



February 13, 2017

*By Electronic Mail*

Dr. Stephen Ostroff  
Acting Commissioner of Food and Drugs  
U.S. Food and Drug Administration  
White Oak Office Building 1  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[Stephen.Ostroff@fda.hhs.gov](mailto:Stephen.Ostroff@fda.hhs.gov)

**Re: Request for Extension and Alignment of Supplier Verification Compliance Dates**

Dear Dr. Ostroff,

The Food Marketing Institute together with the Grocery Manufacturers Association, American Frozen Food Institute, International Dairy Foods Association, United Fresh Produce Association, Association for Dressings & Sauces, Juice Products Association, Vinegar Institute, National Pasta Association, North American Millers' Association, American Bakers Association, National Association of Chemical Distributors, Peanut and Tree Nut Processors Association, SNAC International, Produce Marketing Association, National Confectioners Association, and the National Grocers Association are writing to request that the Food and Drug Administration (FDA) extend the compliance dates for supplier verification under the Preventive Controls for Human Food (PCHF) and Foreign Supplier Verification Program (FSVP) final rules and align the compliance dates as part of this extension. As explained in more detail below, our members need additional time and guidance from FDA to develop compliance programs for the supplier verification requirements under these rules. Additionally, it makes practical sense to align the compliance dates for both rules as part of an extension. Accordingly, we are requesting that FDA extend the compliance dates for supplier verification under PCHF (21 C.F.R. Part 117, Subpart G) and FSVP (21 C.F.R. § 1.500 *et seq.*) until May 28, 2018 for any current compliance deadline currently falling before that date.

The PCHF and FSVP regulations are groundbreaking in many respects. These are the first FDA regulations requiring implementation of comprehensive supplier verification programs. PCHF is the first regulation requiring supplier verification for domestically produced foods. FSVP is the first regulation where FDA has required supplier verification of all imported foods. FSVP also is the only FDA Food Safety Modernization Act (FSMA) regulation that may require entities that do not manufacture food, such as retailers, to engage in supplier verification. Compliance with these regulations is not just a matter of our members modifying existing programs. The regulatory requirements differ significantly from the voluntary supplier verification programs some of our members had implemented prior to FSMA. Further, whereas the Preventive Controls requirements

build on the well-established principles of HACCP, there was no uniform industry approach to supplier verification prior to FSMA. Needless to say, implementing these regulations is requiring considerable time, effort, and resources from our members.

The supplier verification regulations are detailed and record-intensive. For example, the PCHF regulation itemizes 18 different categories of records that need to be maintained to document the program. Compliance with the regulation is not as simple as just getting a copy of a reputable third-party audit for each supplier. Conducting individualized assessments of each supplier and preparing supporting documentation for the program is not an easy endeavor. We continue to receive many questions from our members regarding the legal requirements and compliance strategies, but often have to advise that we need to wait for further input from FDA on these issues.

Guidance from FDA is essential for our members to understand the agency's expectations and develop legally compliant supplier verification programs. There are many open questions that need clarification through guidance, and then once guidance is issued additional time will be necessary to respond to the direction provided in the agency's draft guidance. For example, there are many open questions about who bears FSVP responsibility as the "importer." We have discussed this issue with FDA previously and understand that it will be addressed in the agency's forthcoming draft guidance. Once we receive guidance on this threshold issue, additional time will be needed to respond accordingly so that the appropriate party in the supply chain develops the FSVP.

The first supplier verification compliance date, March 17, 2017, is just over one month away for many companies. The compliance date for FSVP, May 30, 2017, is less than four months away. Even if FDA were to issue draft guidance before these compliance dates, there would not be enough time for companies to adapt their programs to implement the guidance. Many of our members have hundreds or even thousands of suppliers requiring supplier verification, so it will take time to modify programs based on the agency's guidance.

Moreover, recent White House actions make it seem quite unlikely FDA will be able to issue the guidance industry needs to comply with these regulations prior to the compliance deadlines. As you likely know, on January 20, White House Chief of Staff Reince Priebus issued a memorandum to the heads of all executive departments and agencies directing them not to send any new regulations to the *Federal Register* for publication until an agency head appointed by President Donald Trump has reviewed and approved the regulation.<sup>1/</sup> This regulatory freeze applies not just to rulemakings, but also to guidance documents such as FDA's forthcoming FSVP guidance.

