

INDIANA STATE DEPARTMENT OF HEALTH

INDIANAPOLIS

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TO: All Local Health Departments
Attention: Chief Food Specialist

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SUBJECT: Guideline for Excluded Items under Section 191,
“Ready-to-Eat, Potentially Hazardous Food; Date Marking”

As a result of changes in the Food & Drug Administration (FDA) 2005 Model Food Code, Section 3-501.17 and Annex 3 – Public Health Reasons, this guideline is being provided to explain why certain food items in a retail food establishment are excluded from the date marking requirements listed under Section 191 of the Indiana State Department of Health “Retail Food Establishment Rule” (Rule), 410 IAC 7-24, “Ready-to-Eat, Potentially Hazardous Food; Date Marking” and to assist in the application of this section. This guideline document revises and expands upon a previously distributed document on the same topic dated May 8, 2001.

As you are aware, the date marking provision was introduced into the FDA Model Food Code (FDA Code) because of the potential for growth over time of psychotropic organisms, such as *Listeria monocytogenes* (*L. monocytogenes*) in some refrigerated, ready-to-eat foods. *L. monocytogenes* growth is significantly slowed, but not stopped by refrigeration. Over a period of time, this and similar organisms may increase their risk to public health in ready-to-eat (RTE) foods.

The date by which the food must be consumed takes into consideration the differences in growth of *L. monocytogenes* at 41 degrees Fahrenheit (41F) and 45 degrees Fahrenheit (45F). Based on a predictive growth curve modeling program for *L. monocytogenes*, ready-to-eat, potentially hazardous food (PHF) may be kept at 41F a total of 7 days or at 45F a total of 4 days. Therefore, the period of time allowed before consumption is shortened for food in refrigerators incapable of maintaining food at 41F, but capable of maintaining it at 45F or below.

PHF RTE food which is prepared and held refrigerated for more than 24 hours, or prepared, frozen, and thawed must be controlled by date marking to ensure its safety based on the total amount of time it was held at refrigeration temperatures and the opportunity for *L. monocytogenes* to multiply, before freezing and after thawing. PHF RTE foods must be consumed, sold or discarded by the expiration date. Date marking is the mechanism by which the Rule requires active managerial control of the temperature and time combinations for cold holding. Each establishment must implement a system of identifying the date or day by which the date marked food must be consumed, sold, or discarded. Date marking requirements apply to containers of potentially hazardous processed food that have been opened and to potentially

hazardous food prepared by a retail food establishment, in both cases if held for more than 24 hours, and while the food is under the control of the food establishment. This provision applies to both bulk and display containers. It is not the intent of the Rule to require date marking on the labels of consumer size packages.

When required, a date marking system must be used which places information on the food, such as on an over wrap or on the food container, that identifies the first day of preparation, or alternatively, may identify the last day that the food may be sold or consumed on the premises. A date marking system may use calendar dates, days of the week, color-coded marks, or other effective means, provided the system is disclosed to the regulatory authority upon request, during inspections.

FDA/USDA/CDC *L. monocytogenes* Risk Assessment

In September, 2003, FDA, in cooperation with USDA/FSIS and CDC, released the [Quantitative Assessment of the Relative Risk to Public Health from Foodborne *L. monocytogenes* Among Selected Categories of Ready-to-Eat Foods](#). This initiative included the development of 23 separate risk assessments and analysis of the relative risks of serious illness and death associated with consumption of 23 categories of RTE foods. These categories included: seafood, produce, meats, dairy products, and deli salads.

In examining these closely, FDA showed that five (5) factors are important in measuring the public health impact to consumers from foodborne listeriosis. These factors are: (1) amounts and frequency of consumption of a RTE food; (2) frequency and levels of *L. monocytogenes* in a RTE food; (3) potential of the food to support growth of the bacterium during refrigeration; (4) refrigerated storage temperature; and (5) duration of refrigerated storage before consumption. Based on these five (5) factors, the 23 categories of RTE foods were ranked according to their relative risk of contamination and growth of *L. monocytogenes*. The risk categories used were: very high risk; high risk; moderate risk; low risk; and very low risk.

