



**GLOBAL G.A.P.**

**Food Safety Modernization Act  
Produce Safety Rule Add-on**

General Rules Specifications

ENGLISH VERSION 1.3\_SEP22

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## 1 GENERAL BACKGROUND INFORMATION

Name and version of the add-on:	Food Safety Modernization Act Produce Safety Rule add-on version 1.3
Scope:	Any product in the Fruit and Vegetables sub-scope of the GLOBALG.A.P. Integrated Farm Assurance standard
Scheme ID:	TBA
Application in country/countries:	All countries of the world; United States of America as country of destination
Name and version of applicable add-on control points and compliance criteria (CPCC):	Food Safety Modernization Act Produce Safety Rule add-on control points and compliance criteria version 1.3
Applicable documents:	<ol style="list-style-type: none"> <li>1. FSMA PSR add-on general rules specifications (<i>this document</i>)</li> <li>2. FSMA PSR add-on control points and compliance criteria</li> <li>3. FSMA PSR add-on checklist</li> </ol>
Relevant links:	<a href="https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm">https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm</a> <a href="https://www.federalregister.gov/documents/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption">https://www.federalregister.gov/documents/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption</a>

### 1.1 About the FSMA PSR add-on

GLOBALG.A.P. add-on rules build a framework in which a producer can comply with a set of requirements that is additional to compliance with a GLOBALG.A.P. standard. Given that these control points and compliance criteria are voluntary, assessment against them is not covered under GLOBALG.A.P. accreditation.

The Food Safety Modernization Act (FMSA) Produce Safety Rule (PSR) add-on is a voluntary add-on which can be used by any producer within the United States or any producer currently exporting to or with future plans to export to the United States, provided that producer has an existing GLOBALG.A.P. certificate for Integrated Farm Assurance (IFA).

Differences between IFA and the FSMA PSR are adapted in the add-on control points and compliance criteria (CPCCs), so that the user can make the necessary adjustments to implement the requirements of the FSMA PSR. However, every company should review the FSMA PSR for compliance details that may not be covered in this add-on.

### 1.2 FSMA PSR add-on claims

Producers are inspected/audited by GLOBALG.A.P. approved third-party certification bodies, which assess whether the producers comply with the FSMA PSR add-on. The assessment results serve as evidence of FSMA PSR implementation efforts at the farm level, in keeping with the current version of the United States Food and Drug Administration's FSMA PSR (21 C.F.R. Part 112). In combination with the IFA standard, the FSMA PSR add-on will aid producers in identifying FSMA PSR requirements that shall be addressed at the farm level. The add-on and

GLOBALG.A.P. IFA certificates can be provided to retailers and value-chain participants as evidence of a producer’s efforts toward FSMA PSR implementation.

Compliance with the add-on is not an assurance or guarantee of FSMA PSR compliance, as legal compliance can only be determined by a regulatory authority, such as the United States Food and Drug Administration (FDA).

## 2 GENERAL RULES SPECIFICATIONS

This document refers to the clauses in the [GLOBALG.A.P. general add-on rules](#) and defines the specific requirements for the FSMA PSR add-on v1.3.

<b>Clause</b> (Numbering based on “GLOBALG.A.P. general add-on rules”)	<b>General add-on rule</b>	<b>Specific requirements for the FSMA PSR add-on</b>
<b>3 APPLICATION OPTIONS</b>		
Preconditions:		The producer shall have a valid GLOBALG.A.P. IFA certificate for Fruit and Vegetables (FV) or be registered for IFA FV.
3.1 Option 1 – Individual producer		Applicable as in “GLOBALG.A.P. general add-on rules”
3.1.1	Option 1 – Multisite without implementation of a QMS	Applicable as in “GLOBALG.A.P. general add-on rules”
3.1.2	Option 1 – Multisite with implementation of a QMS	Applicable as in “GLOBALG.A.P. general add-on rules”
3.2 Option 2 – Producer group		Applicable as in “GLOBALG.A.P. general add-on rules”
<b>4 REGISTRATION PROCESS</b>		
<b>4.1 Certification bodies/Verification bodies</b>		
a)	The applicant shall register with a GLOBALG.A.P. approved certification body.	The producer shall register with a certification body (CB) approved to conduct assessments against this add-on. The CB shall be the same CB that conducts the IFA FV inspection/audit.

<b>Clause</b> (Numbering based on "GLOBALG.A.P. general add-on rules")	<b>General add-on rule</b>	<b>Specific requirements for the FSMA PSR add-on</b>
c)	Information on approved CBs is available for every add-on and published on the GLOBALG.A.P. website if requested by the program owner.	Applicable as in reference standard: IFA FV.
<b>4.2 Registration</b>		
<b>4.2.1 General</b>		
d)	The duration of the service contract is set between the CB and the producer.	The contract is the same as concluded for the IFA FV inspections/audits.
<b>4.3 Application and Scope</b>		
4.3.2 Parallel production and parallel ownership	Any applicant/certificate holder (individual producer, multisite, or producer group) who owns a product partly as originating from GLOBALG.A.P. certified and partly as originating from noncertified production processes at any time needs to register for parallel production (PP) or parallel ownership (PO).	<p>Not applicable. Registration for parallel production or parallel ownership is not possible with the FSMA PSR add-on itself; only products from production processes already certified under IFA FV can be included in the FSMA PSR add-on certificate of conformance. Producers or producer groups that are registered for parallel production (PP)/parallel ownership (PO) under IFA FV may apply/register for the FSMA PSR add-on, but only the area included in the IFA FV certification will undergo the FSMA PSR add-on assessment <i>and</i> all of the area included in the IFA FV certification per registered product shall be included in the FSMA PSR add-on registration, assessment, and certificate of conformance. A producer may choose to include only one or all of the products listed on the GLOBALG.A.P. certificate.</p> <p>Example: A producer has both tomatoes and lettuce from IFA FV certified production processes. If the add-on certificate of conformance includes tomatoes, it shall include <i>all</i> of the tomato area that is registered in the GLOBALG.A.P. IFA FV certificate. The producer cannot have some IFA FV certified tomato</p>

