



USDA and FDA Announce a Formal Agreement to Regulate Animal Cell Culture Technology

On March 7, 2019, FSIS and the Food and Drug Administration (FDA) announced a formal agreement to jointly oversee the production of human food products derived from the cells of livestock and poultry.

FSIS and FDA released a formal agreement to address the regulatory oversight of human food produced using this new technology. The formal agreement describes the oversight roles and responsibilities for both agencies and how the agencies will collaborate to regulate the development and entry of these products into commerce. This shared regulatory approach will facilitate the development, production, and labeling of a safe, wholesome and accurately labeled product for consumers.

To view the press release, visit the FSIS website at: <https://www.usda.gov/media/press-releases/2019/03/07/usda-and-fda-announce-formal-agreement-regulate-cell-cultured-food>.

To view the formal agreement, visit the FSIS website at: <https://www.fsis.usda.gov/formalagreement>

FSIS Issues Guidance to Industry for Responding to Customer Complaints

FSIS has issued a best practices guideline to help the meat and poultry industry respond to customer complaints that are determined to be associated with adulterated or misbranded meat and poultry products.

In 2012, FSIS announced a regulation requiring all establishments to report to the agency within 24 hours when they have shipped or received an adulterated product and that product is in commerce.

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While this requirement has been in effect for several years, recalls associated with foreign materials in product increased in recent years. FSIS intensified efforts and made presentations in 2018 to industry explaining that product containing foreign materials is adulterated even when a physical food safety hazard is not present. Additionally, the agency hosted two industry meetings to discuss an industry-drafted document of best practices for responding to foreign material customer complaints, which was published in August 2018.

The guideline reflects the agency's current position, and FSIS encourages industry to begin using it now. FSIS welcomes public comments on the guideline. The agency will accept comments for 60 days and will then update the document in response to suggestions, if necessary.

Comments may be submitted via the federal eRulemaking portal at: <http://www.regulations.gov>; by mail including CD-ROMs sent to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue S.W., Mailstop 3758, Room 6065, Washington, D.C., 20250-3700 or by hand-or courier-delivery to 1400 Independence Avenue S.W., Room 6065, Washington, D.C., 20250-3700. All items submitted by mail or electronic mail must include the agency name and docket number FSIS-2018-0034.

A downloadable version of the draft guideline is available to view and print at: <https://www.fsis.usda.gov/wps/wcm/connect/8d0a0e73-1e6f-424f-a41f-ea942247a5ff/Guideline-for-Industry-Response-Customer-Complaint.pdf?MOD=AJPERES>.

For more information, visit: <https://www.fsis.usda.gov/wps/portal/ffsis/topics/regulatory-compliance/compliance-guides-index/retail-guidance>.

Update on Label Approval Backlog and New Tips

FSIS is currently experiencing a delay of 24-25 business days in evaluations for labels that require review prior to use. The agency will continue to provide backlog updates and suggestions via the *Constituent Update* to assist industry in minimizing unnecessary label application submissions and to minimize the number of applications returned to the establishment for missing information. FSIS is hopeful that by providing updates and tips to industry it will achieve a faster, more efficient label evaluation process while reducing the label application backlog.

TIP: When submitting an application for temporary label approval, clearly indicate the specific reason(s) for temporary approval. Combine multiple labels into one temporary approval application if appropriate.

Temporary label approvals may be granted for labels that bear certain labeling deficiencies under the conditions described in 9 CFR 412.1(f). It is important that the specific reason(s) for which the temporary approval is requested is clearly described in the label application.

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FSIS Constituent Update is prepared by the Congressional and Public Affairs Staff, Office of Public Affairs and Consumer Education

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Export Requirements Updates

The Library of Export Requirements has been updated for the following countries:

European Union
Hong Kong
Japan
Morocco
New Caledonia
Panama
Republic of Korea
South Africa
Ukraine
Western Samoa

For a complete list of countries, visit <https://www.fsis.usda.gov/wps/portal/ffsis/topics/international-affairs/exporting-products>.

... Update on Label

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When submitting a label electronically through the Label Submission and Approval System (LSAS), the specific reason(s) for temporary approval can be described in the free text box in the “Temporary” section of the “Label Approval” menu or in a separate attachment. Label applications submitted via paper application (FSIS Form 7234-1) must include the reason(s) for temporary approval on the Continuation Sheet on page 4 or in an attached document.