The practical effect of the Priebus Memorandum is that the release of this guidance likely will be delayed for some time, as the incoming Trump administration officials will need to work through a backlog of pending rules and guidance. In contrast, we expect that a notice delaying the compliance deadlines for existing regulations can be reviewed and approved by Trump administration officials much more quickly than a detailed, substantive guidance document that will require much more consideration.

It also is notable that the Food Safety Preventive Controls Alliance (FSPCA) just recently launched its FSVP training program, so the foundational knowledge base still needs to be built across industry. We understand that many food manufacturers also are looking to this training as a source of guidance on the PCHF supplier verification requirements in Subpart G, to supplement the chapter

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<sup>1/</sup> "Regulatory Freeze Pending Review," Memorandum for the Heads of Executive Departments and Agencies (Jan 20, 2017) ("Priebus Memorandum");

on supplier verification in the PCHF Preventive Controls Qualified Individual training. Further guidance and education is essential given that there is no precedent for these types of supplier verification programs. Industry has consistently expressed its willingness to comply with the supplier verification provisions, but our members have also consistently highlighted the need for training and guidance.

Additionally, because the substantive obligations for supplier verification under both PCHF and FSVP are parallel, it is unnecessarily complicated to have different initial compliance dates for each rule. This has caused confusion in industry and among suppliers that could easily be avoided. We understand that the compliance dates were set based on the different publication dates for each final rule. However, it now makes practical sense to harmonize the initial compliance dates for both rules together with extending the compliance dates.

We request that FDA extend the compliance date until May 28, 2018 for any current compliance deadline currently falling before that date. This would extend the initial FSVP compliance date by one year and extend the initial PCHF Subpart G compliance date by 14 months, as well as harmonizing these dates. We propose that all compliance dates falling after May 28, 2018 would remain the same. For ease of reference, we have identified whether and how each compliance deadline would be affected by the proposal in the chart included in the Appendix. This approach would allow industry time to incorporate FDA's forthcoming guidance into their compliance programs and resolve the challenges caused by having different initial compliance dates for the largest suppliers under both rules.

In summary, our members are anxiously awaiting much needed guidance from FDA in order to comply with the supplier verification requirements in PCHF and FSVP. Industry then will need additional time to incorporate FDA's guidance into their compliance programs. Accordingly, FMI, the Grocery Manufacturers Association, American Frozen Food Institute, International Dairy Foods Association, United Fresh Produce Association, Association for Dressings & Sauces, Juice Products Association, Vinegar Institute, National Pasta Association, North American Millers' Association, American Bakers Association, National Association of Chemical Distributors, Peanut and Tree Nut Processors Association, SNAC International, Produce Marketing Association, and National Confectioners Association request that FDA extend the initial compliance dates for supplier verification under PCHF (21 C.F.R. Part 117, Subpart G) and FSVP (21 C.F.R. § 1.500 *et seq.*) until May 28, 2018 for any current compliance deadline currently falling before that date.

We appreciate your consideration of this issue and look forward to your response. Please do not hesitate to contact us if you have any questions or if further information would be helpful to support this request.

cc: Erik P. Mettler, Associate Commissioner for Foods and Veterinary Medicine and Acting Deputy Commissioner for Foods and Veterinary Medicine

## Appendix:

FMI represents food retailers and wholesalers that operate nearly 40,000 retail food stores and 25,000 pharmacies, representing a combined annual sales volume of almost \$770 billion. FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains and mixed retail stores.

The Grocery Manufacturers Association is the voice of more than 250 leading food, beverage and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe. Based in Washington, D.C., GMA's member organizations include internationally recognized brands as well as steadily growing, localized brands.

The American Frozen Food Institute is the national trade association promoting and representing the interests of all segments of the frozen food and beverage industry. AFFI works to foster industry development and growth, and advocates before legislative and regulatory entities on the industry's behalf. More information can be found at [www.affi.org](http://www.affi.org).

The International Dairy Foods Association (IDFA) 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, the National Cheese Institute, and the International Ice Cream Association. IDFA's 200 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.

United Fresh Produce Association members represent the full breadth of the produce supply chain. From small family businesses to large international corporations, United Fresh member companies bring together companies across the produce industry to speak with one unified voice.

Produce Marketing Association is the leading trade association representing companies from every segment of the global produce and floral supply chain. PMA helps members grow by providing connections that expand business opportunities and increase sales and consumption. For more information, visit [www.pma.com](http://www.pma.com).

