GLOBALG.A.P. General Regulations Specifications for the TR4 Biosecurity Add-on

(Based on GLOBALG.A.P. General Regulations Version 6)

ENGLISH VERSION 2.0_AUG24

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1 INTRODUCTION

GLOBALG.A.P. general regulations specifications for add-ons create the framework within which a producer or producer group shall comply with the add-ons' principles and criteria (P&Cs) in addition to compliance with a GLOBALG.A.P. standard. These add-ons are voluntary and mostly customer-driven. Each add-on has its own specific P&Cs that makes it different and customized. The results of the add-on audit do not affect the audit report of the base standard.

The basis for this document is the latest GLOBALG.A.P. general regulations (rules for individual producers, rules for producer groups and multisite producers with a quality management system (QMS), and rules for plants scope), which should be consulted while reading these GLOBALG.A.P. general regulations specifications.

2 GENERAL INFORMATION FOR THIS ADD-ON

Name and version of the add-on:	TR4 Biosecurity add-on version 2
Common name (if applicable):	
Scope:	Plants
Scheme ID:	354
Application in country/countries:	All
Add-on observers:	
Combinable with the following base standard(s):	☒ IFA v6 Smart for fruit and vegetables ☒ IFA v6 GFS for fruit and vegetables ☐ IFA v6 Smart for flowers and ornamentals ☐ IFA v6 Smart for aquaculture (all products unless finfish are specified) ☐ IFA v6 GFS for aquaculture (all products unless finfish are specified) ☐ Other, please specify:
List of normative documents:	GLOBALG.A.P. general regulations specifications for the TR4 Biosecurity add-on (this document) TR4 Biosecurity add-on P&Cs TR4 Biosecurity add-on checklist

ROLES RELATED TO THIS ADD-ON

The following stakeholders have a role in the rollout of the add-on and are defined as follows:

Producer: N/A

Supplier: N/A

Service provider: N/A

3 GLOBALG.A.P. GENERAL REGULATIONS SPECIFICATIONS

Section (Numbering of sections 3 to 7 is based on the GLOBALG.A.P. general regulations.)	**GLOBALG.A.P. general regulations specifications for the TR4 Biosecurity add-on**
3 CERTIFICATION OPTIONS	
Preconditions:	
It is possible to implement and conduct audits against the add-on for the following options (pick all applicable options): ☒ Option 1 – individual producer ☐ Option 3 – individual producer (☐ benchmarked scheme, ☐ benchmarked checklist) ☒ Option 1 – individual multisite producer with QMS ☐ Option 3 – individual multisite producer with QMS (☐ benchmarked scheme, ☐ benchmarked checklist) ☒ Option 2 – producer group ☐ Option 4 – producer group (☐ benchmarked scheme, ☐ benchmarked checklist)	
5 REGISTRATION WITH THE CERTIFICATION BODY	
5.2 Registration process	
5.2.1 General	
Choice of certification body (CB)	☒ A finally approved CB for the base standard and/or add-on ☒ A provisionally approved CB for the base standard and/or add-on The chosen CB: ☒ Shall be the same CB that conducted the audit against the base standard ☐ Does *not* need to be the same CB that conducted the audit against the base standard A list of GLOBALG.A.P. approved CBs is available on the GLOBALG.A.P. website. Customize the search for CBs by selecting the region, country, and scope. Additional info:

Section (Numbering of sections 3 to 7 is based on the GLOBALG.A.P. general regulations.)	GLOBALG.A.P. general regulations specifications for the TR4 Biosecurity add-on
Duration of the service contract	The duration of the service contract is agreed between the CB and the producer. The contract between the CB and the producer is *independent* of the contract between FoodPLUS GmbH and the owner of the add-on. The CB shall include this add-on as part of the GLOBALG.A.P. sublicense and certification agreement that is signed between the CB and the producer. Additional info:
Registering parts of the products as originating from GLOBALG.A.P. certified production processes (parallel ownership = PO)	☒ PO is possible.* ☐ PO is not possible. *For additional registration requirements, see "GLOBALG.A.P. general regulations – Rules for parallel ownership."
Additional requirements regarding the registration process	
6 AUDIT PROCESS – INDIVIDUAL PRODUCERS (OPTION 1 OR OPTION 3)	
6.1 Self-assessments	
General	Self-assessments are: ☒ Required against all the P&Cs and follow all the rules in the GLOBALG.A.P. general regulations ☐ Not required Additional info: The completed self-assessment checklist shall contain comments of the evidence observed for all not applicable and non-compliant Major Must P&Cs.
6.2 CB audits	
Announced CB audits	☒ Annual ☐ Other, please specify: Additional info: a) Each producer shall undergo one announced CB audit per annum.

