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## Comparison of FSSC 22000 against the Preventive Controls for Human Food (Final Rule)

### Summary

FSSC 22000 as the owner of a GFSI recognized scheme should be very proud of how it compares with the FSMA Preventive Controls (PC) final rule in several areas. Where the FSSC 22000 scheme requirements are not exceeding those of the PC rule, they are in very large measure comparable. Whether discussing the PC final rule or the FSSC 22000 certification scheme, each defines a set of objectives that can be considered a “roadmap” to help companies arrive at a “destination” of proactive food safety management. The level of detail provided in the FSSC 22000 scheme provides a roadmap that reaches this destination, and in some cases, is more explicit and/or stringent in the requirements than is the PC final rule, either by being more detailed or clear about its expectations or by asking that requirements be applied broadly versus more narrowly within a facility. Examples of this include the requirement by the FSSC 22000 scheme for stringent sanitation procedures with documentation regardless of whether it is a PRP or operational PRP/preventive control. An analysis of the comparison was made.

### Introduction

FSSC 22000, which focuses on food safety management system certification, is a Global Food Safety Initiative (GFSI) recognized certification scheme that is increasingly being adopted within the food industry. The signing of the Food Safety Modernization Act (FSMA) by the U.S. President in January 2011 was the most sweeping overhaul of the food-safety system in the United States since the Food, Drug, and Cosmetic Act of 1938. The new legislation expands the authority of the U.S. Food and Drug Administration (FDA), and places new requirements on growers, manufacturers, processors, importers, distributors and to some extent retailers of food in the US. FDA issued seven proposed rules, two of which were finalized on September 17, 2015, three on November 17, 2015 and the remaining two are expected in March and May 2016. Thus it is critical to stay abreast of the new rules and how they impact companies producing human and animal food and as additional



rules are released will be critical to transportation companies, and to some degree food contact packaging companies. Given the clear parallels between GFSI recognized schemes and the FSMA Preventive Controls Rules there have naturally been questions raised relating to the degree of comparability of these requirements to the practices and processes already in place in facilities certified to a GFSI recognized scheme such as FSSC 22000.

As a result, FSSC 22000 asked The Acheson Group (TAG) to assess its current FSSC 22000 scheme against the recently published “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food Preventive Controls Rule” or PC rule.

The FSSC 22000 scheme compared in this analysis consists of 1) the ISO 22000 standard, 2) the prerequisite program for manufacturing, namely ISO Technical Specification (TS) 22002-1 and 3) FSSC 22000 Additional Requirements ([www.fssc22000.com](http://www.fssc22000.com)).

It was compared against the PC rule and specifically the new preventive controls requirements that industry must comply with in order to implement the requirements of Section 103 of FSMA, and the updated current Good Manufacturing Practices (cGMPs) (current 21 C.F.R. Part 110; proposed Part 117 Subpart B available at [www.fda.gov](http://www.fda.gov)).

In general, the Preventive Controls requirements focus on prevention and on developing a holistic food safety management system rather than reacting to problems that can cause foodborne illness. This risk based and management system based thinking aligns with the FSSC 22000 scheme requirements as it too takes a risk based and management system based approach. The PC rule applies to US and foreign firms that manufacture, process, pack or hold human food for US consumption. These firms are required to have written food safety plans that identify significant hazards, specify preventive controls – in essence the steps that will be put in place to minimize or prevent those hazards, --identify monitoring procedures and record their results, specify what actions will be taken to correct problems that arise, validate that control measures are effective and reanalyze the food safety plan every three years or sooner based on specified criteria. Beyond the new Preventive Controls requirements in Section 103, the PC rule will also update and revise certain requirements in the existing cGMP regulations as a new section of the CFR, Section 117.

## Overview

The overview summarized in Table 1 shows that in general, the FSSC 22000 scheme requirements are impressively comparable to the requirements of the PC rule. More strikingly, there are numerous FSSC 22000 scheme requirements that exceed FDA’s regulatory requirements. This stated, it should be acknowledged that some FSSC 22000 scheme requirements may be covered by other existing, non-FSMA related regulations or are addressed in forthcoming FSMA regulations; however other items were simply not contemplated and have not been addressed by the PC rule or other aspects of FSMA. This is where the FSSC 22000 scheme has clearly earned an “exceeds” designation without disclaimer or caveat in the comments.



The terms “Exceeds” or “Comparable” imply that the FSSC 22000 scheme requirement in question exceeds or is comparable to the requirements in the corresponding section of the PC rule, while “different” means that the FSSC 22000 scheme requirement in the same section is either fundamentally different or is less prescriptive than that defined in the PC rule.