<b>Clause</b> (Numbering based on "GLOBALG.A.P. general add-on rules")	<b>General add-on rule</b>	<b>Specific requirements for the FSMA PSR add-on</b>
		<p>production processes included in the add-on, but other IFA FV certified tomato production processes excluded. However, the producer can have tomatoes originating from FSMA PSR add-on certified production processes and lettuce that is excluded from FSMA PSR add-on assessment and certification. This is not the same as PP/PO, as PP/PO applies within the same commodity.</p> <p>For quality management system (QMS) audits (Option 1 multisite producers with QMS and Option 2 producer groups):            Only producers/producer group members, products, and production sites that are registered/certified for IFA for fruit and vegetables are eligible for the FSMA PSR add-on.</p> <p>A multisite producer (with QMS) or producer group may choose only some producer group members with IFA FV certification to achieve the FSMA PSR add-on certificate of conformance. This is not considered parallel production or ownership within the FSMA PSR add-on. However, only production sites/producer groups registered/certified to the FSMA PSR add-on may be listed in the FSMA PSR add-on certificate of conformance.</p> <p>Per section 5.2.2 d): The CB-selected sample of external producer group member inspections shall include a proportional percentage of producers registered for the FSMA PSR add-on. For example, in a producer group with 100 registered producer group members, where 25 registered producer group members are also registered for the FSMA PSR add-on, at least 5 producer group members of 10 shall be selected for external inspections each certification cycle.</p>

<b>Clause</b> (Numbering based on “GLOBALG.A.P. general add-on rules”)	<b>General add-on rule</b>	<b>Specific requirements for the FSMA PSR add-on</b>
<b>5 ASSESSMENT PROCESS</b>		
<b>5.1 Self-assessment</b>		
a)	Self-assessments are required in case the specific add-on includes this requirement in the control points and compliance criteria.	Self-assessments against the FSMA PSR add-on shall be carried out together with the IFA FV self-assessment or IFA FV internal QMS inspection/audit.
<b>5.2 Second- or third-party inspections</b>		
a)	A second (an appointed organization) or third party (an independent certification body) shall conduct the add-on inspections and this shall be defined in the add-on general rules specifications.	Only third-party assessments are allowed. The CB add-on assessment shall be conducted in combination with the IFA FV inspection/audit by the same CB and same inspector/auditor.  The CB has available, as an exception, the FSMA PSR mid-cycle checklist, where assessments may occur after a positive IFA FV certification. The mid-cycle checklist shall be conducted by the same CB.
b)	The inspections shall only be done by the following parties as approved:	
i.	CB inspectors or auditors that are already approved to conduct inspections for accredited standards such as GLOBALG.A.P. IFA.	CBs shall be finally approved by GLOBALG.A.P. for the IFA FV standard. Inspectors/Auditors shall comply with GLOBALG.A.P. inspector/auditor qualification requirements, including those on communication skills, independence, and confidentiality, and demonstrate sufficient competence of the FSMA PSR as specified in section “CB inspector and auditor qualifications” below.  Inspectors/Auditors shall complete the FSMA PSR add-on online technical training (two-hour webinar) with successful completion of all online exams and respective updates within three

<b>Clause</b> (Numbering based on “GLOBALG.A.P. general add-on rules”)	<b>General add-on rule</b>	<b>Specific requirements for the FSMA PSR add-on</b>
		<p>months after release in the inspector’s/auditor’s language.</p> <p>The CBs are responsible for the supervision and maintenance of inspector and auditor competence according to the requirements of this add-on.</p>
ii.	Inspectors or auditors from GLOBALG.A.P. approved CBs conducting inspections against non-accredited standards, or	Not applicable
iii.	Verification bodies/Registered Trainers that have approval for assessing the specific add-on.	Not applicable
<b>5.2.1 Option 1 – Individual producer (without QMS)</b>		
a)	Producer receives an annual inspection.	Applicable as in reference standard: IFA FV.
b)	The duration and timing of inspections will be clarified.	<p>The CB add-on assessment shall be conducted in combination with the IFA FV inspection/audit by the same CB and same inspector/auditor. The duration depends, among other factors, on the complexity of activities and the size of the area under certification. Minimum inspection planning guidelines for certification bodies: one hour. The CB has available, as an exception, the FSMA PSR add-on mid-cycle checklist where assessments may occur after a positive IFA FV certification.</p> <p>The FSMA PSR add-on certificate of conformance may be issued after a positive certification decision from this assessment; however, the certificate expiry shall match the IFA FV certificate expiry. Therefore, FSMA PSR add-on assessments conducted after the IFA FV</p>

