



November 1, 2011

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Dear Ms. Lewis and Mr. Vorgert:

The National Milk Producers Federation (NMPF) and the U.S. Dairy Export Council (USDEC) would like to jointly respond to the draft program proposed by the US Department of Agriculture, Agricultural Marketing Service (USDA-AMS), Dairy Programs to meet the requirements of the EU regulations for dairy product exports to the European Union (EU). We appreciate the efforts of USDA-AMS to include industry stakeholders in this process and to clarify issues related to the proposed program, while minimizing the impact on the US dairy industry. US-EU dairy trade is significant; in 2010, US dairy exports to the EU were \$88 million.

With respect to the draft program proposal, the “European Health Certification Program”, NMPF and USDEC offer the following specific comments about the instructions:

### Compliance with Standard Plate Count Requirement.

1. NMPF and USDEC request that Standard Plate Count (SPC) data only be required for producers of Grade B milk to verify compliance with SPC requirements.

The US regulatory standard for Grade A milk is 100,000 bacteria per mL or less, which is equivalent to the limit in the EU regulations (853/2004). In fact, verifying compliance with the SPC requirement under the US regulatory scheme (whereby a producer loses their Grade A status after 3 of 5 samples exceed the standard) is stricter than a rolling 2-month mean, especially when the SPC exceeds 100,000 in non-consecutive months (see examples below).

#### Example 1: Hypothetical Data

Month	Farm SPC	Rolling 2-month mean	<p>In this example, the farm’s SPC values are below the 100,000 limit during months 1 and 2, and the farm is in compliance.</p> <p>Under the US regulatory scheme, the farm will reach the 3 out of 5 limit during month # 5 and will lose Grade A status (*).</p> <p>Using a rolling 2-month mean, AMS would be notified of a mean above 100,000 in month #3 and, with additional time to come back into compliance, milk from this farm would still be able to be certified as meeting the EU requirements during month #5.</p>
1	95,000		
2	95,000	95,000	
3	200,000	148,000	
4	200,000	200,000	
5	200,000*	200,000	
6	200,000*	200,000	
7	40,000	120,000	

#### Example 2: Actual Producer Data

Month	Farm SPC	Rolling 2-month mean	<p>In this example (with actual producer data), under the US regulatory scheme, the farm will reach the 3 out of 5 limit during month #6 and will lose Grade A status (*).</p> <p>Using a rolling 2-month mean, AMS would be notified of a mean above 100,000 in month #5, and milk from this farm would still be able to be certified as meeting the EU requirements during month #6.</p>
1	24,000		
2	110,000	67,000	
3	15,000	63,000	
4	85,000	50,000	
5	220,000	152,500	
6	110,000*	165,000	

Verifying Grade A status, rather than checking monthly SPC data, will also simplify the Dairy Programs Review of Records. Based on preliminary data we have been able to obtain, approximately 99% of Grade A producers will be in compliance with the US SPC requirements throughout a given 12-month period (i.e., about 1% of Grade A producers will be delisted for some period of time during a year because of SPCs exceeding the 3-of-5 standard).

### **Milk Supplier's Responsibilities.**

2. The instructions proposed by AMS state “while a number of different compliance systems devised by the milk supplier may result in compliance...” (p 3).

We thank AMS for acknowledging a variety of methods may result in compliance with the requirements of the EU regulations. NMPF and USDEC request clarification in the final regulation that AMS will not require milk suppliers to submit their individual systems or methods to AMS for approval prior to participation in the EU Health Certification Program.

Additionally, in the final regulation, it would be helpful if AMS were to provide specific examples of different compliance systems they may consider to be appropriate, as general guidance to industry. For example, determinations based on the calculation of an arithmetic mean are stricter than determinations based on the geometric mean, and should be permitted to verify compliance. Also, some milk suppliers may opt to collect multiple samples during a month for SPC or Somatic Cell Counts (SCC), and would like to have the option to include all of this data in calculating either an average or a weighted average SPC or SCC for each month. As long as a milk supplier is consistent in how they collect and analyze samples, there should be no single system that is considered compliant.

3. NMPF and USDEC would encourage AMS to specify in the final regulations that samples used to verify compliance for the EU Health Certification Program do not necessarily have to be official regulatory samples.

Under the current instructions to verify compliance with EU regulations, the samples are not official. In some States, only one regulatory sample may be collected each month (which would prevent Grade B producers from providing data from at least two regulatory samples per month for SPC). By continuing to allow non-regulatory samples to be collected for verifying compliance, the industry would not have to involve certified milk samplers and additional temperature control samples.