Section (Numbering of sections 3 to 7 is based on the GLOBALG.A.P. general regulations.)	GLOBALG.A.P. general regulations specifications for the TR4 Biosecurity add-on
	b) The duration of CB audits shall be appropriate to the size of the production site. c) CB audits shall be conducted by a CB that has been approved to conduct audits against the TR4 Biosecurity add-on. d) The CB auditor shall conduct the audit using the complete checklist. e) The CB audit shall cover: (i) All accepted products (bananas and plantains) and production processes (ii) All registered production sites (iii) All registered PHUs f) Independence/Impartiality shall be maintained at all times: It is important that the CB auditor conducting the audit is always independent, impartial, and free from any conflicts of interest with the producer at all times between the implementation and issuance of the letter of conformance.
Unannounced CB audits	☒ Together with the audit against the base standard, as per the GLOBALG.A.P. general regulations ☐ Other, please specify: Additional info:
Off-site and on-site stages	☒ Splitting the CB audit against the add-on is possible, as per the GLOBALG.A.P. general regulations. ☐ Splitting the CB audit against the add-on is *not* possible and the audit shall be conducted on site only. Additional info:
Remote CB audits	☒ Possible together with the CB audit against the base standard, as per the GLOBALG.A.P. Full Remote audit procedure ☐ Not allowed Additional info:
CB audit duration	The duration of the CB audit against the add-on depends on the size of the farm and the complexity of the production activities and will be in the range of approximately six hours.

Section (Numbering of sections 3 to 7 is based on the GLOBALG.A.P. general regulations.)	GLOBALG.A.P. general regulations specifications for the TR4 Biosecurity add-on
CB audit timing	☒ Together with the CB audit against the base standard, as per the GLOBALG.A.P. general regulations ☐ Other, please specify:
6.3 Initial and subsequent CB audits	
☒ The same as in the GLOBALG.A.P. general regulations ☐ Other, please specify: Additional info:	
6 AUDIT PROCESS – PRODUCER GROUPS (OPTION 2 OR OPTION 4) OR INDIVIDUAL MULTISITE PRODUCERS WITH QMS (OPTION 1 OR OPTION 3) ☐ *N/A for producer groups or individual multisite producers with QMS*	
6.1 Internal audits	
General	Internal audits are: ☒ Required against all the P&Cs and follow all the rules in the GLOBALG.A.P. general regulations ☐ Required but follow different rules than the GLOBALG.A.P. general regulations: ☐ Not required Additional info:
Internal QMS auditor requirements	☒ As per the GLOBALG.A.P. general regulations ☐ Additional qualifications:
Internal farm auditor requirements	☒ As per the GLOBALG.A.P. general regulations ☐ Additional qualifications:
6.2 CB audits	
Announced CB QMS audits	☒ Annual, as per the GLOBALG.A.P. general regulations, together with the CB audit against the base standard ☐ Other, please specify: Additional info:
Unannounced CB QMS audits	☒ Recertification audit together with the CB audit against the base standard, as per the GLOBALG.A.P. general regulations

Section (Numbering of sections 3 to 7 is based on the GLOBALG.A.P. general regulations.)	GLOBALG.A.P. general regulations specifications for the TR4 Biosecurity add-on
	☐ Other, please specify: Additional info:
CB farm audits	☒ Together with the audit against the base standard, as per the GLOBALG.A.P. general regulations ☐ Specific rules that are different from the GLOBALG.A.P. general regulations, please specify: Additional info:
Off-site and on-site stages	☒ Splitting the CB QMS audit against the add-on is possible, as per the GLOBALG.A.P. general regulations. ☐ Splitting the CB QMS audit against the add-on is *not* possible and the audit shall be conducted on site only. Additional info:
Remote CB audits	☒ Possible together with the CB audit against the base standard, as per the GLOBALG.A.P. Full Remote audit procedure ☐ Not allowed ☐ Additional info:
CB farm and QMS audit duration	The duration of the CB audit against the add-on depends on the size of the farm and the complexity of the production activities and will be in the range of approximately six hours.
CB audit timing	☒ Together with the audit against the base standard, as per the GLOBALG.A.P. general regulations ☐ Other, please specify:
6.3 Initial and subsequent CB audits	
☒ The same as in the GLOBALG.A.P. general regulations ☐ Other, please specify: Additional info:	