<b>Clause</b> (Numbering based on “GLOBALG.A.P. general add-on rules”)	<b>General add-on rule</b>	<b>Specific requirements for the FSMA PSR add-on</b>
		certification will have a shorter certificate expiration until the recertification cycle.
<b>5.2.2 Option 1 – Individual producer with a QMS and Option 2 – Group</b>		Refer to the GLOBALG.A.P. general regulations v5.2, Part I, 5.2 and Part II, as the same rules apply.
a)	The QMS and the producers must be inspected/audited.	Applicable as in reference standard: IFA FV. The internal register and CB register, report, and certificate annex shall reflect actual producers assessed to the FSMA PSR add-on.
b)	The CB does not inspect all producers/sites, but just a sample. It is not the responsibility of the CB to determine the compliance of each producer/site, as this responsibility rests with the applicant. The CB must assess whether the applicant’s internal controls are appropriate.	Applicable as in reference standard: IFA FV. The internal inspection shall include an assessment of the FSMA PSR add-on for each producer group member/production site registered for the FSMA PSR add-on. These assessments shall be carried out by a qualified internal inspector or auditor as per the “QMS internal inspector and auditor qualifications” set below. The internal inspection report shall be reviewed, and the producer group member/production site approved by the internal auditor before the CB assessment takes place. The CB QMS auditor shall review the FSMA PSR add-on assessment reports and internal inspector and auditor qualifications during the external QMS audit.
c)	The duration of inspections will be clarified.	The same rules apply as those for Option 1 multisite producers with QMS or Option 2 producer group under IFA FV: minimum one hour duration per producer group member/production site.
d)	The sampling method, frequency, and timing will be clarified.	The same rules apply as those for Option 1 multisite producers with QMS or Option 2 producer groups under IFA FV. The CB-selected sample of external producer group member inspections shall include a proportional percentage of producer group members registered for the FSMA PSR add-on. For example, in a producer group with 100 registered producer group members, where 25 registered producer group members are also registered for the FSMA PSR add-on, at least 5 producer group

<b>Clause</b> (Numbering based on “GLOBALG.A.P. general add-on rules”)	<b>General add-on rule</b>	<b>Specific requirements for the FSMA PSR add-on</b>
		members of 10 shall be selected for external inspections each year.
<b>5.3 Unannounced surveillance inspections</b>		
a)	It is possible that a specific add-on program requires that producers receive unannounced surveillance inspections.	If the producer is selected for an unannounced surveillance inspection/audit for IFA FV, the FSMA PSR add-on will also be inspected, if applicable.
b)	If it is a requirement, 10% of the add-on producers or groups of a CB/VB shall be assessed annually, unless stated otherwise in the add-on general rules specifications.	The same rules apply as those for Option 1 multisite producers with QMS or Option 2 producer groups under IFA FV.
c)	The inspection shall be announced no longer than 48 hours in advance.	The same rules apply as those for Option 1 multisite producers with QMS or Option 2 producer groups under IFA FV.
<b>6 APPROVAL PROCESS</b>		
<b>6.1 Requirements to achieve and maintain add-on conformance</b>		
a)	The CPCCs of the add-on may consist of different levels (e.g., knock-out points, Major Musts, Minor Musts, and Recommendations) or may have a scoring system.	CPCCs are scored as Major Must. In the case of agricultural water for preharvest, CPCCs are scored as Recommendations until the FDA compliance date is enforced or until CPCCs are amended based on the finalized revised agricultural water rule. Control points marked “N/A” (not applicable) shall have a justification. A certificate of conformance is awarded after all applicable Major Must control points are demonstrated as being in conformance and/or corrective actions are accepted by the CB.

<b>Clause</b> (Numbering based on "GLOBALG.A.P. general add-on rules")	<b>General add-on rule</b>	<b>Specific requirements for the FSMA PSR add-on</b>
		Non-conformance to the FSMA PSR add-on shall <i>not</i> impact compliance with the IFA FV standard.
b)	For each add-on program, the conformance rules based on the constitution of the CPCC and will be stipulated.	All Major Musts shall be 100% complied with. As long as the CPCCs on agricultural water for preharvest are scored as Recommendations, they will not be included in the final scoring.
c)	The compliance percentage shall be calculated, taking into account all the control points applicable to each site and product.	Applicable as in the "GLOBALG.A.P. general add-on rules."
d)	In all cases, after an inspection, the calculation to show compliance (or non-compliance) must be available.	Applicable as in the "GLOBALG.A.P. general add-on rules."  The summary of non-conformity and/or a corrective action report shall be available at the closure of the audit. The certificate of conformance shall be awarded based on the conformance rules. See Table II.1 for detailed requirements on the summary and corrective action report.
<b>6.2 Sanctions</b>		
c)	Outstanding non-conformances identified during the first inspection shall be closed within the timeframe agreed with the program owner.	Applicable as in the "GLOBALG.A.P. general add-on rules."  Corrective action report information contained in Table II.2.
<b>6.5 Letter of conformance and assessment cycle</b>		Certificate of conformance is issued, not a letter of conformance. See Table I, "Certificate of conformance requirements" and template in Annex III.