The Association for Dressings and Sauces (ADS) is the international trade association representing manufacturers of salad dressings, mayonnaise and condiment sauces and the suppliers to the industry.

The Vinegar Institute (VI) is an international trade association representing the vast majority of vinegar manufacturers and bottlers. VI also represents suppliers of goods or services to the vinegar industry.

The Juice Products Association (JPA) is the trade association representing the juice industry. JPA's membership includes processors, packers, extractors, brokers and marketers of fruit and vegetable

juices, drinks, bases, as well as industry suppliers, food testing laboratories and firms engaged in futures trading on behalf of JPA processor members.

The National Pasta Association provides leadership to the industry on public policy issues, serving as its voice in Washington, D.C. The National Pasta Association also forges alliances with key organizations, monitors and addresses technical issues, and organizes events and seminars for the industry.

The North American Millers' Association (NAMA) represents millers of wheat, corn, oats and rye in the US and Canada. Our members take the raw grain and, through grinding and crushing, create flour and other products that are used to make such favorite foods as bread, pasta, cookies, cakes, and snack foods.

The American Bakers Association is the Washington D.C.-based voice of the wholesale baking industry. Since 1897, ABA has represented the interests of bakers before the U.S. Congress, federal agencies, and international regulatory authorities. ABA advocates on behalf of more than 700 baking facilities and baking company suppliers. ABA members produce bread, rolls, crackers, bagels, sweet goods, tortillas and many other wholesome, nutritious, baked products for America's families. The baking industry generates more than \$102 billion in direct annual economic activity and employs over 706,000 highly-skilled people.

The National Association of Chemical Distributors and its nearly 440 member companies are vital to the chemical supply chain providing products to over 750,000 end users. NACD members are leaders in health, safety, security, and environmental performance through implementation of Responsible Distribution, established in 1991 as a condition of membership and a third-party verified management practice. For more information, visit [www.NACD.com](http://www.NACD.com).

The Peanut and Tree Nut Processors Association (PTNPA) serves as "The Voice for America's Nut Industry" through networking, educational and advocacy efforts. Established in 1939, the PTNPA includes and represents Member companies from all aspects of the nut industry including large multinational food companies and small family businesses – along with suppliers and companies that support the success and well-being of the nut industry.

SNAC International (formerly the Snack Food Association) is the international trade association of the snack food industry representing snack manufacturers and suppliers. SNAC International represents over 400 companies worldwide including but not limited to, manufacturers of potato chips, tortilla chips, cereal snacks, pretzels, popcorn, kettle corn, cheese snacks, snack crackers, meat snacks, pork rinds, snack nuts, party mix, corn snacks, pellet snacks, fruit snacks, snack bars, granola, snack cakes, cookies, and various other snacks.

The National Confectioners Association (NCA) is the trade organization representing the \$35 billion US confections industry. Over 250 companies, all members of NCA, manufacture the vast majority of the chocolate and confectionery products in the United States. Another 100 companies supply those manufacturers. NCA members are located in more than 40 states [with particular manufacturing concentration in Pennsylvania, California, New Jersey, Illinois, New York, Wisconsin, Texas, and Ohio]. The confectionery industry directly employs 55,000 people in more than 1,000 facilities across the United States, and more than 400,000 jobs in agriculture, retail, transportation

and other industries rely in part on the sale of confections for their livelihood. For every job that is created in confectionery another seven are supported in related industries. The confectionery industry includes hundreds of small, family-owned businesses that pass on candy-making expertise from generation to generation. Our members export over \$2 billion annually worldwide, and pay more than \$10 billion in taxes in the United States.

The National Grocers Association (NGA) is the national trade association representing the retail and wholesale grocers that comprise the independent sector of the food distribution industry. An independent retailer is a privately owned or controlled food retail company operating a variety of formats. Most are serviced by wholesale distributors, while others may be partially or fully self-distributing. Independents are the true “entrepreneurs” of the grocery industry and dedicated to their customers, associates, and communities. The independent grocery sector is accountable for close to 1 percent of the nation’s overall economy and is responsible for generating \$129.5 billion in sales, 944,000 jobs, \$30 billion in wages, and \$27 billion in taxes. NGA members include retail and wholesale grocers, state grocers associations, as well as manufacturers and service suppliers.

