

ATTACHMENT-33

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July 9, 1999

VIA FACSIMILE

Mali Reddy, Ph.D.
International Media and Cultures
2550 Larimer Street
Denver, CO 80205

Dear Dr. Reddy:

Thank you for your telephone call concerning the status of starter culture and starter culture media (media) for use in cheesemaking. There are no standards established in FDA regulations for starter cultures or media. Generally, the FDA's cheese standards state that a lactic acid-producing bacterial culture may be used in the manufacture of certain cheeses.

Whether or not a cheese has a standard of identity, there is one common requirement on the use of any ingredient; it must be safe and suitable. Basically, it must be GRAS or approved for its intended use by an FDA regulation, and is only added at a level no higher than is necessary to achieve its intended function, e.g., as a starter culture.

As you know, USDA has established procedures and interpretations for its inspectors in evaluating USDA inspected cheese plants. Some of the directions are aimed at preventing the misuse of starter culture and media as a way in which milk for cheese making can be inappropriately fortified. A copy of the relevant language from the USDA's instructions to its inspectors from the Plant Survey Guidelines is enclosed. There is no discussion about the composition of starter culture. Apparently, USDA believes that by limiting the amount of starter culture and media which can be used in cheesemaking the potential for abuse is minimized.

With respect to the labeling of ingredients used in starter culture, they would be subject to the same requirements as all other ingredients used in food. The starter culture may include ingredients which are not required to appear on the label of the finished food.

The exemptions are set forth in 21 CFR § 101.100, a copy of which is enclosed. The one relied on by many food processors is the exemption for incidental additives 21 CFR § 101.100(a)(3).

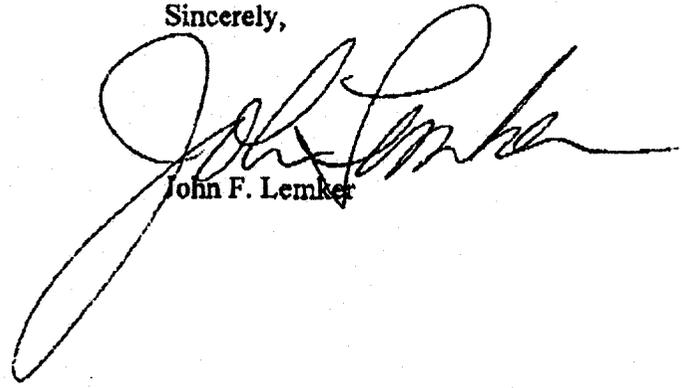
The essence of this exemption is that a substance which is either removed during processing or is present only at an insignificant level and has no technical or functional effect in the finished food, is not required to be listed in the declaration of ingredients.

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I believe that this responds to your questions regarding the use and labeling of starter cultures in cheese. If you have any further questions, please contact me.

Sincerely,

A large, stylized handwritten signature in black ink, appearing to read "John F. Lemker". The signature is written over the printed name below it.

John F. Lemker

JFL:cg

DA INSTRUCTION NO. 918-PS

Starter Facilities**Item C12—Room Construction (58.126, 58.406).**

See the guidelines for Item A1—Room Construction.

The wording of §58.406 permits either, 1) a separate starter room or, 2) "properly designed starter tanks and satisfactory air movement techniques." Although a separate starter room is desirable, it is not required when specially designed bulk starter tanks are used. Such tanks usually have enclosed dome tops, high efficiency filtration of air admitted to the tank, and are mechanically cleaned. Although a separate starter room is not required, starter making is still considered a processing activity. Therefore, the tanks must be located in a processing room or area and shall not be located near areas where contamination is likely to occur. These same requirements apply to secondary starters. In addition, starters shall not be processed in close proximity to equipment such as boilers, open type separators, whey tanks, or other probable sources of contamination.

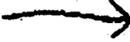
Also check the floor, walls ceiling and lighting in the room or area. Make recommendations as may be necessary. Floor drains are not required if the floor is sloped to drain to an exit.

If the plant is using "direct set" starter, show NA for Items C12-18 because special starter facilities are not needed. In such case, show the heading "Direct set starter used" for blank Item C19. Check the item satisfactory if the plant is thawing the cans of concentrated culture and drying the can exterior in a sanitary manner before adding the contents to the vat (it is not necessary to check plant facilities for storage and thawing of the cans of starter).

Item C13—Lighting & Ventilation (58.126d, 58.406).

See the guidelines for Item A2—Lighting & Ventilation.

The manager should be encouraged to provide a filtered air supply to the starter room. The air should be obtained from an outside source and thereby provide a positive pressure in the room to minimize the possibility of contamination. Air filters for ventilation of starter rooms should have a minimum average efficiency of 90% when tested by the ASHRAE Synthetic Dust Arrestance test (same efficiency as required for spray dryers for air to be heated). This is intended as a guide for management regarding a minimum efficiency for such filters. It is, of course, optional if more efficient filters are chosen. Since this is a "should" item, it will not be necessary to ascertain efficiency of existing filters or to report such information on the report.