<b>Clause</b> (Numbering based on “GLOBALG.A.P. general add-on rules”)	<b>General add-on rule</b>	<b>Specific requirements for the FSMA PSR add-on</b>
		The FSMA PSR add-on certificate of conformance expiry date shall not exceed the expiry date of the GLOBALG.A.P. IFA FV certificate regardless of when the add-on assessment was conducted.
<b>6.6 Certification Integrity Program (CIPRO)</b>		
a)	The possibility of adding CIPRO to the add-on program shall be clarified.	Applicable. If a CB/producer has been selected for a CIPRO assessment, then FSMA PSR add-on criteria shall also be assessed. No additional CIPRO requirements for the FSMA PSR add-on apply.
<b>7 CERTIFICATION BODY REGISTRATION RULES FOR THE ADD-ON PROGRAM</b>		
<b>7.1 GLOBALG.A.P. approved CBs</b>		
iii)	a) Register in the GLOBALG.A.P. CB Extranet ( <a href="http://cb.globalgap.org">http://cb.globalgap.org</a> ) for the new add-on. b) Submit a letter of intent in English to the GLOBALG.A.P. Secretariat. c) Pay an annual registration fee according to the GLOBALG.A.P. fee table that will allow the CB to assess against all scopes of the add-on program. d) Follow the database training for producer registration and checklist uploading when applicable. Register all inspectors for the	Applicable. CB license fee according to GLOBALG.A.P. and GLOBALG.A.P. North America fee tables. Provisional approval is possible for the CB after the license fee is submitted. The CB will achieve final approval when the applicant CB presents at least: <ul style="list-style-type: none"> <li>• The certificate of one inspector/auditor who has completed the Produce Safety Alliance training for trainers (16 hours)</li> </ul> OR <ul style="list-style-type: none"> <li>• The certificates of two inspectors/auditors who have completed the standard face-to-face Produce Safety Alliance training (8 hours)</li> </ul> It is expected that if the in-house trainer has completed the Produce Safety Alliance training for trainers (16 hours), they can train their inspectors/auditors. Otherwise, the GLOBALG.A.P. Secretariat shall verify that the CB has at least the minimum number of qualified

<b>Clause</b> (Numbering based on “GLOBALG.A.P. general add-on rules”)	<b>General add-on rule</b>	<b>Specific requirements for the FSMA PSR add-on</b>
	add-on(s) in the GLOBALG.A.P. database.	personnel to issue a FSMA PSR add-on certificate of conformance (one inspector/auditor and one reviewer both trained in Produce Safety Alliance).  Additionally:  No inspectors and auditors can be approved to take the online exam and conduct inspections/audits until they have completed the FSMA PSR add-on online technical training (two-hour webinar by GLOBALG.A.P.).
<b>7.2 Approved verification bodies or Registered Trainers</b>		Not applicable
<b>Further Specifications</b>		
Data access rules	In case of a different data release level as defined in the Annex III.	The level of data visibility shall be fixed and signed during registration with the CB. The producer or producer group is the data owner and is responsible for determining and granting the level of rights for data access. Public information will be the same as for IFA FV.  See Annex I, “FSMA PSR add-on data access rules.”
CB inspector and auditor qualifications	In the case of other requirements as indicated in GLOBALG.A.P. general regulations, Part III, Annex III.1 and the “GLOBALG.A.P. Registered Trainer program – Online application form.”	Inspectors and auditors shall comply with GLOBALG.A.P. inspector and auditor qualification requirements. In addition, all inspectors and auditors of this add-on shall take part in the FSMA PSR add-on online technical training (two-hour webinar by GLOBALG.A.P.) and take the online exam. Inspectors and auditors shall demonstrate sufficient competence with the FDA’s FSMA PSR through evidence of attendance at a Produce Safety Alliance training with an approved instructor. The minimum expectation for inspectors/auditors is the “Grower Training course” – minimum of eight-hour duration, as offered by any approved trainer. This can be a private training by an approved trainer.  The list of “Grower Training courses” that are registered with PSA can be found <a href="#">here</a> . A list of approved trainers who can conduct a private class is <a href="#">here</a> .  Any one of these trainers can offer the course to

<b>Clause</b> (Numbering based on “GLOBALG.A.P. general add-on rules”)	<b>General add-on rule</b>	<b>Specific requirements for the FSMA PSR add-on</b>
		<p>CBs and CB affiliates.            The person(s) making the certification decision (certifier/reviewer) or at least one member of the CB decision-making committee of the CB shall comply with auditor qualifications as set out above. If the certification decision is related to Option 1 and does not include a QMS, the CB still shall have one person of the CB decision-making committee complying with auditor qualifications and with the above FSMA PSR add-on specific requirements.</p> <p>GLOBALG.A.P. Registered Trainers and verification bodies <i>are not</i> accepted as external inspectors/auditors.</p>
QMS internal inspector and auditor qualifications	In the case of other requirements as indicated in GLOBALG.A.P. general regulations, Part II, Annex II.1 and the “GLOBALG.A.P. Registered Trainer program – Online application form.”	<p>Internal inspectors and auditors shall comply with GLOBALG.A.P. internal inspector and auditor qualification requirements. In addition, internal inspectors and auditors shall demonstrate sufficient competence with the FSMA PSR through evidence of attendance at a Produce Safety Alliance training. The minimum expectation for internal inspectors/auditors is the “Grower Training course” – minimum of eight-hour duration. This may be an internal, public, or private training. The course is not required to be an official Produce Safety Alliance course or led by a “Produce Safety Alliance approved” instructor; however, course content shall be at least equivalent to the content offered in the Produce Safety Alliance approved course curriculum, as required in FSMA PSR subpart C, § 112.22c.</p> <p>GLOBALG.A.P. verification bodies and GLOBALG.A.P. Registered Trainers <i>are</i> accepted as internal inspectors and auditors.</p>
Producer fees	Any additional fees that may apply for the different add-ons.	No additional producer fees to be collected by GGNA in the USA and Canada. Global fees are defined in the general GLOBALG.A.P. fee table (CB shall use the most current fee table available from the GLOBALG.A.P. website. See Annex II for reference).

