order to create an exemption. First, a request for an exemption would need to show that the food would be as safe as if regulated under the preventive controls rule. Second, the request would need to explain where in the Act an exemption would be permitted. We address both these points below.

As discussed above, IDFA and NMPF believe the PMO already achieves the same high standards of food safety as the preventive controls rule would when it is finalized. A sentiment apparently shared by FDA when it stated the following in the Memorandum, “FDA considers these standards, requirements and procedures to be adequate for the protection of the health and safety of the consumer” in reference to the PMO and the NCIMS process and concept. Further, at the public meeting on 3<sup>rd</sup> Party Accreditation and Foreign Supplier Verification on September 19, 2013, FDA Deputy Commissioner Mike Taylor stated that we have a very well established milk safety program in the United States, which we want to preserve and not disrupt. His full comments on that position are below:

*“But I think this question of how the FSMA regime, both domestically and at the import level, relates to Grade “A” milk and fluid milk is a good question because you weren’t exempted, but we have got a very well established program for milk safety in the United States under the Pasteurized Milk Ordinance, under the cooperative program with states and the National Conference of Interstate Milk Shippers. And so, we definitely – this is a good case for my slogan, if you will, that we don’t want to be requiring changes in current practices that don’t make a practical difference for food safety. I’ll ask Jenny and others to, you know, add thoughts to that sort of basic level of how we, you know, preserve the strength of the milk safety system and not disrupt that.”*

With respect to whether an exemption is permitted under the precise language of the FSMA, IDFA and NMPF have identified two areas in Section 103 which we believe establish Congress’s willingness for FDA to use its judgment to create exemptions where warranted, especially for foods subject to the PMO.

First, Section 103(n)(3) states that “[t]he regulations promulgated under paragraph (1)(A) shall . . . (C) acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods.” In essence, Congress has instructed FDA to acknowledge that multiple sets of regulations do not necessarily enhance food safety and that, indeed, FDA should minimize redundant sets of standards. This is particularly appropriate where there is already an existing set of food standards that are directed to a particular set of products. Indeed, Grade “A” dairy products are already regulated under the PMO. Subjecting them to the preventive controls rule would apply two separate standards, doubling rather than

minimizing “the number of separate standards that apply to separate foods.” Instead, FDA should acknowledge the reduced risk profile of foods produced in accordance with the PMO and allow dairy products to continue to be regulated under one standard, the PMO. Moreover, removing PMO-regulated facilities from the preventive controls rule would allow FDA to better tailor its requirements to those foods without such regulatory programs, which would also minimize the need to develop separate guidance and standards for this segment of the dairy industry.

Congress in fact specifically endorsed the PMO and instructed FDA to ensure the preventive controls rules are consistent with it and other domestic and international standards:

In promulgating the regulations under paragraph (1)(A), the Secretary shall review regulatory hazard analysis and preventive control programs in existence on the date of enactment of the FDA Food Safety Modernization Act, including the Grade “A” Pasteurized Milk Ordinance to ensure that such regulations are consistent, to the extent practicable, with applicable domestic and internationally-recognized standards in existence on such date. FSMA § 103(n)(5).

Congress thus specifically recognized the PMO as an appropriate preventive controls program for addressing the food safety hazards motivating the passage of FSMA. The most effective way to ensure the preventive controls requirements for dairy facilities are “consistent, to the extent practicable, with” the PMO is to exempt dairy processors regulated by the PMO from the preventive controls requirements, or otherwise deem dairy facilities that are compliant with the PMO to also be in compliance with FSMA’s preventive controls provision.

FDA’s legal authority under FSMA to exempt Grade “A” dairy processors operating under the PMO from the preventive controls requirements is further buttressed by the agency’s longstanding authority to promulgate regulations “for the efficient enforcement of [the] Act.” FFDCa § 701(a). As explained, the PMO has for years been achieving all the purposes behind the FSMA preventive controls requirement, and FDA can most efficiently enforce the Act by exempting Grade “A” dairy processors from the preventive controls regulation. Such an exemption would avoid disrupting the well-established and historically robust safety procedures followed by the dairy industry while allowing FDA to focus its resources on implementing FSMA for types of foods that historically have lacked such oversight.

To the extent needed, FDA could work with the NCIMS to make such minor adjustments to the PMO as FDA may deem necessary to sustain the exemption requested. We believe that, if challenged, an exemption granted by FDA from the preventive controls regulation for dairy facilities under the PMO would withstand judicial scrutiny. The federal courts give great deference to an agency’s interpretation of its statutory authority and to an agency’s factual determinations, such as a determination that the PMO achieves the food safety results called for by FSMA without subjecting the dairy industry to duplicative regulatory programs.

Taken together, we believe that: (a) Congress’s instructions in FSMA to avoid duplicative sets of requirements; (b) the fact that FSMA itself cites the PMO as a model for food safety regulation, and (c) FDA’s longstanding authority under the FFDCa to efficiently enforce the Act, make it

clear that FDA has ample legal authority to exempt PMO-regulated facilities from the preventive controls rule.

### **Environmental Monitoring under the PMO**

While IDFA and NMPF believe the PMO, as is, is a sufficient preventive controls program, which provides a high level of public health protection, we understand that FDA has concerns that there may be gaps in the PMO when compared to the preventive controls rule. IDFA and NMPF believe the differences in terms of food safety are negligible, but where they exist and concern FDA, we believe that minor modifications to the PMO can be made via the NCIMS process. For example, the PMO does not require environmental monitoring. The reality though, is that, required by the PMO or not, virtually all Grade "A" milk plants have an environmental monitoring program, so incorporating that into the PMO should be relatively easy.

### **Robust Supplier Verification under the PMO**

In addition, PMO-regulated facilities have a robust supplier verification program that covers the majority of inputs into Grade "A" products -- milk and packaging. The supplier verification program, known as the Interstate Milk Shippers Program, was created to verify compliance with the PMO, and may be superior to any supplier verification requirements that will ultimately become part of the preventive controls rule.