*Table 1 Key areas required by the FDA Final Rule for Human Food (preventive controls and/or cGMPs) addressed in the FSSC 22000 certification scheme*

| Key areas  | FDA Preventive Controls Food Safety Plan | FDA GMPs (117 Subpart B) | FSSC 22000 Scheme Equivalence                                 |
|--|--|--------------------------|---|
| 1. Overarching Policy Statement                    | No                                       | No                       | Yes (Exceeds)   |
| 2. Written Plan                                    | Yes                                      | No                       | Yes (Comparable)  |
| 3. Experienced Individual in Charge                | Yes                                      | No                       | Yes (Comparable in qualifications; Exceeds in responsibility) |
| 4. Trained Staff                                   | Yes                                      | Yes                      | Yes (Comparable)  |
| 5. Prerequisite Programs                           | No                                       | Yes                      | Yes (Exceeds)   |
| 6. Raw Material/ Incoming Product Safety Assurance | No                                       | No                       | Yes (Exceeds)   |
| 7. Supplier Verification                           | Yes                                      | No                       | Yes (Comparable)  |
| 8. Allergen Management                             | Yes                                      | Yes                      | Yes (Comparable)  |
| 9. Validation of Controls                          | Yes                                      | No                       | Yes (Comparable)  |
| 10. Finished Product Testing                       | No                                       | No                       | Yes (Exceeds)   |
| 11. Sanitation Control                             | Yes                                      | Yes                      | Yes (Exceeds)   |
| 12. Corrective Actions                             | Yes                                      | No                       | Yes (Comparable)  |
| 13. Traceability                                   | No <sup>1</sup>                          | No                       | Yes (Comparable)  |
| 14. Recall   | Yes                                      | No                       | Yes (Comparable)  |
| 15. Record Retention                               | Yes                                      | No                       | Yes (Different)   |
| 16. Food Defense                                   | No <sup>2</sup>                          | No                       | Yes (Exceeds)   |
| 17. Internal Audit & Management Review             | No <sup>3</sup>                          | No                       | Yes (Exceeds)   |

<sup>1</sup>FDA has already established traceability requirements under regulation stemming from the 2002 Bioterrorism Act, and traceability is a component of sec 204 FMSA which is separate from Preventive Controls

<sup>2</sup>Although FSMA addresses food defense in sec 103, FDA issued a separate rule on Intentional Adulteration while the final rule is expected by May 2016

<sup>3</sup>Some of the record review requirements accomplish similar objectives to the internal audit

1. Overarching policy statement: Exceeds

The FSSC 22000 scheme requires a statement asserting the commitment to food safety and in several places notes the need for a demonstration of management commitment. The PC rule does not have a corresponding requirement by management—only ties responsibilities to the preventive controls qualified individual (PCQI).

2. Written Food Safety Plan: Comparable

Both the FSSC 22000 scheme and the PC rule require food safety plans. While there is minor variation in the requirements, the objective is comparable and achieves the same food safety outcomes. One variation however is radiological hazards are required to be assessed in the PC rule food safety plan under chemical hazard analysis; however, this hazard is not currently specified in the FSSC 22000 scheme, but it does not change the intended outcome.

3. Experienced individual in charge: Comparable in qualifications, Exceeds in responsibility

Both the FSSC 22000 scheme and the PC rule require that a trained individual develop and implement the food safety plan. The PC rule defines this person as the “Preventive Controls Qualified Individual” and the FSSC 22000 scheme requires a “food safety team leader”. However, there are some areas where there are greater expectations of the individual by the FSSC 22000 scheme. In FSSC 22000 this person, along with the food safety team, has a role in internal and external food safety communication which is not required by the PC rule.

4. Trained staff: Comparable

Both the FSSC 22000 scheme and the PC rule require that staff be trained. Some FDA requirements pre-existed in the cGMP requirements and the PC rule sets expectations for either education, experience or training. The FDA has defined a standardized curriculum as part of the PC rule training requirements for Preventive Controls Qualified Individuals and Qualified Individuals (which are akin to Food Safety Team members). The FSSC 22000 scheme requirements surpass those of the PC rule in requiring the designation of a food safety team and ensuring that the team is trained, but does not specify a curriculum. The training requirement for the Qualified Individual defined by the PC rule covers this aspect.

5. Prerequisite programs: Exceeds

The FSSC 22000 scheme requires prerequisite programs (PRP’s) with validation, monitoring with documentation and management that the FDA reserves for the preventive controls. FDA’s cGMPs (pre-existing) cover similar areas to ISO/TS 22002-1. The new preventive controls requirement in the PC rule does not generally address PRP’s, at least not specifically but rather asks companies to evaluate its hazards which may require some PRPs to be elevated to preventive controls demonstrating a shift from HACCP and PRPs to HARPC. Overall, the FSSC 22000 scheme is stronger in the treatment of PRP’s, and has more detailed and explicit requirements for pest control, preventive maintenance, personal hygiene, etc.



6. Raw material/ incoming product safety assurance: Exceeds

The FSSC 22000 scheme specifies requirements for incoming materials. The PC rule does not have corresponding requirements.

7. Supplier verification: Comparable

The FSSC 22000 scheme requires that the organization establish, implement and maintain procedures for the evaluation, approval and continued monitoring of suppliers “which have an effect on food safety”. In addition, the results of evaluations, investigations and any follow up actions have to be recorded. The corresponding PC rule is more detailed but only for suppliers “requiring a preventive control” based on risk of the supplier. So while the PC rule only requires supplier controls for suppliers in certain circumstances, the FSSC 22000 scheme requires it for all suppliers “which have an effect on food safety” which is more broad. The result is that the overall requirements between the two (FSSC 22000 scheme and the PC rule) are comparable in spirit.