<b>Clause</b> (Numbering based on “GLOBALG.A.P. general add-on rules”)	<b>General add-on rule</b>	<b>Specific requirements for the FSMA PSR add-on</b>
Any additional rule/requirement not mentioned in this document	GLOBALG.A.P. database	<p>The following documents shall be available in Audit Online Hub after the certification decision, either uploaded or directly entered:</p> <ul style="list-style-type: none"> <li>• FSMA PSR add-on assessment report</li> <li>• <i>Full</i> IFA FV or Produce Safety Assurance inspection/audit report</li> <li>• Corrective action report</li> <li>• Certificate of conformance (until such time as this is available for direct printing via the GLOBALG.A.P. IT systems)</li> </ul> <p>These documents shall be sent to the certificate holder as protected PDF documents or other controlled document form within a reasonable timeframe after the certification decision.</p> <p>Please see tables below:</p> <ul style="list-style-type: none"> <li>• Certificate of conformance requirements</li> <li>• Summary of non-conformity requirements</li> <li>• Corrective action report requirements</li> </ul>
	GLOBALG.A.P. Audit Online Hub	<p>All FSMA PSR add-on control points and all IFA FV control points are available in Audit Online Hub, a tool for capturing all assessment/inspection/audit information. Inspectors and auditors shall fill out individual control points in Audit Online Hub using the system directly, uploading the preliminary report using the provided excel template, or automatically transfer audit data using a specified API.</p> <p>CBs shall use Audit Online Hub for all FSMA PSR add-on assessments and the accompanying IFA FV inspection/audit.</p>

<b>Table I: Certificate of conformance requirements</b>		
<b>I.1 Certificate of conformance requirements</b>		
a)	Certificate of conformance requirements	The certificate of conformance shall include all the content specified in the FSMA PSR add-on certificate of conformance template (see Annex III).  This certificate of conformance is valid for only as long as the GLOBALG.A.P. IFA FV certificate is valid.
b)	Uploading the certificate of conformance to the GLOBALG.A.P. database	The certificate of conformance shall be uploaded to Audit Online Hub (until such time as this is available for direct printing via the GLOBALG.A.P. IT systems).

<b>Table II: Requirements on summary of non-conformity and corrective action report</b>		
<b>II.1 Summary of non-conformity</b>		
a)	Requirements related to summary of non-conformity	The summary of non-conformity shall comply with all content specified in the FSMA PSR add-on checklist under the relevant section. Upon completion of the FSMA PSR add-on assessment, the written summary will be produced by the inspector/auditor and shall include: <ul style="list-style-type: none"> <li>• Producer/Entity assessed</li> <li>• GLOBALG.A.P. Number (GGN)</li> <li>• Certification scope</li> <li>• Products included in the FSMA PSR add-on</li> <li>• Date of assessment</li> <li>• Duration of assessment</li> <li>• Listing of any non-conformances identified for both IFA FV and the FSMA PSR add-on</li> <li>• The objective evidence of all non-conformities identified</li> <li>• The first and last name of the inspector/auditor</li> <li>• Producer/Company signature</li> <li>• Inspector/Auditor signature</li> </ul>

b)	Uploading the summary of non-conformity to the GLOBALG.A.P. database	The completed summary of non-conformity shall be available in Audit Online Hub, either using the system directly, uploading the preliminary report using the provided MS Excel template, or automatically transferring audit data using a specification API at the closure of the assessment/inspection/audit.
<b>II.2 Corrective action report</b>		
a)	Requirements related to the corrective action report	<p>The corrective action report shall comply with all content specified in the FSMA PSR add-on checklist under the relevant section.</p> <p>On completion of the FSMA PSR add-on assessment, the written corrective action report will be produced by the inspector/auditor and shall include:</p> <ul style="list-style-type: none"> <li>• Producer/Entity assessed</li> <li>• GGN</li> <li>• Certification scope</li> <li>• Products included in the FSMA PSR add-on</li> <li>• Date of assessment</li> <li>• Duration of assessment</li> <li>• Listing of any non-conformances identified</li> <li>• The objective evidence of all non-conformances identified</li> <li>• The objective evidence of implementation of the correction(s) or corrective action(s)</li> <li>• The first and last name of the inspector/auditor</li> <li>• Producer/Company signature</li> <li>• Inspector/Auditor signature</li> </ul>
b)	Uploading the corrective action report to the GLOBALG.A.P. database	The completed corrective action report shall be available in Audit Online Hub, using the system directly, uploading the preliminary report using the provided MS Excel template, or automatically transferring audit data using a specification API. Where corrective actions are not required or will not be submitted by the producer, a corrective action report is not required to be uploaded; section II.1 b) of this document applies.

## ANNEX I FSMA PSR ADD-ON DATA ACCESS RULES

### 1 PRODUCER/COMPANY DATA

Producer data covers all data described in the GLOBALG.A.P. general regulations.