Impact of the *L. monocytogenes* Risk Assessment on Date Marking

Based on the results of the risk assessment and the recommendations from the 2004 Conference for Food Protection meeting, it was necessary to re-evaluate date marking in an effort to focus the provision on very high and high risk foods, while at the same time, exempting foods that present a very low, or low risk of contamination and growth of *L. monocytogenes*. Based on this evaluation, exceptions currently listed under Section 191(e) of the Rule are being expanded to exclude the following foods from date marking:

Deli Salads Prepared and Packaged in a Food Processing Plant

According to data from the risk assessment, deli salads prepared and packaged by a food processing plant contain sufficient acidity, along with the addition of preservatives (e.g., sorbate, benzoates), to prevent the growth of *L. monocytogenes*. Examples of deli salads include ham salad, chicken salad, egg salad, seafood salad, pasta salad, potato salad, and macaroni salad, manufactured according to 21 CFR 110. There are estimates that 85% of all deli salads are

prepared and packaged in a food processing plant and do not support growth. Based on discussions with deli salad manufacturers and trade associations, it is a nearly universal practice for food processing plants preparing and packaging deli salads to add one or more preservatives that inhibit the growth of *L. monocytogenes*. Based on their wide use within this segment of the industry and their effectiveness at inhibiting the growth of *L. monocytogenes*, all deli salads prepared and packaged in a food processing plant are exempt from date marking. However, all deli salads prepared in a food establishment **do require** date marking.

Hard and Semi-Soft Cheeses

In December, 1999, FDA issued an exemption from date marking for certain types of hard and semi-soft cheeses (<http://www.cfsan.fda.gov/~ear/ret-chdt.html>), based on the presence of several factors that may control the growth of *L. monocytogenes*. These factors may include organic acids, preservatives, competing microorganisms, pH, water activity, or salt concentration. The results of the risk assessment support this interpretation and therefore, hard and semi-soft cheeses each manufactured according to 21 CFR 133 are exempt from date marking.

LIST OF SOME HARD AND SEMISOFT CHEESES EXEMPT FROM DATE MARKING			
EXAMPLES OF HARD CHEESES CONTAINING NOT MORE THAN 39% MOISTURE (21 CFR 133.150)		EXAMPLES OF SEMISOFT CHEESES CONTAINING MORE THAN 39%, BUT NOT MORE THAN 50% MOISTURE (21 CFR 133.187)	
Asadero	Lorraine	Asiago soft	Manchego
Abertam	Oaxaca	Battelmatt	Monterey
Appenzeller	Parmesan	Bellelay (blue veined)	Monterey Jack
Asiago medium or old	Pecorino	Blue	Muenster
Bra	Queso Anejo	Brick	Oka
Cheddar	Queso Chihuahua	Caciocavallo Siciliano	Pasteurized Process
Christalina	Queso de Prensa	Camosum	Cheese (labeled as
Cotija Anejo	Romanello	Chantelle	containing an
Cotija	Romano	Colby(not more than	acidifying agent)
Coon	Reggiano	40% moisture)	Port du Salut
Derby	Sapsago	Edam	Provolone
Emmentaler	Sassenage (blue	Fontina	Queso de Bola
English Dairy	viened)	Gorgonzola (blue	Queso de la Tierra
Gex (blue viened)	Stilton (blue viened)	viened)	Robbiole
Gloucester	Swiss	Gouda	Roquefort (blue
Gjetost	Tignard (blue viened)	Havarti	viened)
Gruyere	Vize	Konigskase	Samsoe
Herve	Wensleydale (blue	Limburger	Tilsiter
Lapland	veined)	Milano	Trappist

Cheeses that are *NOT* exempt from the date marking provisions include soft cheese, such as Brie, Camembert, Cottage Cheese, Ricotta, and Teleme.