The Interstate Milk Shipment Program ensures regulations are being evenly implemented in the states that produce Grade "A" fluid milk products. The program relies upon Interstate Milk Shipment Rating Officers (IMS Officers) who are responsible for conducting surveys according to the requirements of the PMO and related documents. IMS Officers must be certified by the FDA in order to be permitted to conduct surveys. Although they are State employees, the IMS officers must interact regularly with their FDA counterparts to ensure they are enforcing regulations uniformly. Surveys are performed on both farms and plants by IMS Officers. Surveys record observations and then those observations are scored and tallied for a final survey score.

Farms are handled differently than plants and are grouped into units for surveys based on the plant or organization to which they market their milk. These are called Bulk Tank Units (BTU's). Each dairy plant that wishes to sell Grade "A" products interstate is surveyed every two years. Surveys of farm BTU's are also conducted every two years. During farm surveys, IMS officers may visit only a proportion of the farms identified for a given BTU with the number depending upon the size of the farm BTU. Surveys are scored using two components: the farm or plant score and the enforcement score. The farm or plant score relates directly to the observations made during inspections of those facilities. The enforcement score is calculated by reviewing the inspection and sampling records of dairy program staff for compliance with requirements.

There are significant economic consequences to failing a survey. If a farm BTU or plant survey fails their portion of the survey, milk from that BTU or products from that plant cannot be shipped interstate until corrections are made. If the enforcement portion of a survey fails, the

plant or BTU may continue to ship products until a resurvey is conducted and passed. If this is not completed within 6 months, the plant or BTU would not be able to ship Grade “A” products interstate.

In addition, Single Service Closures & Containers (packaging), commonly referred to as SSSC, used for Grade “A” products are inspected and approved (rated) and listed in the FDA IMS listing. If the supplier fails this rating, its products can no longer be used to contain Grade “A” products. This rating /inspection is done by FDA-approved personnel and can be done by third parties.

### **Laboratories and PMO**

Finally, in addition to farms (milk) and packaging, the IMS program is also applied to laboratories that serve the PMO-regulated entities. All these factors combined clearly show that while somewhat different in some respects from the preventive controls rule, in many cases they are the same and in many cases the PMO is more robust.

Please see the attached IMS document for more information about this program and note that this resides on the FDA website.

The one area where some additional work may be required is allergen control and again we have confidence that the NCIMS process can be used to address that issue. That said, historically Grade “A” milk products do not have a significant problem with allergens.

### **IDFA’s and NMPF’s Recommendation to FDA**

During the aforementioned September 19, 2013 public meeting, Deputy Commissioner Mike Taylor made several related statements with which we strongly agree. First he stated:

*“We don’t want to be prescribing changes for change sake. We want to be sure that any changes that happen in a food production system as a result of our rules make a practical difference for food safety.”*

Later he reiterated that point by saying:

*“And again, I’m just going to reiterate the principle that we have spoken to repeatedly. We’re building on a foundation of effort to improve food safety. FSMA has given us a mandate to put that within a certain framework. We are going to implement the regulatory framework and committed to do that as fully as possible that ensures that any changes that are required in current practices are changes that make a practical difference and that’s just crucial to us from a food safety standpoint and to avoid diverting resources, public and private, to activities, to regulatory compliance, that’s not making a practical difference—that, in our view, does not serve anybody.”*

When FDA issues its final preventive controls rule for food, FDA should exempt facilities that are subject to the PMO, or otherwise determine that dairy facilities that are compliant with the

PMO are also deemed to be in compliance with FSMA's preventive controls provisions. We believe this exemption should be applied to all PMO-regulated facilities.<sup>1</sup> Should FDA find it necessary, as an interim step, IDFA and NMPF request that the agency stay the application of the preventive controls rule to PMO-regulated facilities and work with the NCIMS cooperative program to enact any minor modifications to the PMO as may be needed to warrant the full exemption or comparability determination being requested. Proceeding in this manner is consistent with the remarks and principles that Deputy Commissioner Taylor has advocated so many times and is a good application of common sense.

Please do not hesitate to contact us if we can be of further assistance.

Sincerely,



Clay Detlefsen  
Vice President & Counsel  
International Dairy Foods Association



Beth Briczinski, Ph.D.  
Senior Director, Regulatory Affairs  
National Milk Producers Federation

Attachments:  
MOU  
IMS Program

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<sup>1</sup> We note that the PMO contains an Appendix K, which sets out a voluntary HACCP regime that may be utilized as an alternative to the standard PMO requirements – essentially, being deemed to provide the same high level of public health protection. We understand there are 12 PMO-regulated facilities that are utilizing this option. We believe these facilities should be treated the same by FDA as other PMO-regulated facilities because they have already been found by the PMO itself to be applying comparable standards.

# Attachment 1

# **MEMORANDUM OF UNDERSTANDING BETWEEN THE U.S. FOOD AND DRUG ADMINISTRATION AND THE NATIONAL CONFERENCE ON INTERSTATE MILK SHIPMENTS**

## **BACKGROUND**

The Food and Drug Administration (FDA) is the federal agency responsible for enforcing the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq. Included within the FDA's responsibilities under the Act is the responsibility for regulation of foods shipped in interstate commerce including milk and milk products.

The National Conference on Interstate Milk Shipments (NCIMS) is a voluntary organization directed and controlled by the member States and open to all persons interested in its objective of promoting the availability of a high quality milk supply. It is governed by an Executive Board whose members include representatives from state departments of health and agriculture, the FDA, the U.S. Department of Agriculture and industry.

Through their collaborative efforts, the FDA and the NCIMS have developed a cooperative, federal-state program (the Interstate Milk Shipper Program) to ensure the sanitary quality of milk and milk products shipped interstate. The Program is operated primarily by the States, with FDA providing varying degrees of scientific, technical and inspection assistance as provided by FDA Publication No. 72-2022, Procedures Governing the Cooperative Federal-State Program for Certification of Interstate Milk Shippers ("Procedures Manual")\*. The result has been the establishment of a viable and effective certification and enforcement program which has been of significant benefit to consumers.