8. Allergen Management: Comparable

Both the FSSC 22000 scheme and the PC rule emphasize the importance of allergen controls. One of the main updates to cGMPS is the inclusion of the prevention of cross contact with allergens and allergen preventive controls are a specific type of preventive control designated by the rule.

9. Validation of Controls: Comparable

Both the FSSC 22000 scheme and the PC rule require validation of controls and specifically process controls.

10. Finished Product Testing: Exceeds

The FSSC 22000 scheme requires that organizations implement a system to assure that analyses of inputs critical to the confirmation of product safety is undertaken and that the analyses be performed to standards equivalent to those described in ISO 17025 where the PC rule does not.

11. Sanitation Control: Exceeds

Both the FSSC 22000 scheme and the PC rule require sanitation. Requirements are both in cGMPS, and a subset are noted in the Preventive Controls. The FSSC 22000 scheme requires validation of sanitation where the PC rule does not.

12. Corrective Actions: Comparable

Both the FSSC 22000 scheme and the PC rule require a documented process to make corrective actions.

13. Traceability: Comparable

Traceability requirements of the FSSC 22000 scheme are consistent with existing FDA regulations stemming from the Bioterrorism Act (2002). FSMA has authorized FDA to make changes to traceability requirements for high risk food as a separate rule making process. However, to date FDA has not issued any proposed rules in this regard and traceability is outside the scope of the PC rule. One particular place where the FSSC 22000 scheme exceeds FDA requirements is with respect



to specifying that rework must be traceable although the PC rule does designate that rework must be identified and work in progress must be labeled.

14. Recall: Comparable

Both the FSSC 22000 scheme and the PC rule require a recall process.

15. Record retention: Different

The FSSC 22000 scheme requires that documentation procedures are in place to demonstrate compliance and all records required to demonstrate the effective operation and control of the processes and management of food safety are securely stored for a time period required to meet customer or legal requirements, effectively controlled and readily accessible when needed. This seems different because the retention period is based on legal requirements like the statute of limitations or customer mandated requirements and not a flat, dictated year requirement like the PC rule which prescribes a straight 2 years across the board which is not tied to legal or customer retention reasons.

16. Food defense: Exceeds

The FSSC 22000 scheme has specific requirements around food defense. FDA excluded food defense/intentional contamination requirements in the PC rule, but a separate forthcoming final rule on Intentional Adulteration relating is expected Spring 2016.

17. Internal audits and management review: Exceeds

The FSSC 22000 scheme requires internal audits as well as continuous improvement of the food safety management system. The PC rule does not require an equivalent internal audit but does require very frequent review of records by the PCQI. This is specifically to ensure that processes and programs are in control, but is not as comprehensive as the evaluation required by the FSSC 22000 scheme.

There are some terminology differences to be aware of. Even with this knowledge that some terms in the FSSC 22000 scheme differ from those in the PC rule, there are very few if any FDA requirements that are not covered by the FSSC 22000 scheme. The key terms and concepts that FSSC 22000 will want to review in order to ensure alignment are:

- HACCP and operational PRPs versus Preventive Controls while the FSSC 22000 scheme distinguishes them, FDA classifies both as “preventive controls”,
- Food safety team leader versus Preventive Controls Qualified Individual as these are functionally the same and
- Withdrawal versus recall since from FDA’s perspective recalls and withdrawals are defined and managed differently.



## Conclusion

There are no elements of the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Control for Human Food and cGMP requirements that are clearly just “missing” in the FSSC 22000 that we could determine or see from this analysis. Some FSSC 22000 scheme requirements may be “different” but that did not equate to missing.

Based on this analysis, a facility that has achieved FSSC 22000 certification is in an excellent place with regard to compliance with the FDA PC rules. The biggest challenge companies will have from a regulatory perspective and scheme compliance perspective in our opinion is maintaining the ongoing documentation and record keeping requirements which we see as the most critical factor in how regulators view a facility.

FDA has stated that an assessment of a company’s food safety management system will start with a review of the facility’s food safety plan. If it looks robust, rational, and well documented and addresses relevant hazards, FDA may not delve into other aspects of their business or records. However, if the food safety plan appears weak, a company may face challenges. Achieving FSSC 22000 certification and understanding the requirements of the PC rule together with knowing the expectations of FDA, will help facilities build strong, well-documented programs. We hope this report helps to do just that.

## References

- *GFSI Guidance Document, Sixth Edition, January 2011*
- *ISO 22000:2005, Food safety management systems – Requirements for any organization in the food chain*
- *ISO/TS 22002-1: 2009, Prerequisite programs for food safety – Part 1: Food manufacturing*
- *FSSC 22000 Additional Requirements – Part II Requirements and Regulations for Certification Bodies, Version 3.2 (2015) ([www.fssc22000.com](http://www.fssc22000.com))*
- *“Preventive Controls Rule” or “the Final Rule” consisting of the “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food” (see [www.fda.gov](http://www.fda.gov))*