#### 1.1 Initial producer data setting

By participating in the FSMA PSR add-on, the producer grants the respective data access groups access to the specified information of the producer/company data listed below. This setting represents the minimum data access setting. The producer or designated verification body can extend access via the GLOBALG.A.P. IT systems at any time.

**x** = This data is visible to users assigned to the respective data access group.

	GLOBALG.A.P. Secretariat	Certification body	Public
<b>Company</b>			
Company name	<b>x</b>	<b>x</b>	<b>x<sup>2)</sup></b>
Company address <sup>1)</sup>	<b>x</b>	<b>x</b>	
Company city	<b>x</b>	<b>x</b>	<b>x<sup>2)</sup></b>
Company country	<b>x</b>	<b>x</b>	<b>x</b>
Company contact information <sup>3)</sup>	<b>x</b>	<b>x</b>	
Company website (if available)	<b>x</b>	<b>x</b>	
Current GGN/GLN	<b>x</b>	<b>x</b>	<b>x</b>
Previous GGN/GLN	<b>x</b>	<b>x</b>	<b>x</b>
Legal registration per country	<b>x</b>	<b>x</b>	
Location <sup>4)</sup>	<b>x</b>	<b>x</b>	
<b>Contact person (responsible for legal entity)</b>			
Contact name <sup>5)</sup>	<b>x</b>	<b>x</b>	
Contact address <sup>1)</sup>	<b>x</b>	<b>x</b>	
Contact city	<b>x</b>	<b>x</b>	

	GLOBAL G.A.P. Secretariat	Certification body	Public
Contact country	X	X	
Contact information <sup>3)</sup>	X	X	
<b>PHU/Site Information</b>			
Name of product handling unit (PHU)/site	X	X	
PHU/Site address <sup>6)</sup>	X	X	
PHU/SITE city	X	X	
PHU/SITE country	X	X	
PHU/Site contact information <sup>3)</sup>	X	X	
Sub-GLN(s)	X	X	X
Legal registration per country	X	X	
Location <sup>4)</sup>	X	X	
<b>Contact person (responsible for PHU/site)</b>			
Contact name <sup>5)</sup>	X	X	
Contact address <sup>1)</sup>	X	X	
Contact information <sup>3)</sup>	X	X	

<sup>1)</sup> Address includes: street name and house number, postal address, postal code, federal state

<sup>2)</sup> For every legal entity with a product in an active status, data access of the company name, country, and city is granted to the public. This applies to Option 1 as well as to Option 2 producer groups. Producer group members (Option 2) may optionally release data to different data access groups.

<sup>3)</sup> Contact information includes: phone no., fax no., email address

<sup>4)</sup> Location includes: (North/South) latitude + (West/East) longitude

<sup>5)</sup> Contact name includes: title, first name, and last name

<sup>6)</sup> PHU/Site address includes: street name and number, postal address, postal code

## 2 PRODUCT DATA

Product data covers all data described in the GLOBALG.A.P. general regulations. Access to product data not explicitly listed in this section cannot be altered and is transparent as long as the respective product is displayed in the GLOBALG.A.P. IT systems.

### 2.1 Initial product data setting

By participating in the FSMA PSR add-on, the producer/company grants the respective data access groups access to the specified product data listed below. This setting represents the minimum data access setting. The producer or designated verification body can extend access via the GLOBALG.A.P. IT systems at any time. For more information on this topic, please see the latest version of the IT systems.

**x** = This data is visible to users assigned to the data access group listed on top.

	GLOBALG.A.P. Secretariat	Certification body	Public
<b>&lt;product&gt; (*)</b>			
Checklist result <sup>7)</sup>	<b>x</b>	<b>x</b>	
Quantity data	<b>x</b>	<b>x</b>	

(\*) This configuration can be set for each product individually or set for modules (scopes/sub-scopes) to cover all products included in that module.

<sup>7)</sup> This includes all uploaded documents that are mentioned in “Further specifications.”

## ANNEX II FSMA PSR ADD-ON PRODUCER REGISTRATION FEES

Valid from: 1 April 2018

Options: Option 1 – individual producer; Option 2 – producer groups

Scope: Crops base

Sub-scope: Fruit and vegetables

### 1 PRODUCER REGISTRATION FEE FOR PRODUCERS IN THE USA AND CANADA

There is no separate/additional registration fee applied to producers in USA and Canada; this fee is included for producers with IFA certification in the USA and Canada.

### 2 PRODUCER REGISTRATION FEE FOR PRODUCERS OUTSIDE THE USA AND CANADA

Covered production*		Noncovered production*	
Area under covered production [hectares]	Annual fee	Area under noncovered production [hectares]	Annual fee
<0.1	€19.00	<0.1	€9.00
≥0.1 – <0.5	€54.00	≥0.1 – <0.5	€22.00
≥0.5 – <1	€104.00	≥0.5 – <2	€40.00
≥1 – <1.5	€134.00	≥2 – <5	€64.00
≥1.5 – <5	€218.00	≥5 – <15	€109.00
≥5 – <10	€322.00	≥15 – <100	€193.00
≥10 – <30	€370.00	≥100 – <1,000	€325.00
≥30 – <100	€591.00	≥1,000 – <5,000	€591.00
≥100 – <500	€1,182.00	≥5,000 – <10,000	€1,182.00
≥500	€2,170.00	≥10,000	€2,170.0

\* “Covered production” is primarily intended to mean “produced in a greenhouse.” A crop is considered covered if it is grown beneath or within a structure. Any other form of production is considered non-covered. For further details, see the “Definitions” section of the GLOBALG.A.P. fee table.

