

FSSC 22000 Webinar 25 June 2018 – FSSC 22000 FSMA Addendum

Answers to questions related to the FSSC 22000 FSMA Addendum

Original questions were kept as much as possible but modifications and combinations may have been made to facilitate the reading of this document.

Question – Timing and Introduction	Answer
When will the addendum be published and when will this become effective?	The FSSC 22000 FSMA Addendum will be published in July 2018. It will come into effect from the date of publication.
Will there be an update for your comparison in xls. FSSC 22000-FSMA Alignment - September 2017	The FSSC 22000-FSMA alignment document will be updated when required. There is no date set at this time for the next update.
When will FSSC start to use ISO 22000:2018? How will it affect the FSSC 2200 scheme? When ISO 22000 is updated to 2018 version, how soon after that is FSSC recertifying us to that standard?	A gap assessment document between the old and the new ISO 22000 standard will be released in July 2018. A more detailed plan for revising the FSSC 22000 Scheme based on the new standard is expected to be released in October 2018.

Question – Who can benefit from the Addendum?	Answer
If we have latest FSSC V-4.1, then is it necessary to go with FSMA?	The FSMA addendum is a voluntary option for those interested in seeking or demonstrating knowledge of the FSMA regulations. While you do not have to complete the addendum as part of the FSSC 22000 V4.1 Audit, you do have to

	meet the legal requirements of the countries you are exporting to. So if you export your product to the US, you do have to meet FSMA legislation, regardless of whatever certificates you may have.
Please touch base with regards to FSSC FSMA addendum's applicability to non-US based certified organizations.	The addendum is fully applicable to non-US based organisations that wish to demonstrate their capacity to meet the requirements of FSMA for export to the US.
If your FSSC 22000 certified facilities don't need to be registered with the FDA the addendum is n/a, correct?	The addendum is applicable to companies based in the US and to those exporting to the US. It is voluntary and not required by companies not registered with the FDA to export to the US.
For samples send to USA for testing in any laboratory in USA, would this be subjected to FSVP?	Samples for lab testing are exempt from FSVP requirements (as long as they do not enter commerce).
Is FSVP applicable to commercial samples going to USA?	The Foreign Supplier Verification Program (FSVP) is applicable to all food entering the US for commercial use.
This addendum can be used for produce?	No. FSSC 22000 does not currently have a scope to cover produce. The addendum is related to FSSC 22000 certification scope for Manufacturing of food and (bio)chemicals.
If some products are not supplied to US, is the audit will focus/applicable only the US supplied?	The addendum needs to be applied to those products destined for the US.

Question – Purpose	Answer
Can you confirm: the addendum gives no 'statement of conformity' but gives only information to the importing company for their own verification if the supplier fits the FDA requirements.	This is true. The addendum is intended to provide a mechanism for companies to share the information sought as part of a supplier verification audit. The addendum is not a statement of compliance.

So, how does 21 CFR 113 fit in. Low acidified canned foods has certain exemptions to FSMA	Companies subject to LACF HAACP have modified FSVP obligations.
The addendum is a certified scheme? Is it accredited?	The addendum is not a certified scheme. It is an addendum to the existing FSSC 22000 Scheme for manufacturing of food and (bio)chemicals. The outcome is an attestation in the form of a Voluntary FSSC 22000 FSMA Addendum Report - not a certificate. It is not accredited.
When a conformity assessment body are accredited on FSSC 22000 with this addendum automatically this body are accredited in FSMA?	No, FDA accreditation of AB's for FSMA is a separate process not covered by FSSC 22000. The FSSC 22000 FSMA Addendum does not provide an accredited FDA audit.
Will you be accredited by FDA to carry out their audits as a 3rd party?	The FSSC 22000 FSMA Addendum is not accredited by the FDA.
Since BRC has added FSMA voluntary module at first, it was assumed that it compensates all FSMA requirements, but this has not lead FDA not to make audit. If FSSC 22000 certified company has this voluntary module. Is FDA going to make audit?	Completion of the FSSC 22000 FSMA Addendum will not have any influence on the incidence of FDA audits to a facility. The inspection program of the FDA is independent of whether companies have completed the addendum or not.
The CB's may certify this addendum? Or is just a guidance for producers? I mean, the addendum audited, but not certified, is that?	The addendum provides information relating to a facilities' conformity. It is not a certificate but an assessment that is based on an existing FSSC 22000 certificate.
How does the addendum help the conformity assessments bodies to get an easy accreditation process with this two schemes?	The addendum will not help AB's or CB's achieve FDA accreditation. This is a separate process.

Question – Content	Answer
Is Food Fraud part of the Addendum for Intentional Adulteration (I know that Food Defense is included)	The FSMA requirements for Food Fraud are covered for by the FSSC additional requirement 2.1.4.4.

Does the Addendum cover Intentional Adulteration?	FSSC additional requirement Food Defense can be seen similar to the IA rule (which will come into force in 2019). As this topic is covered by the FSSC 22000 Additional requirements, no info in the addendum shall be necessary.
If we are implementing HACCP, VACCP and TACCP, that will make us close to have FSMA regulations accomplished?	<p>Yes, implementing controls for hazards, Food Fraud and food defense will help in meeting the FSMA requirements but please see the additional information relating to the FSMA requirements at https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm</p> <p>The FSSC 22000 FSMA Supplement, Food Fraud and Food Defense guidance documents may be of help:</p> <p>http://www.fssc22000.com/documents/graphics/version-4-1-downloads/supplement-fssc-22000-and-fsma-v1-final-september-2017.pdf</p> <p>http://www.fssc22000.com/documents/graphics/version-4-1-downloads/fssc-22000-guidance-on-food-fraud-final-100418.pdf</p> <p>http://www.fssc22000.com/documents/graphics/version-4-1-downloads/fssc-22000-guidance-on-food-defense-final-100418.pdf</p>