4. The proposed instructions state “at the implementation of these instructions, all farms, as well as new farms subsequently entering the program, will be given three months to establish initial means for somatic cell counts...” (p 3).

NMPF and USDEC seek additional clarification in the final regulation on the definition of a “new farm”, and suggest this term include new farm establishments, transfers of ownership, as well as issuance of new Grade A permits. “New” farms should also include farms that have not previously participated in the EU Health Certification Program.

5. The proposed instructions state “if a farm’s rolling mean... exceeds the maximum EU requirements, the milk supplier must notify AMS Dairy Programs...” (p 3).

NMPF and USDEC request clarification in the final regulation as to the responsibilities of the milk supplier when the farm’s rolling mean returns below the maximum EU requirements. For example, if a farm’s SCC mean exceeds 400,000 for August, the milk supplier must notify AMS. If the farm’s SCC mean is less than 400,000 in September, is additional communication with AMS necessary?

6. The proposed instructions state “if either of the farm’s means exceeds the EU requirements for three consecutive months...” (p 3).

NMPF and USDEC request clarification in the final regulation that these means (SPC and SCC) are mutually exclusive. For example, if a farm’s SPC mean exceeds the requirement in June, and the farm’s SCC means in July and August exceed the requirement, this farm should not be considered out of compliance simply because these three months occurred consecutively.

7. The proposed instructions state “if either of the farm’s means exceeds the EU requirements for three consecutive months after the above notification to AMS Dairy Programs...” (p 3).

NMPF and USDEC request clarification in the final regulation (perhaps by including an example) of the timeline before a producer would be considered out of compliance – at which point the milk supplier must make decisions about the fate of milk from that farm. Our understanding, based on the draft proposal, is that after notifying AMS, the farm has three additional, consecutive months to reduce their mean. After this point, the farm would no longer be able to ship milk for export to the EU. As an example, if the rolling three-month mean for SCC for a particular farm were greater than 400,000 beginning in

month #1 below (and continuing to be above 400,000 thereafter):

**Example 3. Actions of milk supplier when a farm's rolling SCC mean exceeds 400,000.**

Month	Actions
1	Milk ok for export. Notify AMS.
2	Milk ok for export. (1 <sup>st</sup> month)
3	Milk ok for export. (2 <sup>nd</sup> month)
4	Milk ok for export. (3 <sup>rd</sup> month)
5	Milk NOT ok for export. Milk supplier must suspend, segregate, discontinue certification, or request derogation for month #5.

**Derogations.**

8. According to the proposed instructions from AMS, “if either of the farm’s means exceeds the EU requirements for three consecutive months after the above notification to AMS Dairy Programs, the milk supplier must... ask for a derogation” (p 3).  
NMPF and USDEC request clarification in the final regulation as to when a derogation may be requested. For example, some milk suppliers, in anticipation of a producer being out of compliance, may want to request a derogation in advance of actually needing one for a particular farm. Or, for logistical reasons, a milk supplier may want to request derogations for multiple farms at a single time, rather than requesting derogations for single farms over multiple days or weeks. We recognize that, by requesting a derogation in advance, the milk supplier is assuming the costs associated with that derogation request, regardless of whether or not it is eventually needed. However, as the instructions are currently worded, it suggests that a derogation may only be requested after a farm has exceeded the EU requirements for three consecutive months after notifying AMS.
9. With respect to derogations, NMPF and USDEC also request clarification in the final regulation as to whether the derogation for a farm is specific to being out of compliance for either the SPC or the SCC requirements, or for both requirements. If the derogations are specific to either SPC or SCC, a farm could operate under two derogations simultaneously. As an example: while a farm has a derogation in place for exceeding the SPC requirement, corrective actions and monitoring activities are expected to continue. Therefore, it is possible during this time period that the farm could also exceed the SCC requirement. Would AMS Dairy Programs have to be notified when the farm first exceeds the SCC requirement? If the high SCC means continue, would another

derogation need to be requested for this farm?