The reason(s) for temporary approval need to be as specific as possible. For example, in the case of a formulation change resulting in a non-compliant ingredients statement, simply stating that the “formula has changed” or that there are “minor changes to the order of predominance” does not provide enough information for the FSIS staff officer to evaluate the request for temporary label approval. The impact of the formulation change on the information on the label must be noted in the application (e.g., specific ingredients not listed in the label, ingredients that have changed in the order of predominance and where in the ingredients statement they should be listed). One efficient way to clearly convey this information is to display the new formula and the old formula (or current non-compliant ingredients statement) side by side with the impacted ingredients highlighted.

When the same labeling deficiency impacts multiple products and, therefore, multiple labels, such as a change in order of predominance of ingredients in a purchased soy sauce impacting the sublisting of the soy sauce on multiple product labels, the establishment may submit one label in the temporary label application and reference all of the different products impacted rather than submitting one application for each product impacted.

In FSIS’ experience, the following information is often missing from temporary label applications, resulting in returned applications with requests for additional information:

- Addressing the four criteria for temporary label approval described in 9 CFR 412.1(f)(1)(i-iv);
- Providing the number of impacted labels on hand, information about the prior label approval and the amount of time requested to use the non-compliant labels. This information should be completed in the “Label Approval” section of LSAS after selecting “Temporary” as the label approval type, or by completing all of the fields in Box 6b of FSIS Form 7234-1; and
- Noting if the changes impact nutrition information on the label. When ingredients have changed, the application should note if the nutrition information on the label is impacted and if so, indicate which values have changed and provide the new values.

For assistance when applying for a temporary label approval in LSAS please see the “Approval Information” section beginning on page 95 at: <https://www.fsis.usda.gov/wps/wcm/connect/45a29f18-52cc-4012-8790-ab7ea9f980c9/LSAS-Industry-User-Guide-063015.pdf?MOD=AJPERES>.

Additional information about temporary label approval, can be found on the FSIS website at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures/requesting-temporary-approval/requesting-temporary-approval>.

Policy Update

FSIS notices and directives on public health and regulatory issues are available at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations>. The following policy update was recently issued:

Directive 1306.21

Privacy Controls for FSIS Information Systems

FSIS and CDC Create Infographic for Chefs, Cooks, and Caterers on Chicken Liver

Recent outbreaks of illness have been linked to undercooked chicken liver dishes prepared at restaurants or other foodservice settings. To encourage foodservice personnel to cook chicken liver to a safe minimum internal temperature of 165°F, FSIS and the Centers for Disease Control and Prevention (CDC), in collaboration with other public health partners, have created an infographic, available at: <https://www.cdc.gov/nceh/ehs/publications/chicken-liver-infographic.html>. For additional information on preventing foodborne illnesses associated with chicken liver, please visit: <https://www.fsis.usda.gov/ChickenLiver>.

FSIS Updates Online Consumer Complaint Form

FSIS has released an updated version of its online complaint reporting system, the Electronic Consumer Complaint Form (eCCF). The eCCF is available 24 hours a day and offers consumers, including state and local departments of health and schools, an additional means to report complaints associated with FSIS-regulated products. The new form offers information pop-ups to assist consumers through the complaint entry process and an interface designed to improve overall user experience. Now, consumers can report complaints in Spanish using the Spanish version of the form, upload pictures related to their complaint, and check the status of their complaint online. The new eCCF is available at <https://www.fsis.usda.gov/wps/portal/portal/fsis/topics/recalls-and-public-health-alerts/report-a-problem-with-food>.

New Tool Launched To Improve Consumer Food Safety At Home

On March 7, 2019, the Partnership for Food Safety Education (PFSE) launched a new tool that is expected to improve consumers' food safety behaviors at home. PFSE announced the release of a new Safe Recipe Style Guide at the 2019 Consumer Food Safety Education Conference in Orlando, Fla., where more than 400 public and private sector experts convened to address how to improve food safety behaviors.

The Safe Recipe Style Guide is designed for use by any recipe writer who writes and publicizes recipes for distribution to the public. It provides specific recipe text to address the four major areas of most food safety violations in home kitchens: temperature, handwashing, cross contamination and produce handling. It can be found online at: <https://www.saferecipeguide.org/>.

For more than 20 years, PFSE has led the charge on educating consumers about safe food handling practices – Clean, Separate, Cook, Chill – in the United States. It is comprised of 28 partner organizations including consumer groups, food industry associations, commodity groups, and professional associations in health and the sciences, as well as partnerships with the USDA, FDA and CDC. For more information, visit: <https://www.prnewswire.com/news-releases/new-tool-launched-to-improve-consumer-food-safety-at-home-300808596.html>.