The Interstate Milk Shippers Program relies upon the Grade "A" Pasteurized Milk Ordinance and related technical documents referred to in the Procedures Manual for the sanitary standards, requirements and procedures it follows to ensure the safety and wholesomeness of Grade "A" milk and milk products. FDA considers these standards, requirements and procedures to be adequate for the protection of the health and safety of the consumer. Sources of Grade "A" milk and milk products intended for use on interstate conveyances and subject to the Interstate Conveyance Sanitation Regulations (21 CFR 1250 et seq.) promulgated pursuant to the Public Health Service Act (42 U.S.C. 264) are considered approved sources for purposes of 21 CFR 1250.26 if they have a State or local permit, are under the routine inspection of a State or local regulatory agency and meet the provisions of the Procedures Manual.

## **PURPOSE**

The purpose of this Memorandum is to strengthen the Interstate Milk Shippers Program by stating the responsibilities of the FDA and the NCIMS for execution of the Program, the means for resolving questions of interpretation that may arise in the execution of the Program, and the means for making modifications in the Program.

## AGREEMENT

The FDA and NCIMS have agreed upon the following principles:

- A. The Interstate Milk Shippers Program shall be governed by the provisions of the current FDA Publication No. 72-2022, Procedures Governing the Cooperative Federal-State Program for Certification of Interstate Milk Shippers\*, and by the documents referenced therein. Copies of all governing documents are available for review in the office of the Food and Drug Administration, Hearing Clerk.
- B. The responsibilities of the NCIMS, the participating States, and FDA for execution of the Interstate Milk Shippers Program shall be as stated in the above referenced Procedures Manual.
- C. Failure on the part of any certified state milk sanitation rating officer, state milk laboratory survey officer, or state sampling surveillance officer to comply with the provisions of this Memorandum or the Procedures Manual shall be sufficient cause for FDA to proceed to a hearing to provide said rating officer, laboratory survey officer, or sampling surveillance officer an opportunity to show cause why his/her certification or approval should not be revoked.
- D. It shall be the right of the NCIMS and each participating State to request and receive consultation with the appropriate representative of the FDA to discuss the provisions of this Memorandum or problems encountered in the execution of the provisions of the Procedures Manual. The initial contact office at FDA for all inquiries pertaining to the Program is Bureau of Foods (HFF-415)\*\*, FDA, 200 C Street, S.W., Washington, D.C. 20204.
- E. It shall be the right of the FDA to request and receive consultation with appropriate officials of the NCIMS or any of its member States to discuss the provisions of this Memorandum or problems encountered in the execution of the provisions of the Procedures Manual. The Executive Board of NCIMS can be contacted by FDA personnel through the Bureau of Foods (HFF-415)\*\* at the address indicated in paragraph D, above.
- F. Problems of interpretation regarding provisions of the Procedures Manual and the documents referenced therein, or their application, shall be subject to resolution by mutual agreement of the parties.
- G. Changes in the provisions of the Procedures Manual and the documents referred to therein shall be mutually concurred in by NCIMS and FDA.
- H. This Memorandum of Understanding may be modified by mutual consent of the parties and may be terminated by either party upon a thirty (30) day advance written notice to the other. Any modification or notice of termination will be published in the Federal

Register.

For the FDA.

Dated: August 5, 1977.

Donald Kennedy,  
Commissioner of  
Food and Drugs.

For the NCIMS.

Dated: June 28, 1977.

H. H. Vaux  
Chairman, NCIMS.

Effective date: This Memorandum of Understanding became effective August 5, 1977.

Dated: September 12, 1977.

Joseph P. Hile  
Associate Commissioner  
for Compliance

(FR Doc. 77-37071 Filed 9/19/77; 8:45 a.m.)

\* Current document is titled: Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments.

\*\*Note: HFF-415 mail symbol for Dairy and Lipid Technology Branch, DFT, Bureau of Foods is now HFS-316, Center for Food Safety and Applied Nutrition, Milk Safety Team, 5100 Paint Branch Parkway, College Park, MD 20740.

## Attachment 2

# Interstate Milk Shippers List

## Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers List

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**Sanitation Compliance And Enforcement Ratings Of Interstate Milk Shippers - Domestic**  
(Dynamic --May be updated daily when new data is available)

**Southeast Region**<sup>8</sup>

- ALABAMA<sup>9</sup>
- FLORIDA<sup>10</sup>
- GEORGIA<sup>11</sup>
- LOUISIANA<sup>12</sup>
- MISSISSIPPI<sup>13</sup>
- NORTH CAROLINA<sup>14</sup>
- PUERTO RICO<sup>15</sup>
- SOUTH CAROLINA<sup>16</sup>
- TENNESSEE<sup>17</sup>

**Pacific Region**<sup>18</sup>

- ALASKA<sup>19</sup>
- ARIZONA<sup>20</sup>
- CALIFORNIA<sup>21</sup>
- HAWAII<sup>22</sup>
- IDAHO<sup>23</sup>
- MONTANA<sup>24</sup>
- NEVADA<sup>25</sup>
- OREGON<sup>26</sup>
- WASHINGTON<sup>27</sup>

**Southwest Region**<sup>28</sup>

- ARKANSAS<sup>29</sup>
- COLORADO<sup>30</sup>
- IOWA<sup>31</sup>
- KANSAS<sup>32</sup>
- MISSOURI<sup>33</sup>
- NEBRASKA<sup>34</sup>
- NEW MEXICO<sup>35</sup>
- OKLAHOMA<sup>36</sup>
- TEXAS<sup>37</sup>
- UTAH<sup>38</sup>
- WYOMING<sup>39</sup>