10. With respect to derogations, NMPF and USDEC would like some additional information from AMS as to how long the approval process for a derogation is expected to take. Our current understanding from discussions with AMS is that the request will be computerized, and that a derogation will be granted (potentially by an automatic confirmation email, etc.) immediately. If this is not correct, we request clarification of the derogation review process as well as an estimated length of time to complete this review, as this will affect our understanding of the logistics and timing of the program with respect to determining how to handle milk from farms that may be out of compliance.
11. The proposed instructions from AMS state the milk supplier shall provide a COC for milk collected in a given month (p 4).  
NMPF and USDEC request clarification in the final regulation that the COC cover the milk that was delivered in a given month. Milk can be collected without entering commerce, and “delivery” of milk more specifically describes milk entering commerce.
12. The proposed instructions from AMS state the milk supplier shall provide a COC for milk collected (*delivered*) in a given month, based on the rolling three-month mean from the previous month (p 4).  
NMPF and USDEC agree that the data collected should be used to verify farm compliance looking forward. Given that regulation of somatic cell count levels in milk products is a quality parameter, the most feasible method of testing and monitoring would be to implement a system where tests conducted are used to determine compliance for the immediately subsequent month (i.e. tests conducted in January will determine compliance for February). This avoids a milk supplier having to recall product that may have moved significantly through the supply chain before the monthly sample is collected and analyzed.

By implementing the system in this manner, milk suppliers can adequately track the individual farms supplying milk and apply for derogations when they expect a farm will be out of compliance. This avoids a potential gap (or lag in time) between the time that a farm is out of compliance and the time when a derogation is requested. As an example:

**Example 4. Using monthly SCC data to calculate a rolling three-month mean to determine compliance of product for export to EU.**

	Data for determining compliance for export of product to EU		
Month	Monthly data for rolling three-month mean for SCC	Result of rolling three-month mean for SCC	Actions
January	Oct, Nov, Dec	> 400,000	Milk ok for export in Jan. Notify AMS.
February	Nov, Dec, Jan	> 400,000	Milk ok for export in Feb. (1 <sup>st</sup> month)
March	Dec, Jan, Feb	> 400,000	Milk ok for export in Mar. (2 <sup>nd</sup> month)
April	Jan, Feb, Mar	> 400,000	Milk ok for export in Apr. (3 <sup>rd</sup> month)
May	Feb, Mar, Apr	> 400,000	Milk NOT ok for export in May. Producer is out of compliance. Milk supplier will request derogation for the month of May.

Based on this example, the producer is in compliance and can supply milk for export to the EU during the months of January through April. For the month of May, the producer would be out of compliance and the supplier would need a derogation in place (or segregate, etc.).

If the data collected always refers to the compliance status of the producer going forward, the milk supplier has some time (between the time the sample is analyzed and the end of the month) to determine how to handle out-of-compliance farms. In the example above, when the data from the April sample is reviewed, the supplier would then know that this farm would be out-of-compliance in May. Knowing in advance when a derogation will be needed allows the milk supplier to submit a request for a derogation in a timely manner (otherwise, derogations would have to apply retroactively, or derogations would have to be requested in anticipation of being out of compliance, which represents an increased cost to industry if not eventually needed ).

13. The proposed instructions state, “In the event of a farm’s continued non-compliance, a derogation must be reapplied for one year following the issuance of a derogation” (p 3). NMPF and USDEC request AMS clarify the conditions under which a derogation would be denied.
14. The proposed instructions state that a milk supplier may request a “seasonal derogation”, provided the farm is able to demonstrate through records this variation is truly seasonal (p

4).

NMPF and USDEC appreciate AMS acknowledging flexibility for seasonal increases in SCC, which are beyond the control of the producer. We request that AMS recognize a variety of data and records formats be acceptable to support a request for a seasonal derogation, and that examples of such data/records be indicated in the final regulation (i.e., DHIA data, pay stub information, etc.). We would also suggest that APHIS data for a general geographic region of the US be considered acceptable for a farm in that region, in the event that other records are unavailable.

NMPF and USDEC also request that AMS indicate in the final regulation that more than one year's worth of data to support a request for a seasonal derogation would not be required, as this would be unfair and unduly burdensome to new producers.

15. The proposed instructions state, "a seasonal derogation will be granted to a farm that can demonstrate for a majority of the year they are in compliance" (p 4).

NMPF and USDEC request AMS approve seasonal derogations when the producer can demonstrate compliance at least eight months of the year. Current APHIS data suggests increases in SCC due to seasonality occur over a period of four months.

16. With respect to seasonal derogations, NMPF and USDEC request additional detail in the final regulation about how the derogations will be applied, and which monthly calculations will be supported by the derogation.