### Proposed Extended Compliance Dates

Category	Original Deadline	Proposed New Deadline
<b>Human Food Preventive Controls, Subpart G (Supplier Verification)<sup>2</sup></b>		
<b>A receiving facility that is a small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule</b>	September 18, 2017	May 28, 2018
<b>A receiving facility that is a small business and its supplier is subject to the human preventive controls rule or the produce safety rule</b>	The later of: September 18, 2017 or 6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the applicable rule	The later of: May 28, 2018 or 6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the applicable rule
<b>A receiving facility that is not a small business or a very small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule</b>	March 17, 2017	May 28, 2018
<b>A receiving facility that is not a small business or a very small business and its supplier will be subject to the human preventive controls rule or the produce safety rule</b>	6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the applicable rule	The later of: May 28, 2018 or 6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the applicable rule
<b>Foreign Supplier Verification Program<sup>3</sup></b>		
<b>FSVP importer whose foreign supplier is not subject to the PC or produce safety rules</b>	May 30, 2017	May 28, 2018
<b>FSVP importer whose foreign supplier is required to comply with the PC rule for human food. Compliance dates when foreign suppliers are in these categories:</b>		
-Small businesses as defined in 21 CFR 117.3	Mar. 19, 2018	May 28, 2018
-Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 117.3	Mar. 18, 2019	No change
-Suppliers subject to the Pasteurized Milk Ordinance	Mar. 18, 2019	No change

<sup>2</sup> Categories taken from Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. 55908, 56128 (Sept. 17, 2015).

<sup>3</sup> Categories taken from FDA guidance, "Compliance Dates for the Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals," <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm503822.htm>.

Category	Original Deadline	Proposed New Deadline
-“All Other” Businesses Suppliers	May 30, 2017	May 28, 2018
<b>FSVP importer of animal food whose foreign supplier is subject to the current good manufacturing practices (“CGMP”) requirements in subpart B of 21 CFR part 507 in the PC rule for animal food. Compliance dates when foreign suppliers are in these categories:</b>		
-Small Businesses as defined in 21 CFR 507.3	Mar. 19, 2018	May 28, 2018
-Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 507.3	Mar. 18, 2019	No change
-“All Other” Businesses	May 30, 2017	May 28, 2018
<b>FSVP importer whose foreign supplier is required to comply with the animal food preventive controls requirements in subpart C of part 507 of the PC rule for animal food, but that is not required to comply with the CGMP requirements in subpart B of 21 CFR part 507.</b>		
-Small Businesses as defined in 21 CFR 507	Mar. 18, 2019	No change
-Qualified Facilities (including Very Small Businesses) as defined in 21 CFR 507.3	Mar. 17, 2020	No change
-All Other” Businesses	Mar. 19, 2018	May 28, 2018
<b>FSVP importer whose foreign supplier is required to comply with the produce safety rule, except for the requirements applicable to sprouts in subpart M of 21 CFR part 112. Compliance dates when foreign suppliers are in these categories:</b>		
-Small Businesses as defined in 21 CFR 112.3	July 29, 2019	No change
-Very Small Businesses as defined in as defined in 21 CFR 112.3	July 27, 2020	No change
-“All Other” Businesses	July 26, 2018	No change
<b>FSVP importer whose foreign supplier is required to comply with the requirements in the produce safety rule applicable to sprouts in subpart M of 21 CFR part 112. Compliance dates when foreign suppliers are in these categories:</b>		
-Small Businesses as defined in 21	July 26, 2018	No change

<b>Category</b>	<b>Original Deadline</b>	<b>Proposed New Deadline</b>
CFR 112.3		
-Very Small Businesses as defined in 21 CFR 112.3	July 29, 2019	No change
-“All Other” Businesses	July 26, 2017	May 28, 2018
<b>FSVP importer whose foreign supplier is subject to the produce safety rule and eligible for a qualified exemption (other than when the foreign supplier is a farm producing sprouts). Compliance dates when foreign suppliers are in these categories</b>		
-Small Businesses as defined in 21 CFR 112.3	July 29, 2019	No change
-Very Small Businesses as defined in 21 CFR 112.3	July 27, 2020	No change
<b>FSVP importer whose foreign supplier is a farm producing sprouts that is eligible for a qualified exemption under the produce safety rule. Compliance dates when foreign suppliers are in these categories:</b>		
-Small Businesses as defined in 21 CFR 112.3	July 26, 2018	No change
-Very Small Businesses as defined in 21 CFR 112.3	July 29, 2019	No change