FSMA TAKEAWAY FOR CHEESE MAKERS

- **Have you registered your facility with the FDA?**
  - If not, it's not too late to do so. It requires filling out an on-line form, and then updating that form every two years. (http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm)
- **Do you expect to become a Qualified Facility beginning in 2018?**
  - If YES, then
    - you must begin keeping financial records in 2016 that will prove you meet the sales criteria beginning in 2018
    - you must plan to submit the required Attestations for QF status by December 18th of 2018
  - If NO, then are you a "Small Business" (less than 500 employees)?
    - If YES then you have until late 2017 to comply with the full HARPC provisions.
    - If NO then you have until late 2016 to comply with the full HARPC provisions.

KEY TERMS (see GLOSSARY on page 4)

KEY DATES FOR FSMA IMPLEMENTATION

- **January 1, 2013**
  - Registration of Food Facilities is required of most food processors, including cheese makers and dairy processors. It's never too late to register… (http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm)
- **September 17, 2015**
  - Official start date for implementation of new FDA rules for cheese makers
- **January 1, 2016**
  - Sales records must begin to be retained if a manufacturer wished to become a Qualified Facility (QF)
- **December 17, 2018**
  - QFs that choose not to implement HARPC provisions must have submitted required Attestations:
    - A statement that their financial records show they satisfy the definition of a "very small business"
    - A statement that the facility is in compliance with the relevant non-Federal food safety laws (i.e. State licensing and regulation)
      - This option includes additional labeling requirements

DETAILS

In response to the new statutory provisions of the FSMA the FDA has amended their CGMPs in two fundamental ways: first by modernizing the long-standing current good manufacturing practice requirements; second by adding requirements for domestic and foreign facilities subject to our regulation for Registration of Food Facilities to establish and implement hazard analysis and risk-based preventive controls (HARPC) for human food.

They also revised certain definitions for Registration of Food Facilities to clarify the scope of the exemption from registration requirements provided for "farms" and, in so doing, to clarify which domestic and foreign facilities are subject to the requirements for hazard analysis and risk-based preventive controls for human food.

Federal Register list of exemptions: (https://www.federalregister.gov/articles/2015/09/17/2015-21920/current-good-manufacturing-practice-hazard-analysis-and-risk-based-preventive-controls-for-human#p-2979)

A more human readable list of exempt products on SustainableAgriculture.net: (http://sustainableagriculture.net/blog/pc-rule-analysis-part-2/)

Dairy farms that only ship their milk probably fall under the "farm" exemption (each farm must determine this for themselves). Cheese making and dairy processing do not fall under the exemption for "farms" and therefore these food processors will be expected to follow the amended CGMPs and HARPC provisions.

Cheese makers and dairy processers (as well as other food processers) who meet the definition of a "Qualified Facility" will still have to follow the new CGMPs, they will not be required to meet the HARPC provisions as long as they maintain their QF status by updating their Food Facility registration and updating their Attestations of sales, licensing, and labeling (see QF definition above). If a qualified facility plans to start operating after the very small business compliance date -- September 17, 2018 -- then they must submit the attestations before they start operating.

Qualified Facility status may be withdrawn by the FDA for two reasons:

- there is an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility;
- and/or if FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

In the case of QF status being withdrawn that food facility would then be regularly inspected to make sure they meet the same HARPC provisions as all other non-QF food businesses.

The FDA has said they will be issuing guidance that explains the types of records that a qualified facility must maintain to comply with the rule. There is also currently no form or webpage available for submitting attestations.

Records that must be maintained to support the various exemptions from certain parts of this rule are subject to review upon inspection. Records must be kept as either original records, true copies (i.e. photocopies, pictures, scanned copies, or other accurate reproductions), or as electronic records. This means you are not required to keep all of your records electronically, though you may choose to.

Financial records that are maintained to document the status of a qualified facility — that is, the preceding three years' worth of sales — must be retained at the facility as long as necessary to support the facility's status during the applicable calendar year. All other records must be retained at least two years after the date they were prepared.

Do not confuse "Qualified Facility" with "Qualified Individual" who is important in any non-QF. A **Qualified Individual** is a worker who the education, training, or experience (or some combination of the three) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to their assigned duties. They also must receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, again, as appropriate to the food, the facility, and the individual's assigned duties.

Supervisors must also have the education, training, or experience (or some combination) necessary to supervise the production of clean and safe food. Facilities must retain records documenting the training provided to employees as required by the rule.

The rule does not specify a specific training program. However, the rule does acknowledge that the Food Safety Preventive Controls Alliance has been funded by FDA to develop a model curriculum that can be used in-house to provide the needed training as can online CGMP or other food safety courses.

Repurposed from: http://sustainableagriculture.net/blog/pc-rule-analysis-part-2/

GLOSSARY OF TERMS FOR CHEESE MAKERS UNDER FSMA

- **FSMA** (often pronounced "FIZZ mah")
    - *Food Safety and Modernization Act*, signed into law in 2011, which tasked the US Food and Drug Administration (FDA) to review and re-regulate (where necessary) the rules and process for ensuring the safety of the food supply in the US. (http://www.fda.gov/Food/GuidanceRegulation/FSMA/)
- **CGMP**s
    - *Current Good Manufacturing Practices*: the guiding rulebook for safe food manufacturing and processing in the US. (https://www.federalregister.gov/articles/2015/09/17/2015-21920/current-good-manufacturing-practice-hazard-analysis-and-risk-based-preventive-controls-for-human)
- **HACCP** (often pronounced "HASS ip")
    - *Hazards Analysis of Critical Control Points*: a program for identifying and documenting the food safety practices of a food manufacturer and/or processor
- **PC** Rule
    - *Preventive Controls Rule* : A new addition to CGMPs under the FSMA that adds *prevention* of potential food safety threats to the HACCP protocol of controlling present food safety risks. (see CGMP link above)
- **HARPC** (often pronounced "harp SEE")
    - *Hazards Analysis and Risk-based Preventive Controls*: Combines HACCP and the PC Rule to create a set of documents for each food manufacturer/processor that will be regularly audited by the FDA and other regulators. (https://en.wikipedia.org/wiki/Hazard_analysis_and_critical_control_points)
- **QF**
    - *Qualified Facility* which is the FDA's strange term for a food manufacturer/processor that is a "very small business" as defined and that the facility remains in the good graces of its local regulators and inspectors: This is stated in the form of two annual Attestations:
        - That your facility "grosses less than $1 million in annual sales of human food averaged over the three preceding business years" and can prove it with retained sales and financial records;
        - That your facility is in compliance with all non-Federal (i.e. State and Local) regulatory requirements (i.e. your licenses are up-to-date).

      QFs must also provide consumers with the name and complete business address of the facility where the food was manufactured or processed via a label, sign at point of sale, documents arriving along with the food in the normal course of business (i.e. an invoice), or electronically for internet sales. (https://www.federalregister.gov/articles/2015/09/17/2015-21920/current-good-manufacturing-practice-hazard-analysis-and-risk-based-preventive-controls-for-human#p-2967)