**Northeast Region**<sup>40</sup>

- CONNECTICUT<sup>41</sup>
  - MAINE<sup>42</sup>
- MASSACHUSETTS<sup>43</sup>
- NEW HAMPSHIRE<sup>44</sup>
- NEW YORK<sup>45</sup>
- RHODE ISLAND<sup>46</sup>
- VERMONT<sup>47</sup>

**Central Region**<sup>48</sup>

- DELAWARE<sup>49</sup>
  - ILLINOIS<sup>50</sup>
  - INDIANA<sup>51</sup>
  - KENTUCKY<sup>52</sup>
  - MARYLAND<sup>53</sup>
  - MICHIGAN<sup>54</sup>
  - MINNESOTA<sup>55</sup>
  - NEW JERSEY<sup>56</sup>
  - NORTH DAKOTA<sup>57</sup>
    - OHIO<sup>58</sup>
  - PENNSYLVANIA<sup>59</sup>
  - SOUTH DAKOTA<sup>60</sup>
    - VIRGINIA<sup>61</sup>
  - WEST VIRGINIA<sup>62</sup>
  - WISCONSIN<sup>63</sup>
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**Sanitation Compliance And Enforcement Ratings Of Interstate Milk Shippers - Foreign**  
(Dynamic --May be updated daily when new data is available)

**Foreign Countries**<sup>64</sup>

**Certified Manufacturers Of Single-Service Containers and Closures And Related Products**  
(Dynamic --May be updated daily when new data is available)

**Southeast Region**<sup>65</sup>

- ALABAMA<sup>66</sup>
- FLORIDA<sup>67</sup>
- GEORGIA<sup>68</sup>
- LOUISIANA<sup>69</sup>
- MISSISSIPPI<sup>70</sup>
- NORTH CAROLINA<sup>71</sup>
- PUERTO RICO<sup>72</sup>
- SOUTH CAROLINA<sup>73</sup>
- TENNESSEE<sup>74</sup>

**Pacific Region**<sup>75</sup>

- ALASKA<sup>76</sup>
- ARIZONA<sup>77</sup>
- CALIFORNIA<sup>78</sup>
- HAWAII<sup>79</sup>
- IDAHO<sup>80</sup>
- MONTANA<sup>81</sup>
- NEVADA<sup>82</sup>
- OREGON<sup>83</sup>
- WASHINGTON<sup>84</sup>

**Southwest Region**<sup>85</sup>

- ARKANSAS<sup>86</sup>
- COLORADO<sup>87</sup>
- IOWA<sup>88</sup>
- KANSAS<sup>89</sup>
- MISSOURI<sup>90</sup>
- NEBRASKA<sup>91</sup>
- NEW MEXICO<sup>92</sup>
- OKLAHOMA<sup>93</sup>
- TEXAS<sup>94</sup>
- UTAH<sup>95</sup>
- WYOMING<sup>96</sup>

**Northeast Region**<sup>97</sup>

- CONNECTICUT<sup>98</sup>
- MAINE<sup>99</sup>
- MASSACHUSETTS<sup>100</sup>
- NEW HAMPSHIRE<sup>101</sup>
- NEW YORK<sup>102</sup>
- RHODE ISLAND<sup>103</sup>
- VERMONT<sup>104</sup>

**Central Region**<sup>105</sup>

- DELAWARE<sup>106</sup>
- ILLINOIS<sup>107</sup>
- INDIANA<sup>108</sup>
- KENTUCKY<sup>109</sup>
- MARYLAND<sup>110</sup>
- MICHIGAN<sup>111</sup>
- MINNESOTA<sup>112</sup>
- NEW JERSEY<sup>113</sup>
- NORTH DAKOTA<sup>114</sup>
- OHIO<sup>115</sup>
- PENNSYLVANIA<sup>116</sup>
- SOUTH DAKOTA<sup>117</sup>
- VIRGINIA<sup>118</sup>
- WEST VIRGINIA<sup>119</sup>
- WISCONSIN<sup>120</sup>

**Milk Laboratories Approved By Federal And State Agencies**  
(Dynamic --May be updated daily when new data is available)

**Southeast Region**<sup>121</sup>

- ALABAMA<sup>122</sup>
- FLORIDA<sup>123</sup>
- GEORGIA<sup>124</sup>
- LOUISIANA<sup>125</sup>
- MISSISSIPPI<sup>126</sup>
- NORTH CAROLINA<sup>127</sup>
- PUERTO RICO<sup>128</sup>
- SOUTH CAROLINA<sup>129</sup>
- TENNESSEE<sup>130</sup>

**Pacific Region**<sup>131</sup>

- ALASKA<sup>132</sup>
- ARIZONA<sup>133</sup>
- CALIFORNIA<sup>134</sup>
- HAWAII<sup>135</sup>
- IDAHO<sup>136</sup>
- MONTANA<sup>137</sup>
- NEVADA<sup>138</sup>
- OREGON<sup>139</sup>
- WASHINGTON<sup>140</sup>

**Southwest Region**<sup>141</sup>

- ARKANSAS<sup>142</sup>
- COLORADO<sup>143</sup>
- IOWA<sup>144</sup>
- KANSAS<sup>145</sup>
- MISSOURI<sup>146</sup>
- NEBRASKA<sup>147</sup>
- NEW MEXICO<sup>148</sup>
- OKLAHOMA<sup>149</sup>
- TEXAS<sup>150</sup>
- UTAH<sup>151</sup>
- WYOMING<sup>152</sup>

**Northeast Region**<sup>153</sup>

- CONNECTICUT<sup>154</sup>
  - MAINE<sup>155</sup>
- MASSACHUSETTS<sup>156</sup>
- NEW HAMPSHIRE<sup>157</sup>
  - NEW YORK<sup>158</sup>
- RHODE ISLAND<sup>159</sup>
- VERMONT<sup>160</sup>