Is the derogation specific to certain times of year? Or, if the derogation is related to a specific weather condition (i.e., heat), could the seasonal derogation apply to any months in a general timeframe around which hot weather may be typical (which may allow for the effects of an early/late summer)?

If the derogation is specific to certain months, how is it applied relative to the rolling three-month mean calculation? For example, if a specific farm can demonstrate seasonal increases in June, July, and August, does their seasonal derogation apply only to those times when that data is used to calculate the farm's rolling three-month mean (July through November, per example below)?



**Example 5. SCC data collected during a derogation relative to the rolling three-month mean.**

Month	Monthly data for rolling three-month mean for SCC
<b>June*</b>	March, April, May
<b>July*</b>	April, May, <b>June*</b>
<b>August*</b>	May, <b>June*</b> , <b>July*</b>
September	<b>June*</b> , <b>July*</b> , <b>August*</b>
October	<b>July*</b> , <b>August*</b> , Sept
November	<b>August*</b> , Sept, Oct

17. NMPF and USDEC request additional information in the final regulation about the methods by which a farm re-establishes compliance after being on a derogation (or being segregated, or suspended).

What is needed for a farm to re-qualify in the program? How are the rolling three-month means calculated after a derogation? What are the responsibilities of the milk supplier with respect to communicating the re-entry of a farm into the program to AMS?

NMPF and USDEC urge AMS to consider that, when a farm re-establishes compliance (after seasonal or non-compliant derogations), the farm should be treated as a new farm to the program; the farm should have three months to re-establish a baseline mean. During derogations, monitoring activities are expected to continue, so farms that are on derogations will have data collected during these time periods. However, samples collected while the farm is covered by a derogation (or is on suspension, or segregation), should not be used in determining the rolling three-month mean as this will unfairly negate the farm's corrective actions.

Likewise, the months immediately prior to the derogation request should not be considered in the post-derogation baseline mean (i.e., the derogation should not be treated as a "gap" in data collected). These pre-derogation SCC or SPC data were high enough to require a derogation, and to include them toward the post-derogation mean would also unfairly negate the farm's corrective actions.

This issue is particularly important when considering seasonal derogations or renewed derogations where a farm may have been on a derogation for a significant time period (> 1 year). In the example below, the farm was able to implement corrective actions and

reduce their SCC until it was below 400,000 after one year, at which point the derogation expired. This producer should have three months to re-establish their rolling mean (data from April, May, June). It would not be fair to the producer to include either the data from when the farm was on the derogation (Year 2: January, February, March) or prior to the derogation taking effect (Year 1: February, March, April).

**Example 6. Calculating rolling three-month means around derogations.**

Data for determining compliance for export of product to EU			
Month	Monthly data for rolling three-month mean for SCC	Result of rolling three-month mean for SCC	Actions
<b>Year One</b>			
January	Oct, Nov, Dec	> 400,000	Milk ok for export in Jan. Notify AMS.
February	Nov, Dec, Jan	> 400,000	Milk ok for export in Feb. (1 <sup>st</sup> month)
March	Dec, Jan, Feb	> 400,000	Milk ok for export in Mar. (2 <sup>nd</sup> month)
April	Jan, Feb, Mar	> 400,000	Milk ok for export in Apr. (3 <sup>rd</sup> month)
May	Feb, Mar, Apr	> 400,000	Milk NOT ok for export in May. Producer is out of compliance. Milk supplier requests derogation, and farm operates under derogation.
June through... farm is on derogation, and monitoring of SCC continues, but remains > 400,000			
<b>Year Two</b>			
March	Dec, Jan, Feb	> 400,000	
April	Jan, Feb, Mar	> 400,000	
May: Derogation expires in May, and SCC data collected from the previous month (April) is below 400,000. Farm is back in the program and in compliance, but does not have a 3-month baseline mean.			
June: SCC data collected from previous month (May) is below 400,000. But farm still does not have a 3-month baseline mean.			
July	Apr, May, June	< 400,000	New baseline mean has been established.

## Review of Records and Product Traceback

- The proposed instructions indicate an AMS Dairy Programs Review of Records will verify COCs provided by the milk supplier demonstrate compliance with EU requirements.

NMPF and USDEC request AMS provide additional information in the final regulation about how the Review of Records will specifically be performed by AMS. How will documentation be tracked back from the applicant? Does the applicant need to identify

the raw milk supplier, or are they only responsible for identifying the entity immediately preceding them in the production chain?