Cultured Dairy Products

Cultured dairy products include yogurt, sour cream, and buttermilk, each manufactured according to 21 CFR 131. Many of these products often are low pH foods manufactured with lactic acid fermentation. Data from the risk assessment show that *L. monocytogenes* does not grow in these foods and therefore, these products are exempt from date marking.

Preserved Fish Products

Preserved fish products include pickled herring and dried, or salted cod, and other acidified fish products, manufactured according to 21 CFR 114. Data from the risk assessment show that the high salt and/or acidity of these products does not allow for the growth of *L. monocytogenes* and therefore, these products are exempt from date marking.

This exemption does not apply to hot or cold smoked fish products, nor does it apply to fish products that are dried, marinated, or otherwise preserved on-site, in a food establishment, such as ceviche.

USDA/BOAH-regulated products

Date marking provisions of the Rule do not apply to shelf stable RTE meat and poultry products. Shelf stable RTE meat and poultry products are not required by USDA to be labeled “Keep Refrigerated.” For these products, the nitrite and salt in the cure and the lower pH resulting from fermentation give additional protection against microbial growth. Some fermented sausages and salt-cured products are shelf stable, do not require refrigeration, and do not bear the label “Keep Refrigerated.” To be shelf stable, a product manufactured under USDA inspection must have a process that results in a product that meets one of the recognized objective criteria for shelf stability, such as water activity, moisture/protein ratio (MPR), or combination of MPR and pH (acidity). Therefore they are exempt from the Section 191 date marking requirements.

Shelf stable fermented sausages, such as pepperoni and dry salami, do not have to be refrigerated or date marked. Shelf stable salt-cured products such as prosciutto, country cured ham, or Parma ham do not require refrigeration or date marking. Other salt-cured products include basturma, breasaola, coppa, and capocola.

Some RTE fermented sausages and salt-cured products must be refrigerated and therefore, bear the USDA-required label “Keep Refrigerated.” Examples of these products are cooked bologna, cooked salami, and sliced country hams which are RTE fermented products that need refrigeration. Bologna is a cooked, perishable sausage and there are other salamis, e.g., cotto, that are perishable.

Regarding the exemption from date marking for shelf-stable sausages in a casing, the exemption does not apply if the casing is removed. The intact casing on shelf-stable sausages may be over

wrapped to protect the cut face of the sausage. With shelf stable non- potentially hazardous sausages, the intact casing provides a barrier to contamination (although not an absolute one), the exposed face is likely to be sliced again within 4 or 7 days, and contamination is minimized because only the face is exposed. The coagulated protein that occurs on the surface of some nonshelf stable cooked sausages is not a casing.

Slices of cured and fermented sausages that require refrigeration and are kept for 24 hours or longer do need to be date marked. If open dating information is applied to lunchmeats at a federally inspected meat or poultry establishment, the information must comply with the requirements in 9 CFR 317.8 and 381.129; however, such dating is not required by USDA/FSIS.

Manufacturer's "Use-by" Dates

It is not the intent of this provision to give a product an extended shelf life beyond that intended by the manufacturer. Manufacturers assign a date to products for various reasons, and spoilage may or may not occur before pathogen growth renders the product unsafe. Most, but not all, sell-by or use-by dates are voluntarily placed on food packages.

Although most use-by and sell-by dates are not enforceable by regulators, the manufacturer's use-by date is its recommendation for using the product while its quality is at its best. Although it is a guide for quality, it could be based on food safety reasons. It is recommended that food establishments consider the manufacturer's information as good guidance to follow to maintain the quality (taste, smell, and appearance) and salability of the product. If the product becomes inferior quality-wise due to time in storage, it is possible that safety concerns are not far behind.

If you have questions regarding this topic or this document, please contact the Food Protection Program at 317-233-7360 or your Regional Food Protection Specialist.