**ANNEX III CERTIFICATE OF CONFORMANCE TEMPLATE FOR FSMA PSR ADD-ON**



**GGN\_**[xxxxxxxxxxxxxxxxxxxxxx]<sup>2</sup>

Registration number of company (from CB) [xxxxxxxx]<sup>3</sup>

**CERTIFICATE OF CONFORMANCE**

according to the

**GLOBALG.A.P. Food Safety Modernization Act Produce Safety Rule add-on**

version [xx]<sup>4</sup>

issued to

[Producer/Company]

[Company name, address]<sup>5</sup>

**[Country of production/Company location]<sup>6</sup>**

The certification body [CB name] declares that the producer/company has been assessed to the FSMA PSR add-on version mentioned above.

Product(s) <sup>7</sup>	Production area included for FSMA PSR <sup>8</sup>	Product handling assessed to the FSMA PSR add-on <sup>9</sup>

**Date of issuing (printing date):** [dd/MMM/yyyy]<sup>10</sup>

**Valid from:** [dd/MMM/yyyy]<sup>11</sup>

**Valid to:** [dd/MMM/yyyy]<sup>12</sup>

**Authorized by**<sup>13</sup>

\_\_\_\_\_

\_\_\_\_\_

**Date of certification decision:** [dd/MMM/yyyy]<sup>14</sup>

*Conformance with the FSMA PSR add-on is not an assurance or guarantee of FSMA PSR compliance. Legal compliance can only be determined by a regulatory authority, such as the United States Food and Drug Administration. This certification is based on observations during the assessment regarding the standards established by the FSMA PSR add-on. No certification can provide an assurance that all food produced by the assessed company is safe for consumption.*<sup>15</sup>

This certificate of conformance is valid for only as long as the GLOBALG.A.P. IFA certificate for Fruit and Vegetables is valid.<sup>16</sup>

**The current status of this certificate of conformance is always displayed at:** <http://www.globalgap.org/search>.<sup>17</sup>

## Notes

The certificate of conformance shall be in English. The CB may add a second language in the certificate.

- 1 The CB logo shall appear on all certificates of conformance.
- 2 GLOBALG.A.P. Number (GGN) shall appear on all certificates of conformance. If a certificate holder owns a Global Location Number (GLN), this number shall replace the GGN.
- 3 A producer/company's or producer group's registration number, which is assigned by the CB, *may* (voluntarily) appear on the certificate of conformance. It consists of the word "CB-Short" and a number (with exactly one space between: CB-Short xxxxxxxxxxxx.)
- 4 Please enter "GLOBALG.A.P. Food Safety Modernization Act Produce Safety Rule add-on version [version number]". Always mention the version used.
- 5 Name of the certificate holder and the address shall be printed on the paper certificate of conformance.
- 6 Country of the producer/company location.
- 7 Products mentioned in the FSMA PSR add-on certificate of conformance shall be listed on the GLOBALG.A.P. IFA FV certificate.
- 8 "Production area included for FSMA PSR" (in ha) shall be included per product. This area shall always match the production area with IFA FV certification for that product.
- 9 Product handling assessed to the FSMA PSR add-on: Product handling inclusion in the FSMA PSR add-on is dependent on whether the handling activities performed occur within the farm as defined in the FSMA PSR and whether the activities meet the product and ownership criteria for either a primary or secondary activities farm. For definitions and examples, see:  
<https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm517567.htm> Where the product handling unit (PHU) does not meet the definition of a farm, and the PHU is potentially subject to the FSMA "Preventive Controls for Human Food" rule, enter "no" to specify that product handling was *not* inspected as a part of the FSMA PSR add-on assessment, regardless of whether or not product handling was inspected as a part of the IFA inspection/audit. If product handling *is* included in the FSMA PSR add-on, indicate whether it takes place in-field ("in-field") or in a facility ("facility") or both ("in-field + facility").
- 10 Date of issuing is the printing date of the paper certificate of conformance. It shall be added to the first page of the certificate of conformance and to the Annex to connect each other. The dd/MMM/yyyy format is prescribed for international acceptance and understanding. Example: 03/MAR/2018
- 11 The certificate of conformance's "Valid from" date defines the beginning of a conformity cycle.
- 12 The certificate of conformance's "Valid to" date is the expiry date of the validity. The expiry date shall never exceed the expiry date of the GLOBALG.A.P. IFA FV certificate.
- 13 The first and the last name of the person who has authorized the certificate of conformance shall be written in block letters. This person shall sign the certificate of conformance.

- 14 The date of the certification decision shall appear on the certificate of conformance and shall be the same as the certification decision date of the GLOBALG.A.P. IFA FV certificate.
- 15 This statement shall be added to the certificate of conformance: *“Conformance with the FSMA PSR add-on is not an assurance or guarantee of FSMA PSR compliance. Legal compliance can only be determined by a regulatory authority, such as the United States Food and Drug Administration. This certification is based on observations during the assessment regarding the standards established by the FSMA PSR add-on. No certification can provide an assurance that all food produced by the assessed company is safe for consumption.”*
- 16 This note (*“This certificate of conformance is valid as for only as long as the GLOBALG.A.P. IFA certificate for Fruit and Vegetables is valid.”*) shall be added to the paper certificate of conformance to point out that the FSMA PSR add-on assessment relies on a GLOBALG.A.P. IFA FV certificate.
- 17 *“The current status of this certificate of conformance is always displayed at: <http://www.globalgap.org/search>.”* shall be added to the paper certificate of conformance to point out that only a validation in the GLOBALG.A.P. IT systems proves the current status of the certificate of conformance.