NMPF and USDEC would like to discuss concepts related to product traceback with AMS, and how these complicated logistics will affect the Dairy Programs Review of Records. For example, if one milk supplier routinely ships to seven different processing plants, and one of those plants is identified as producing an ingredient or product that was exported to the EU, would AMS consider (1) all farms shipping for that milk supplier in a single audit (i.e., audit all farms for which that supplier issued COCs for milk complying with EU regulations), or would AMS (2) ask that milk supplier to provide records for only those farms that specifically shipped milk to that designated processing plant?

The logistics of transporting milk in the US are complicated. We hope to discuss some of our concerns about applying product traceback to the farm-level with AMS in the upcoming weeks.

19. The proposed instructions indicate records documenting compliance must be kept for a minimum of 12 months or since the last review, whichever is longer (p 4).

NMPF and USDEC seek additional clarification from AMS in the final regulation how the Review of Records will be conducted as it relates to recordkeeping. How will AMS conduct reviews so that milk suppliers will be assured of meeting the expectations for proper recordkeeping? For example, considering a group of farms shipping milk through a certain milk supplier to multiple processing facilities, where this milk is processed into a variety of products for export to the EU – after AMS conducts a Review of Records for a product that was shipped to the EU, what records is the milk supplier able to dispose of? Can the milk supplier dispose of all records for all farms from which they typically receive milk? Can the milk supplier dispose of only records for the 10% of farms that were randomly selected by AMS for review? If the milk supplier disposes of records, these farms may subsequently be identified by AMS through another Review of Records tracing back from a different product that was exported to the EU. We request additional clarification from AMS about recordkeeping expectations, perhaps through more detailed discussions between industry and AMS.

20. NMPF and USDEC request additional discussions with AMS to review the logistics and expectations of product traceback. NMPF and USDEC would urge AMS to not require COCs issued by milk suppliers to indicate the specific farms on which the COC is based.

Simply referencing the milk supplier would be sufficient.

### **Responsibility of Processors**

21. The proposed instructions indicate a processor's COC will include... the dates the products/ingredient (for which the COC is issued) were processed (p 5).

NMPF and USDEC urge AMS to consider the "dates" of product/ingredient manufacture to be the calendar month and year during which the products were manufactured, rather than a specific day of manufacture.

### **Fees**

22. The proposed instructions indicate AMS will charge the milk supplier an administrative fee of two hours for each derogation application (seasonal or otherwise) (p 4).

NMPF and USDEC request AMS explain the methodology for determining two hours of time for each derogation. Additionally, we urge AMS to consider charging fees based on actual time spent processing the derogations.

A standard derogation is valid for one year, while seasonal derogations are valid for three years. The fact that AMS is charging a two-hour fee for both derogations – for their administration and recordkeeping – suggests that time spent on record maintenance is minimal and that the fee is primarily to compensate AMS for the time spent on issuing the derogations. The evaluation of relevant paperwork or supporting documentation (as is requested for the derogations) and actual issuance of a derogation does not seem to support a two-hour timeframe. If the derogation request is managed electronically and automatically via a computer system, and with minimal AMS staff oversight, two hours of time seems to be an overestimate.

23. The proposed instructions indicate that AMS will charge the entity that supplied milk to the processor for the AMS Dairy Programs Review of Records (p 6). In verbal communications with AMS staff after the most recent version of the program document was prepared, it has been reported that the exporter will be charged for the Review of Records.

NMPF and USDEC request clarification on this point to understand the process AMS will undertake to review records and prepare invoices for applicants. The milk supplier should not be financially responsible for the actions of the entire supply chain. The

applicant for the export certificate should be responsible for the fees associated with the Review of Records.

We look forward to discussing these comments, as well as other details of the draft program, in person later this month. In the mean time, please contact us for additional information or questions.

Sincerely,



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*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 31 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.*

*The U.S. Dairy Export Council (USDEC) is a non-profit, independent membership organization that represents the global trade interests of U.S. dairy producers, proprietary processors and cooperatives, ingredient suppliers and export traders. Its mission is to enhance U.S. global competitiveness and assist the U.S. industry to increase its global dairy ingredient sales and exports of U.S. dairy products. USDEC accomplishes this through programs in market development that build global demand for U.S. dairy products, resolve market access barriers and advance industry trade policy goals. USDEC is supported by staff across the United States and overseas in Mexico, South America, Asia, Middle East and Europe.*