**Central Region**<sup>161</sup>

- DELAWARE<sup>162</sup>
- ILLINOIS<sup>163</sup>
- INDIANA<sup>164</sup>
- KENTUCKY<sup>165</sup>
- MARYLAND<sup>166</sup>
- MICHIGAN<sup>167</sup>
- MINNESOTA<sup>168</sup>
- NEW JERSEY<sup>169</sup>
- NORTH DAKOTA<sup>170</sup>
  - OHIO<sup>171</sup>
- PENNSYLVANIA<sup>172</sup>
- SOUTH DAKOTA<sup>173</sup>
  - VIRGINIA<sup>174</sup>
- WEST VIRGINIA<sup>175</sup>
- WISCONSIN<sup>176</sup>

**Milk Laboratory Supervisors**

(Dynamic --May be updated daily when new data is available)

**Southeast Region**<sup>177</sup>

**Pacific Region**<sup>187</sup>

**Southwest Region**<sup>197</sup>

- [ALABAMA](#)<sup>178</sup>
- [FLORIDA](#)<sup>179</sup>
- [GEORGIA](#)<sup>180</sup>
- [LOUISIANA](#)<sup>181</sup>
- [MISSISSIPPI](#)<sup>182</sup>
- [NORTH CAROLINA](#)<sup>183</sup>
- [PUERTO RICO](#)<sup>184</sup>
- [SOUTH CAROLINA](#)<sup>185</sup>
- [TENNESSEE](#)<sup>186</sup>

- [ALASKA](#)<sup>188</sup>
- [ARIZONA](#)<sup>189</sup>
- [CALIFORNIA](#)<sup>190</sup>
- [HAWAII](#)<sup>191</sup>
- [IDAHO](#)<sup>192</sup>
- [MONTANA](#)<sup>193</sup>
- [NEVADA](#)<sup>194</sup>
- [OREGON](#)<sup>195</sup>
- [WASHINGTON](#)<sup>196</sup>

- [ARKANSAS](#)<sup>198</sup>
- [COLORADO](#)<sup>199</sup>
- [IOWA](#)<sup>200</sup>
- [KANSAS](#)<sup>201</sup>
- [MISSOURI](#)<sup>202</sup>
- [NEBRASKA](#)<sup>203</sup>
- [NEW MEXICO](#)<sup>204</sup>
- [OKLAHOMA](#)<sup>205</sup>
- [TEXAS](#)<sup>206</sup>
- [UTAH](#)<sup>207</sup>
- [WYOMING](#)<sup>208</sup>

### [Northeast Region](#)<sup>209</sup>

- [CONNECTICUT](#)<sup>210</sup>
  - [MAINE](#)<sup>211</sup>
- [MASSACHUSETTS](#)<sup>212</sup>
- [NEW HAMPSHIRE](#)<sup>213</sup>
  - [NEW YORK](#)<sup>214</sup>
- [RHODE ISLAND](#)<sup>215</sup>
  - [VERMONT](#)<sup>216</sup>

### [Central Region](#)<sup>217</sup>

- [DELAWARE](#)<sup>218</sup>
- [ILLINOIS](#)<sup>219</sup>
- [INDIANA](#)<sup>220</sup>
- [KENTUCKY](#)<sup>221</sup>
- [MARYLAND](#)<sup>222</sup>
- [MICHIGAN](#)<sup>223</sup>
- [MINNESOTA](#)<sup>224</sup>
- [NEW JERSEY](#)<sup>225</sup>
- [NORTH DAKOTA](#)<sup>226</sup>
  - [OHIO](#)<sup>227</sup>
- [PENNSYLVANIA](#)<sup>228</sup>
- [SOUTH DAKOTA](#)<sup>229</sup>
  - [VIRGINIA](#)<sup>230</sup>
- [WEST VIRGINIA](#)<sup>231</sup>
- [WISCONSIN](#)<sup>232</sup>

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This IMS list is provided as an on-line guide to assist regulatory program management and others who utilize the IMS list to stay current by providing continuous updates. The IMS list is also posted on FDA's Website as a Portable Document Format (PDF) file quarterly by the FDA Milk Safety Team at the bottom of this page.\*

### **Electronic Format Subscription**

As announced in the July 2005 issue of the IMS List, due to budget constraints, the printed version of the IMS list has been discontinued. Beginning in January 2006, it is being made available on FDA's web site in PDF format with notification of availability given by an electronic mailing list.  [Subscribe to IMS mailing list](#)<sup>233</sup>.

## **Rules For Inclusion In The IMS List**

Interstate milk shippers who have been certified by State Milk Sanitation Rating Authorities as having attained the identified milk sanitation compliance and enforcement ratings are indicated in the following IMS list. These ratings are based on compliance with the requirements of the USPHS/FDA Grade "A" Pasteurized Milk Ordinance (PMO) and were made in accordance with the procedures set forth in the Methods of Making Sanitation Rating of Milk Shippers (MMSR).

\*Proposal 301 that was passed at the 2001 NCIMS Conference, held May 5-10, 2001, in Wichita, Kansas, and concurred with by FDA states: "Transfer Stations, Receiving Stations and Milk Plants must achieve a sanitation compliance rating of 90 or better in order to be eligible for a listing in the IMS List. Sanitation compliance rating scores for Transfer and Receiving Stations and Milk Plants will not be printed in the IMS List". Therefore, the publication of a sanitation compliance rating score for Transfer and Receiving Stations and Milk Plants will not be printed in the IMS List.

\*Proposal 316 that was passed at the 2003 NCIMS Conference, held April 16-May 1, 2003 in Seattle, WA, and concurred with by FDA authorized the NCIMS Hazard Analysis and Critical Control Point (HACCP) Listing of milk plants, receiving stations and transfer stations. The HACCP Listing shall be made by a State Milk Rating Officer who has been certified to conduct HACCP Listings by a USPHS/FDA representative. Milk plants, receiving stations and transfer stations must achieve an acceptable HACCP Listings in order to be eligible for a listing in the IMS List.