## VERSION/EDITION UPDATE REGISTER

New Document	Replaced Document	Date of Publication	Description of Modifications
180608_GG_FS MA_ PSR_GR_V1_0_ en	180417_DRAFT_ GG_ FSMA_GR_V1_0_ IF_en	8 June 2018	<p>1.1 Claims: changed certification to standard</p> <p>4.2 added requirements of Parallel Production and Ownership</p> <p>5.2 b i) added: within 3 months after release in the inspector's language. Changed 'certificate of compliance' to 'certificate of conformance':</p> <ul style="list-style-type: none"> <li>• 6.1d</li> <li>• 6.5</li> <li>• Any additional rule/requirement not mentioned in this document</li> <li>• Table I: Certificate Requirements</li> </ul> <p>TABLE II: added:</p> <ul style="list-style-type: none"> <li>• Producer/Entity assessed,</li> <li>• GGN,</li> <li>• certification scope,</li> <li>• Producer/Company signature, and</li> <li>• Auditor/Inspector signature.</li> </ul> <p>II.2 CAR added:</p> <ul style="list-style-type: none"> <li>• Producer/Entity assessed,</li> <li>• GGN,</li> <li>• certification scope,</li> <li>• products included in the FSMA PSR Add-on</li> </ul> <p>Producer/Company signature, and</p> <ul style="list-style-type: none"> <li>• Auditor/Inspector signature</li> </ul> <p>Annex 1: Changed 7.2 to "Further Specifications"</p> <p>Deleted Annex 4</p>
190215_GG_FS MA_ PSR_GR_V1_1_ en	180608_GG_FSM A_ PSR_GR_V1_0_e n	15 February 2019	<p>1 Table – changed data access information, removed add-on observer</p> <p>4.3.2 – added explanation of how the add-on can exclude IFA FV certified commodities</p> <p>5.2.i – improved wording</p> <p>5.2.1.b – changed desk review assessment date</p> <p>5.2.2.a, b, d – added Option 2 explanations</p> <p>6.1.d – Summary of Non-Conformity is optional to upload where corrective actions are not required.</p> <p>Deleted 5-day rule for upload.</p> <p>Further Specifications: DAR – removed reference to FSMA Observers</p>

New Document	Replaced Document	Date of Publication	Description of Modifications
			<p>Further Specifications: Inspector Qualifications – added PSA training information and resource</p> <p>Further Specifications – additional rule/requirement document upload to GLOBALG.A.P. database requires <i>full</i> IFA audit report. CB required to send documents to certificate holder.</p> <p>Table II.1 – clarification of Summary of Non-Conformity requirements.</p> <p>Annex 1 – removed Data Access Group FSMA Observer Group</p> <p>Annex 2 – removed discount levels</p>
191111_GG_FS MA_ PSR_GR_V1_2_ en	190215_GG_FSM A_ PSR_GR_V1_1_ en	11 November 2019	<p>Added reference to Produce Safety Assurance throughout</p> <p>5,2,1b – deleted desk review timeline</p> <p>6.5 – clarification</p> <p>6.6a – wording change</p> <p>7.1iii – clarification of CB onboard process</p> <p>Further Specifications CB Inspector and Auditor Qualifications – including Auditors, clarification for certifiers/reviewers</p> <p>QMS Internal Inspector and Auditor Qualifications – added</p> <p>Any additional rule/requirement not mentioned in this document: – added text, added GLOBALG.A.P. Audit Online section</p> <p>Annex 3 – Certificate of Conformance – deleted (8)</p>
220907_GG_FS MA_PSR_add- on_general_rules_ specs_v1_3_en	191111_GG_FSM A_ PSR_GR_V1_2_ en	07 September 2022	<p>Removed reference to Produce Safety Assurance throughout</p> <p>Clarified inspector/auditor and inspection/audit throughout</p> <p>4.3.2 – PP/PO clarification</p> <p>5.1 – self-assessment/internal assessment</p> <p>5.2.1 – clarified mid-cycle assessment</p> <p>5.2.2(a) – clarification of QMS internal inspector/auditor requirements and (b) duration</p> <p>6.1 – minor language edits</p> <p>6.6(a) – minor language edits</p> <p>7.1– clarification of training</p> <p>Further Specifications – clarification of training – inclusion of Audit Online Hub requirements</p>

New Document	Replaced Document	Date of Publication	Description of Modifications
			Table I – inclusion of Audit Online Hub requirements Table II – summary of non-conformity clarification, inclusion of Audit Online Hub requirements Certificate template – clarification of included area and expiry date

If you want to receive more information on the modifications in this document, contact the GLOBALG.A.P. Translations and Document Support team at [translation\\_support@globalgap.org](mailto:translation_support@globalgap.org).

When the changes do not introduce new requirements to the standard, the version will remain “1.0” and an edition update shall be indicated with “1.0-x”.

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