Section (Numbering of sections 3 to 7 is based on the GLOBALG.A.P. general regulations.)	**GLOBALG.A.P. general regulations** **specifications for the TR4 Biosecurity add-on**
7 CERTIFICATION PROCESS	
7.1 Requirements for achieving GLOBALG.A.P. certification	
7.1.1 Certification rules	
Compliance system	☐ Major Musts, Minor Musts, and Recommendations ☒ Other, please specify: All P&Cs are Major Musts, 4-level rating Additional info: a) Compliance is rated as a percentage (%) based on the achievement level demonstrated by the producer. All P&Cs are of equal importance. b) There is an overall 4-level rating for compliance with the TR4 Biosecurity add-on audit: (i) Fully compliant (ii) Some improvements required (iii) Not compliant, but some steps taken (iv) Not compliant The overall compliance level is calculated based on the total number of P&Cs with which the producer has complied, excluding P&Cs that are not applicable (N/A) from the total score.
7.1.2 Minor Must compliance calculation	
Compliance levels for CB farm audits	☐ 100% compliance with Major Musts, 95% compliance with Minor Musts ☒ Other, please specify: No Minor Must P&Cs

Assessment result		Compliance level
From	To	
≥ 99%	100%	Fully compliant
≥ 66%	< 99%	Some improvements required
≥ 40%	< 66%	Not compliant, but some steps taken
0%	< 40%	Not compliant

Section (Numbering of sections 3 to 7 is based on the GLOBALG.A.P. general regulations.)	**GLOBALG.A.P. general regulations** **specifications for the TR4 Biosecurity add-on**
Compliance levels for CB QMS audits (if applicable)	☐ 100% compliance with the QMS requirements, as per the GLOBALG.A.P. general regulations ☒ Other, please specify: No Minor Must P&Cs ☐ Not applicable if a QMS is not implemented
7.1.3 Decision (whether or not to issue a letter of conformance)	
☒ The same as in the GLOBALG.A.P. general regulations regarding decision-making and the audit report ☐ Different rules regarding decision-making and the audit report, please specify: ☐ The same person that reviews the report may make the certification decision. ☐ The same person that reviews the report *shall not* take the certification decision. Additional info:	
7.2 Letter of conformance Instead of a certificate, the individual producer or producer group receives a letter of conformance. See Annex I of this document. Additional info:	
7.3 Letter of conformance validity extension	
☒ Together with the base standard, as per the GLOBALG.A.P. general regulations ☐ No extension allowed	
7.4.3 Sanctions	
Corrective action following initial CB audit	☐ Rules for closing non-conformances follow the GLOBALG.A.P. general regulations. ☒ Different rules apply, please specify: a) The CB shall make a decision regarding the producer's result within a maximum of 28 calendar days after closure of any outstanding non-compliances. b) If a non-conformance is detected, the producer shall be given the opportunity to decide whether to close the non-conformance or to receive the letter of conformance with the rating they have obtained. The producer shall have 28 days to implement any corrective actions before the letter of conformance is issued.

Section (Numbering of sections 3 to 7 is based on the GLOBALG.A.P. general regulations.)	GLOBALG.A.P. general regulations specifications for the TR4 Biosecurity add-on
	c) Once the letter of conformance has been issued, the producer's status in the GLOBALG.A.P. IT systems shall be changed from "Accepted" to "Verified". Additional info:
Corrective action following subsequent CB audits	☒ Non-conformances shall be closed within 28 calendar days, as per the GLOBALG.A.P. general regulations. ☐ Non-conformances shall be closed within X calendar days. ☐ It is not necessary to implement corrective action within a certain period of time. Additional info:
CB REQUIREMENTS	
General	☒ The GLOBALG.A.P. approved CB has: a) Registered for the new add-on in the GLOBALG.A.P. IT systems b) Submitted a letter of intent in English to the GLOBALG.A.P. Secretariat (obsolete for registration through CB-AT) c) Paid an annual registration fee according to the GLOBALG.A.P. fee table for conducting audits against the add-on d) Assigned the add-on in CB-AT to the auditors so they can complete any applicable online tests ☐ The CB approval process is different, please specify:
CB auditor approval	☒ Auditors from GLOBALG.A.P. approved CBs that are already approved to conduct audits against accredited standards such as IFA, or schemes successfully benchmarked to the specific product category ☐ Auditors from GLOBALG.A.P. approved CBs that already conduct audits against not accredited standards ☐ In addition to the IFA approval, the in-house trainer shall conduct one witness audit against the add-on. Additional info:

Section (Numbering of sections 3 to 7 is based on the GLOBALG.A.P. general regulations.)	GLOBALG.A.P. general regulations specifications for the TR4 Biosecurity add-on
CB auditor qualifications	If other requirements as indicated in the GLOBALG.A.P. general regulations – Rules for certification bodies apply, please specify: a) Each CB auditor who conducts audits against the TR4 Biosecurity add-on shall be trained by the CB using the training provided by the GLOBALG.A.P. Academy or using a training provided by another organization that lasts a minimum of six hours. The training shall provide all the information contained in the TR4 Biosecurity add-on, updated knowledge on scientific advances in disease control, and the current list of countries in which Foc TR4 has been confirmed, among other things. A certificate of participation shall be presented. b) CB auditors shall pass a TR4 Biosecurity add-on online test once it becomes available. c) CB auditors shall be aware of the current list of countries with a confirmed presence of Foc TR4. The CB shall keep this country list updated. d) The CB shall maintain records of each auditor's travel log and ensure that they are not transmitting Foc TR4. These records shall be kept for each CB auditor visit to a banana or plantain production site. The records may be maintained in any format that includes the following information: (i) Name of the CB auditor conducting the audit against the TR4 Biosecurity add-on (ii) List of the countries visited (where the CB auditor visited banana or plantain production sites) in chronological order (iii) List of the GGNs of the producers visited by this CB auditor prior to the audit (iv) List of the GGNs for production sites where the Foc TR4 pathogen has been identified, including the date of the visit e) The CB auditor shall have access to a disinfection kit*, shall make proper use of it at all times, and shall implement preventive measures to ensure that no (cross) contamination takes place during travel and audits. In specific cases, the disinfection kit may be provided to the CB auditor by the producer. Proper measures shall be implemented, not just at farm level, but also before and after any travel. The respective risk levels for the regions (countries) of destination shall be taken into consideration.

Section (Numbering of sections 3 to 7 is based on the GLOBALG.A.P. general regulations.)	**GLOBALG.A.P. general regulations** **specifications for the TR4 Biosecurity add-on**
	*A disinfection kit shall include the necessary disinfecting agents and items for ensuring that all the CB auditor's belongings are disinfected (i.e., pathogen free) after visiting a country and/or production site where the presence of Foc TR4 is suspected (or has been confirmed).
CERTIFICATION INTEGRITY PROGRAM	
The possibility of adding the Certification Integrity Program (CIPRO) to the add-on shall be clarified	☒ Yes ☐ No Additional info:
ADD-ON LOGO USE	
☒ No TR4 Biosecurity add-on logo available ☐ A(n) add-on logo is available that shall be used as per the following rules:	
DATA ACCESS RULES	
Rules regarding data access	☒ GLOBALG.A.P. data access rules in its current version ☐ Additional or other data access rules
FEES	
Add-on fees	GLOBALG.A.P. system participation fees for this add-on shall be charged in addition to the base standard fees (see the GLOBALG.A.P. fee table). The producer shall not pay any fees directly to the supplier or service provider. Fees are payable to the CBs only. Add-on fees for producers, depending on the applicable scope: ☒ Per producer • Option 1 or 3: €25 per producer • Option 2 or 4 (or Option 1 or 3 with QMS): €130 per producer group or producer with QMS + €1 per producer group member or production site ☐ Flat fee, please specify: € XY
ADDITIONAL RULES	
Any additional rule(s)/requirement(s):	

ANNEX I ADD-ON LETTER OF CONFORMANCE TEMPLATE

CB logo [1]

GLOBALG.A.P. identification number: (GGN) xxxxxxxxxxxxxxxx [2]

[TR4 BIOSECURITY] ADD-ON[3]

LETTER OF CONFORMANCE

According to the TR4 Biosecurity add-on

Option X [4]

Issued to

Producer group/Individual producer
company name, address [5]

Country of production [6]

The annex contains details of the producer group members/production sites/product handling units included in the scope of this letter of conformance.[7]

The certification body [company name] declares that the production of the products mentioned on this letter of conformance has been found to be compliant in accordance with the TR4 Biosecurity add-on:

TR4 Biosecurity add-on version XXXX[8]

Result[9]:

Product[10]	Harvest included/excluded, product handling included/excluded[11]	Number of producer group members/production sites[12]