**THIS IMS LIST SUPERSEDES ALL IMS LISTS WHICH HAVE BEEN ISSUED; HERETOFORE, ALL PRECEDING IMS LISTS AND SUPPLEMENTS THERETO ARE VOID.**

The rules for inclusion in the IMS list were formulated by the official representatives of State Milk Regulatory and Rating Agencies and FDA who have participated in the meetings of the National Conference on Interstate Milk Shipments (NCIMS). These rules are as follows:

1. The interstate milk shipper's milk supply must be under the routine supervision of an official Regulatory Agency-State or local. Supervision shall be based on the procedures and standards of the USPHS/FDA Grade "A" (PMO), MMSR and Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (Procedures).
2. Ratings of interstate milk shipper's supplies must be made by State Milk Rating Officers who have been certified by a USPHS/FDA representative. Ratings to be listed shall include the sanitation compliance ratings of the producing farms, receiving stations, transfer stations, and milk plants and the enforcement rating of the supervising Regulatory Agency.
3. Ratings must be made on individual shipper's supplies, unless the supply is part of an area rating, which has been awarded a rating of 90% or more on the basis of an official rating. Individual ratings and area ratings shall be made at a frequency of not less than

once every 24 months. All ratings shall be reported and listed to the nearest whole number.

4. The interstate milk shipper's supply must be under a program of routine laboratory control which has been checked by the State laboratory approval agency as complying substantially with Standard Methods for the Examination of Dairy Products, published by the American Public Health Association (most current edition), and with provisions of the Grade "A" PMO, and the Evaluation of Milk Laboratories (EML). Officially designated laboratories periodically checked by the State may perform this routine laboratory control.
5. USPHS/FDA shall periodically make check ratings or HACCP audits, if applicable, of the sanitation compliance and enforcement status of listed IMS shippers to assure the validity of published IMS Listings. They also shall certify the rating, and laboratory procedures of the reporting State.

USPHS/FDA will not include on this IMS list the ratings of any shipper's supply unless the written signed permission of the shipper concerned has been obtained by the State Milk Rating Agency.

Those shippers who have correctly completed Form FDA 2359i "Interstate Milk Shipper's Report" and which is received by the Milk Safety Team, HFS-626, College Park, MD will be included in the IMS List.

We are limiting the company's name to the name of the parent organization or its subsidiary, but not both. If the preferred listings is not indicated on the Form FDA 2359i, the editor will select the listing which is considered appropriate.

The use of the IMS list is entirely optional, and that its sole purpose is to assist those States who wish to utilize this information in the furtherance of their own milk sanitation regulatory program.

### **National Uniform Coding System For Packaging Identification Of Milk Plants**

The voluntary national uniform coding system, developed by the National Labeling Committee and recommended for utilization by the Ninth NCIMS, is a system for the identification of milk plants at which milk and milk products are packaged by means of nationally recognized State and plant code numbers identified on the package. It is exclusively applicable to products pasteurized in a milk plant other than shown under the trade name, distributor's names, or private label. If this voluntary national uniform code system is not used, the name and address of the milk plant at which pasteurization took place will be identified on the cartons or containers. (Refer to Section 4, Grade "A" PMO).

Since the start of this program, the numerical code for State identification has been utilized. Public Law 89-306, October 30, 1965, authorized the Secretary of Commerce "to make appropriate recommendations to the President relating to the establishment of uniform Federal automatic data processing standard." The numerical code for the States developed under this

Public Law is known as Federal Information Processing Standards (FIPS) and is utilized in the IMS List.

Each State, in cooperation with local jurisdictions, may assign individual identification numbers to milk plants within the State. When a State assigned number is indicated on the Form FDA 2359i, it is published in the IMS list following the name of the shipper.

If the name and address of the milk plant, at which pasteurization took place is not imprinted on the container, or included on the label proper, labeling of a container may include the name and main address of the manufacturer, processor, or distributor, plus the code number that identifies the State and milk plant in which the product was pasteurized.

<b>FIPS Numerical Code for States</b>			
<b>State</b>	<b>FIPS Code Number</b>	<b>State</b>	<b>FIPS Code Number</b>
Alabama	01	Montana	30
Alaska	02	Nebraska	31
Arizona	04	Nevada	32
Arkansas	05	New Hampshire	33
California	06	New Jersey	34
Colorado	08	New Mexico	35
Connecticut	09	New York	36
Delaware	10	North Carolina	37
District of Columbia	11	North Dakota	38
Florida	12	Ohio	39
Georgia	13	Oklahoma	40
Hawaii	15	Oregon	41
Idaho	16	Pennsylvania	42
Illinois	17	Puerto Rico	43
Indiana	18	Rhode Island	44
Iowa	19	South Carolina	45
Kansas	20	South Dakota	46
Kentucky	21	Tennessee	47
Louisiana	22	Texas	48
Maine	23	Utah	49
Maryland	24	Vermont	50
Massachusetts	25	Virginia	51
Michigan	26	Washington	53
Minnesota	27	West Virginia	54

Mississippi	28	Wisconsin	55
Missouri	29	Wyoming	56

Example: 37-275, 37 indicates the milk plant is located in North Carolina and 275 identifies a plant within the State.

It is recommended that the part of the code indicating the State or origin always consist of two digits followed by a hyphen; for example, 05- .

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## **Sanitation Compliance And Enforcement Ratings Of Interstate Milk Shippers**

### **Product Codes**

1. Raw Milk for Pasteurization (May Include Lowfat, Skim or Cream).
2. Pasteurized Milk, Reduced Fat, Lowfat, Skim.
3. Heat-Treated (May Include Reduced Fat, Lowfat, Skim or Cream).
4. Pasteurized Half & Half, Coffee Cream, Creams.
5. Ultra-Pasteurized Milk and Milk Products
6. Aseptic Milk and Milk Products (Including Flavored).
7. Cottage Cheese (Including Lowfat, Nonfat or Dry Curd).
8. Cultured or Acidified Milk and Milk Products.
9. Yogurt (Including Lowfat or Skim).
10. Sour Cream Products (Acidified or Cultured).
11. Whey (Liquid).
12. Whey (Condensed).
13. Whey (Dry).
14. Modified Whey Products (Condensed or Dry).
15. Condensed Milk and Milk Products.
16. Nonfat Dry Milk.
17. Buttermilk (Condensed or Dry).
18. Eggnog.
19. Lactose Reduced Milk and Milk Products.
20. Low-Sodium Milk and Milk Products.
21. Milk and Milk Products with Added Safe and Suitable Microbial Organisms (Such as *Lactobacillus acidophilus*).
22. Dry Milk and Milk Products.
23. Anhydrous Milk Fat.
24. Cholesterol Modified Anhydrous Milk Fat.
25. Cholesterol Modified Fluid Milk Products.
26. Cream (Condensed or Dry).
27. Blended Dry Products.
28. Whey Cream.