Question – Execution of addendum	Answer
<p>Will the FSSC 22000 FSMA Addendum audit be added onto the current FSSC 22000 certification audit? Or is it a separate audit?</p> <p>Is this addendum applicable at (re)certification audit only or any audit within the 3-yr cycle?</p>	<p>The FSMA Addendum audit can only be conducted in conjunction with an FSSC 22000 audit, it is not a stand-alone audit.</p> <p>It can be completed in conjunction with any FSSC 22000 audit in the 3-year cycle (initial, surveillance or re-certification audit).</p>
<p>What about those audits which have already been performed against FSSC 22000 v4.1?</p>	<p>For audits conducted already in 2018 against version 4.1 and conducted before the issue date of the addendum, FSSC allows for a one-off stand-alone check of the addendum. This shall be done on-site.</p>

<p>Do you have calculation rule for audit FSMA addendum? How much time for duration will be added?</p> <p>How many extra hours/days audit, what costs?</p>	<p>It is the responsibility of the auditing CBs to determine the amount of additional time required to complete the addendum.</p> <p>The time required will depend on the size of company, number of food safety plans and number of Preventive Controls etc. FSSC 22000 does not charge a fee for the addendum.</p>
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Question – Reporting	Answer
<p>How does the addendum fit with your current v 4 database? Does it have to be loaded with specific information?</p>	<p>The FSMA addendum will not be loaded onto the FSSC 22000 Portal at this time.</p>
<p>Are there plans to include a description of the hazards that are controlled by the facility?</p> <p>FSSC- one challenge today is getting confirmation from suppliers on which hazards are controlled. Will the report include a list of the hazards that are being controlled?</p> <p>Will the report identify which hazards are being controlled?</p> <p>Clarification on hazards: will the report identify which hazards are controlled by the specific PC that is identified by the supplier?</p>	<p>The addendum report asks for a list of Preventive Controls, not for a list all individual potential hazards.</p> <p>However, customers and/or importers may still want to see the whole Food Safety Plan.</p>
<p>So, if a non-conformance is found during the audit on FSMA, does it affect the FSSC audit as a whole?</p> <p>Also, will there be any NC grading for this voluntary module, which might affect whole FSSC certificate?</p>	<p>The FSSC certification status is only affected when FSSC 22000 requirements are not met.</p>
<p>Will the auditor be able to review the specific hazard that the manufacturer is interested in?</p>	<p>The addendum is extra to a full FSSC 22000 audit so the auditor will be auditing the Food Safety Management System of the facility and details of the hazards</p>

	controlled should be part of the FSSC 22000 audit report. The FSSC 22000 FSMA addendum comes in addition to this.
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Question – Auditor requirements	Answer
What are the requirements for auditors to perform this addendum audit?	<p>The addendum states following:</p> <p>1.4.2 The qualification requirements are:</p> <ul style="list-style-type: none"> • The auditor is qualified to conduct FSSC 22000 certification audits for human food. • The auditor shall have sufficient knowledge to effectively examine the implementation of the FSMA PCHF (CFR Title 21 part 117). • The auditor shall have knowledge and understands the contents of this document and the FSMA report addition • The CB shall upload records of appropriate training and briefing in the FSSC 22000 auditor database as evidence that the auditor requirements are met. <p>Training and/or briefing shall be done by a person with demonstrable knowledge of the FSMA PCHF rule (e.g. a PCQI or a FSMA PCHF or FSVP Lead Instructor).</p>
<p>Does FSSC provide training on FSMA or can they recommend training providers?</p> <p>Will preventive control PCQI training be a requirement of FSSC auditors?</p>	<p>FSSC 22000 does not provide training.</p> <p>The FDA recognised PCQI training is provided by Lead Instructors approved by the Food Safety Preventive Controls Alliance and courses are listed on their website https://www.ifsh.iit.edu/fspca</p> <p>PCQI training is not listed as a requirement for an FSSC 22000 auditor although knowledge of the regulations is required.</p>

Question – Other	Answer
How many PCQI are mandatory in food manufacturer premises?	<p>Each site shall have minimum one PCQI.</p> <p><i>§ 117.3 Definitions</i> Preventive controls qualified individual (PCQI): means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.</p>
I read in news that Trump is aimed to make a fusion between FDA and USDA; if true and goes on; Will this affect FSMA and how do you expect?	<p>We cannot comment on the US political situation.</p> <p>It is unlikely that FSMA will change in the foreseeable future.</p>
Please clarify the difference and difference in requirements between food fraud and food defense.	<p>We would like to refer to the Guidance documents on Food Fraud and Food Defense that have been issued earlier this year. They can be found on the FSSC website:</p> <p>http://www.fssc22000.com/documents/graphics/version-4-1-downloads/fssc-22000-guidance-on-food-fraud-final-100418.pdf</p> <p>http://www.fssc22000.com/documents/graphics/version-4-1-downloads/fssc-22000-guidance-on-food-defense-final-100418.pdf</p>
Could you confirm us the last date of implementation and provide training material for the FSMA?	<p>For FSMA implementation dates, please refer to the FDA website https://www.fda.gov/Food/GuidanceRegulation/default.htm</p>
Is FSSC 22000 Transportation (Logistics) already GFSI approved? When it will be?	<p>The FSSC 22000 Transport and Storage Scope has been submitted and is currently undergoing GFSI benchmarking which is expected in the fall of 2018.</p>