 **Item C14—Media Storage & Reconstitution (58.126e, 58.128).**

Many plants use special dry bulk starter preparations to make up bulk starter. It is not necessary for bulk starter media to be manufactured in a USDA approved plant. All other dairy

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ingredients in the cheese that are allowed by a standard of identity shall be from approved sources.

Check for orderly storage of bags of starter media up off the floor on racks or pallets. When considerable amounts of starter are made, a separate room should be recommended for storing a small supply of media and for performing the dumping and reconstitution operations.

Inspect the equipment used for reconstitution (usually a funnel and recirculating pump). If a Ladish Company "Tri-Blender" is used, check that the valve between the funnel and pump is an approved 3-A sanitary type. They are sometimes supplied for food uses with a series 55 butterfly type valve that does not conform to 3-A requirements. If so, recommend replacement. If possible during the survey, also check that bag dumping is carried out in a sanitary manner.

Misuse of starter media in the cheese making process is a serious problem. This involves the use of excessive amounts of starter media or the inappropriate addition of dry starter media for the fortification of milk for cheese making. Some things to check include:

1. In cheese making, active starter culture is generally added to milk at the rate of 1-2%. Excessive addition of starter media is unsatisfactory as it is a method of fortification, consider amounts of 3% or more as excessive. When observed usage is greater than 3% recommend discontinuing the improper use of starter to fortify the cheese (category A deficiency).
2. Whey cream can also be used to standardize the cheese milk, in the plant where it was produced, provided it is properly handled and the process is inspected by the USDA (Page W is required). The whey cream shall be pasteurized prior to the vats, either in separate equipment at a minimum of 166 for not less than 15 seconds, or by addition to the balance tank. If the whey cream is added to the balance tank, it can be pasteurized at a minimum of 161°F for not less than 15 seconds. Alternately, the cheese shall be labeled as "raw milk cheese" or "cheese for manufacturing" (see the guidelines for Item C54 for labeling requirements).
3. Whether using commercial starter media or plant blended whey fractions, the starter culture shall be viable. If the starter does not contain an active culture, it is being used to fortify the cheese milk. However, only the optional ingredients listed in the Standard of Identity can be used to fortify the cheese milk. Therefore, secondary starter that contains whey fractions cannot be heat-treated just before being added to the vats. If the starter is being misused in this manner, notify the National Field Office and assign the INELIGIBLE status (category A deficiency).

The use of secondary starters is acceptable, provided they are used according to all the above guidelines. In summary:

1. Less than 3% total starter is used.

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2. Appropriate temperatures are used.
3. Handled as a starter (i.e., made in the starter room or specially designed starter tanks).
4. Appropriate powder handling equipment is used for reconstituting the secondary starter media.

Item C15—Media Heat-Treating Equipment (158.128j, k).

See the guidelines for Item A27—Product Cooler.

Use this item to cover inspection of equipment used for continuous heat-treating of bulk starter media prior to piping to starter vats for inoculation. Such equipment usually consists of heat exchangers to bring the temperature to 200-250°F, a hold tube, and regenerative cooler. The equipment should be "3-A" engineered for pasteurization, but this is not a requirement. Make recommendations as may be applicable.

Show NA for this item if the plant performs the heat-treating in the starter making vats, which is a common practice in small or medium sized operations.

Item C16—Processing Vats (58.415).

Inspect the processing vats for condition and cleanliness giving particular attention to appurtenances, such as vents, agitator, valve outlet, etc. Also, check that the vats are made of stainless steel, in good repair, equipped with tight fitting lids and have adequate temperature controls such as valves, indicating thermometers, and recording thermometers.

§58.415 requires that, "New or replacement vats shall be constructed according to the applicable 3-A Sanitary Standards" (formerly a "should" item). There is no special 3-A Sanitary Standard that pertains only to starter vats. However, there are two 3-A Sanitary Standards which are applicable to commonly used processes of starter making:

1. When the bulk starter media is mixed, heat-treated or pasteurized, set, incubated, and cooled in the same vat, *3-A Sanitary Standards for Non-Coil Type Batch Pasteurizers, Number 24* is applicable (this process is likely to be encountered at only small or medium size cheese operations).
2. When the bulk starter media is heat-treated with continuous type heating equipment and is then piped to a vat for subsequent inoculation and incubation, *3-A Sanitary Standards for Non-Coil Type Batch Processors for Milk and Milk Products, Number 25* is applicable for the vat (this process is most popular at medium or large size cheese operations).

If inspection of new or replacement vats reveals no 3-A symbol, handle in the same manner as outlined for item A3—Pumps, Pipelines, & Valves.