29. Whey Cream and Cream Blends.
  30. Grade 'A' Lactose
  31. Raw Goat Milk for Pasteurization.
  32. Pasteurized Goat Milk and Milk Products .
  33. Cultured Goat Milk and Milk Products.
  34. Condensed or Dry Goat Milk and Milk Products.
  35. Ultra-Pasteurized Goat Milk and Milk Products.
  36. Aseptic Goat Milk and Goat Milk Products.
  37. Raw Sheep Milk for Pasteurization.
  38. Pasteurized Sheep Milk and Milk Products.
  39. Cultured Sheep Milk and Milk Products.
  40. Concentrated Raw Milk Products for Pasteurization.
  41. Concentrated Pasteurized Milk Products.
  42. Ultrafiltered Permeate from Milk.
  43. Ultrafiltered Permeate from Whey.
  44. Raw Water Buffalo Milk for Pasteurization.
  45. Pasteurized Water Buffalo Milk and Milk Products.
  46. Cultured Water Buffalo Milk and Milk Products.
  47. Raw Camel Milk for Pasteurization.
  48. Pasteurized Camel Milk and Milk Products.
  49. Cultured Camel Milk and Milk Products.
- 

## Abbreviations

The following abbreviations are used in this IMS list:

AMPI	Associated Milk Producers Inc.
ASSN	Association
BTU	Bulk Tank Unit
CRY	Creamery
CTY	County
DCA	Dairymen Creamery Assn.
DFA	Dairy Farmers of America
DMCI	Dairymen Marketing Coop Inc
DMS	Dairy Marketing Services
DYMEN	Dairymen
DY	Dairy
DYS	Dairies
ED	Environmental Department

FCC	Farmers's Coop Creamery
FDFA	Florida Dairy Farmers Assn
FM	Farm
FMS	Farms
GP	Group
HD	Health Department
ICMPA	Independent Coop Milk Producers Association
LOL	Land O'Lakes
MGF	Morning Glory Farms
MMI	Milk Marketing Inc.
MMPA	Michigan Milk Prods. Assn.
NDA	Northwest Dairy Assn.
NFO	National Farmers Organization
PH	Public Health
PRODS	Producers
RS	Receiving Station
SDA	State Dept. of Agriculture
SDL	State Dept. of Livestock
SHD	State Health Department
STA	Station
SVF	Swiss Valley Farms
TR	Transfer Station

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### **Certified Manufacturers Of Single-service Containers, Closures And Related Products for Milk and Milk Products-Domestic**

The names of domestic manufacturers of single-service containers, closures and related products for milk and milk products who have been certified by State Milk Rating Authorities as being in satisfactory compliance with the requirements of Appendix J. Fabrication of Single-Service Containers and Closures for Milk and Milk Products of the Grade "A" PMO are listed on the following pages.

This listing of certified single-service manufacturing plants includes only the names of those plants reported to the Milk Safety Team as having been certified by State Milk Rating Officers.

If furnished to FDA, the coding or identification system used by the manufacturer will be found following the name of the plant and city where it is located.

Space limitations compel us to limit the company's name to the name of the parent organization or the name of the division, but not both. If the preferred listing is not indicated on FDA Form 2359d, Report of Certification (Fabrication of Single-Service Containers and Closures for Milk and Milk Products) the editor will select the listing which is considered appropriate.

### **Certified Manufacturers Of Single-Service Containers And Closures And Related Products for Milk and Milk Products - Foreign**

The names of foreign manufacturers of single-service containers, closures and related products for milk and milk products who have been certified by Single-Service Consultants or International Certification Pilot Program Third Party Certifiers identified in the IMS List as being in satisfactory compliance with the requirements of Appendix J. Fabrication of Single-Service Containers and Closures for Milk and Milk Products of the Grade "A" PMO are listed on the following pages.

This listing of certified single-service manufacturing plants includes only the names of those plants reported to the Milk Safety Team as having been certified by State Milk Rating Officers. If furnished to FDA, the coding or identification system used by the manufacturer will be found following the name of the plant and city where it is located.

Space limitations compel us to limit the company's name to the name of the parent organization or the name of the division, but not both. If the preferred listing is not indicated on FORM FDA 2359d, Report of Certification (Fabrication of Single-Service Containers and Closures for Milk and Milk Products) the editor will select the listing which is considered appropriate.

\*Proposal 316 that was passed at the 2005 NCIMS Conference, held May 12-17, 2005 in Columbus, OH, and concurred with by FDA, authorized the NCIMS Voluntary International Certification Pilot Program and the utilization of Third Party Certifiers, certified by FDA, to list a limited number of foreign shippers and associated single-service manufacturers and laboratories in the IMS List. This provision will expire December 31, 2007, unless extended by future NCIMS Conference action.

#### **Explanation of Product and Material Code**

<b>First Column-Product</b>	<b>Second Column-Material</b>
1 - Containers	1 - Metal
2 - Closures	2 - Paper (includes laminates)
3 - Other products (Including sample containers and closures, valves, films, etc.)	3 - Plastic
4 - Containers and closures	4 - Metal and Paper
5 - Containers and other products	5 - Metal and Plastic

6 - Closures and other products  
7 - Containers, closures and other products

6 - Paper and Plastic  
7 - Metals, Paper and Plastic  
8 - Glass  
9 - Rubber  
10- Paper, metal, plastic and glass

### **Expiration Date**

This date is 15 or 24 months following the survey date. Certifications of single-service manufacturing plants may be valid for 1 or 2 years. In case of a 1 year certification a 90 day grace period was inserted in this list to provide time for the transmission of the completed FORM FDA 2359d from States to the Regional Offices and forwarded to Headquarters.

Following are the criteria for IMS Listing<sup>234</sup> are:

1. Single-service manufacturers that operate in conjunction with an IMS listed milk plant may be listed for 24 months, if the single-service plant is inspected at least quarterly using Form FDA 2359c- Manufacturing Plant Inspection Report, and records of such inspections and all required tests are maintained by the Regulatory Agency. Provided that, single-service manufacturers that operate in conjunction with an IMS HACCP listed milk plant may be listed for 24 months, if the single-service plant is integrated into the milk plant's NCIMS HACCP system and if the single-service plant is inspected at the minimum milk plant audit frequency specified in Appendix K, using Form FDA 2359c and records of such inspections and all required tests are maintained by the Regulatory Agency. The permit for the milk plant shall also include the inspection of the single service manufacturing areas.
2. Single-service manufacturers that operate in conjunction with an IMS Listed milk plant and are not inspected at least quarterly and/or are not included under a permit system may be optionally listed for twelve (12) months, plus a 90-day grace period after an evaluation.
3. Single-service manufacturers that operate as a separate entity may be listed for 24 months if the regulatory agency has a permit system and inspects the plants, using the FDA form 2359c, at least quarterly. All testing of containers and individual water supplies shall be under the direction of the regulatory agency and kept on file.
4. Single-service manufacturers that operates as a separate entity and are not inspected by Regulatory Agency personnel at least quarterly and/or do not have permit may be optionally listed for twelve (12) months, plus a 90-day grace period, after an evaluation.

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### **LISTING TYPE:**

**FULL (F):** A "FULL" listing shall mean that all manufacturing production rooms, fabrication lines or machines have been evaluated and certified in regard to containers and/or closures and conform to the specifications of Appendix J-Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products of the *Grade "A" Pasteurized Milk Ordinance* (PMO).

**PARTIAL (P):** A "PARTIAL" listing shall mean only specific production rooms, fabrication lines or machines have been evaluated and certified in regard to specific containers and/or closures or specific size of containers and/or closures and conform to the specifications of Appendix J-Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products of the *Grade "A" Pasteurized Milk Ordinance* (PMO).

### **Milk Laboratories Approved By Federal And State Agencies**

Milk laboratories and the laboratory procedures performed, which have been found to be in substantial compliance with the EML and Standard Methods for the Examination of Dairy Products (most current edition) and are listed on the following pages. State Central Laboratories (Cen.) and procedures are approved by Milk Laboratory Evaluation Officers of the Food and Drug Administration (FDA). Official (Off.), Commercial (Com.), Dairy Industry (Ind.) and **Certified** industry supervisor (CIS.) laboratories and procedures are approved by FDA certified State Milk Laboratory Evaluation Officers.

The IMS list includes the laboratory names, locations, numbers assigned by the FDA, expiration dates, the dates of the last two split samples participated in, and the procedures for which the laboratories are approved.

#### **Laboratory Procedure Codes**

- **Code #      Procedures**
- 2. Standard Plate Count
- 3. Plate Loop Count (raw milk only)
- 4. Spiral Plate Count (raw milk only)
- 5. Petrifilm Aerobic Count
- 7. BactoScan FC (raw milk only)
- 9. Detection of Inhibitory Substances
  - B2. Charm BSDA
  - C2. Charm II Competitive
  - C3. Charm II Sequential
  - C4. Charm II Quantitative
  - C9. Charm II Cloxacillin
  - C10. Charm II Sulfa
  - C11. Charm II Chloramphenicol

- C12. Charm II Tetracycline
- C13. Charm SL (Safe Level)
- C14. Charm SL6
- C15. Charm SL3
- C16. Charm FLUSLBL
- D1. Delvotest P
- D3. Delvotest P 5 Pack
- I1. New Snap BL
- N1. Neogen BetaStar
- 12. Direct Somatic Cell Count
- 16. Electronic Somatic Cell Count
- 20. Petrifilm Coliform Count/High Sensitivity Coliform Count
- 21. Coliform Plate Count
- 22. Pasteurized Milk Containers
- 24. Dairy Water
- 25. Dairy Water Testing, Other
- 26. Disintegration Test
- 27. Flat Lid or Pour Contact Tests
- 28. Phosphatase Test-Flourophos
- 29. Phosphatase Test-Charm
- 30. Vitamin Analysis (A, D or A & D)

**Expiration Date**

The expiration date (EXP. DATE) shown is the date that the laboratory's approval status actually expires. A two (2) month grace period, however, is allowed to accommodate the transmission of laboratory reports to the FDA.

**Laboratory Number Code**

Five (5) digit numbers are assigned to each laboratory by the FDA. The first two (2) digits identify the State in which the laboratory is located according to the FIPS Numerical Code for States (Refer to page iv). The following three (3) digits are assigned according to the laboratory type as shown below:

- |              |                                    |
|--------------|------------------------------------|
| -- 001--099  | Central and Officials Laboratories |
| -- 100--299  | Commercial Laboratories            |
| -- 300--599  | Industrial Laboratories            |
| -- 600--799* | Certified Industry Supervisors     |
| -- 800--899  | Certified Vitamin Laboratories     |
| -- 900--999  | Federal Laboratories               |

\* The names of Certified Industry Supervisors are listed at the end of the individual State listings.

**Laboratory Classifications**

F = Approved, this laboratory may perform the indicated procedures for IMS purposes.

C = Conditionally approved, this laboratory does not have full status, but may perform the indicated procedures for IMS purposes.

N = Not approved, this laboratory has recently had its approval removed and may no longer be used for official IMS testing.

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