Date of CB audit[13]:

Valid from: xx/xx/xxxx [14]

Valid to: xx/xx/xxxx [15]

Authorized by[16]

_____

Date of approval decision: xx/xx/xxxx [17]

CB contact data[18]

Company name, address (incl. email)

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ANNEX for GLOBALG.A.P. Identification Number: (GGN) xxxxxxxxxxxxxx [20]

Date of CB audit: xx/xx/xxxx [13]

Producer group members (Option 2)[21]

GLOBALG.A.P. identification number/GLN[22]	Producer group member name and address[23]	Product(s)[24]

Production sites (Option 1 individual multisite producer with QMS)[26]

Production site name and address[27]	Product(s)[25]

Product handling units (PHUs)[27]

GLOBALG.A.P. identification number/GLN[28]	PHU name and address[29]	Product(s)[24]

Notes

The letter of conformance (LoC) *shall be in English*. A second language may be added in the LoC.

[1] The certification body (CB) logo shall appear on all LoCs.

[2] The GLOBALG.A.P. identification number (GGN) shall appear on all LoCs.

[3] Name of the add-on

[4] The options shall appear on the LoC as follows:

"Option 1 – individual producer"

"Option 1 – individual multisite producer without QMS"

"Option 1 – individual multisite producer with QMS"

"Option 2 – producer group"

[5] The name of the LoC holder (legal entity) and the address. The address includes that of the legal entity and that of the production site. If these are different, and there is only one site, the site address can be included on the LoC or in the annex. For individual multisite producers (with/without QMS), the addresses of the registered production sites shall be listed in the LoC annex.

[6] The country of production shall appear on all LoCs.

[7] Only applicable if any of the following is true:

a) The LoC holder is an Option 2 producer group. All producer group members shall be listed in the annex.

b) Product handling* or packing is included in the scope of the LoC. If the address of the PHU is different, all product packing and handling unit(s) shall be listed in the annex.

c) The LoC refers to an Option 1 individual multisite producer (with/without QMS). All production sites of the producer shall be listed in the annex.

*Product handling definition:

Any type of postharvest handling of products, such as storage, chemical treatment, trimming, washing, or any other handling in which a harvested product may have physical contact with other materials or substances.

[8] Version of the TR4 Biosecurity add-on

[9] Indicate the overall level of conformance as explained in section 7.1.2 of this document.

[10] The product that complies with all the applicable requirements.

[11] Indicate if harvest is included/excluded; product handling included/excluded.

[12] Applicable to Option 2 producer groups/Option 1 multisite producers (with/without QMS) including the following possible options under the scope of this add-on:

i. For Option 2 producer groups, the item refers to the number of producer group members registered for the add-on.

ii. For Option 1 multisite producers (with/without QMS), the item refers to the number of production sites.

[13] Date the audit against the add-on was conducted

[14] The LoC “valid from” date defines the beginning of an audit cycle. If the add-on is added mid-cycle initially, the validity date/period of the LoC shall be adjusted to match the base standard cycle.

[15] The LoC “valid to” date is the expiry date of the LoC. If the add-on is added mid-cycle initially, the validity date/period of the LoC shall be adjusted to match the base standard cycle.

[16] The first and the last name of the person who has authorized the LoC, written in block letters. This person shall sign the LoC.

[17] “Date of approval decisions” shall appear on all LoCs. It is the date when the approval decision was made.

[18] CB contact data (company name, address, email) shall appear on all LoCs.

[19] Page numbering shall be included (Page x of y) to show the total number of pages.

[20] The annex (incl. the GLOBALG.A.P. identification number of the certificate holder) shall be added, if applicable.

[21] For Option 2 producer groups, all approved members of the producer group shall be listed in a table for each product.

[22] All approved members of the Option 2 producer groups are different legal entities and receive a GLOBALG.A.P. identification number, which shall appear in the table. They may have an own GLN instead of the GLOBALG.A.P. identification number.

[23] Name and address of the approved producer group members shall be printed on the LoC.

[24] Products approved per producer group member, production site, or PHU.

[25] For Option 1 multisite producers (with/without QMS), all registered sites shall be listed.

[26] The names and addresses of the production sites shall be listed.

[27] Where product handling takes place, all registered PHUs shall be listed.

[28] If the PHU has its own GLOBALG.A.P. identification number/GLN, it shall be listed.

The names and addresses of the PHUs shall be listed, unless the address is the same as that of the production site.

VERSION/EDITION UPDATE REGISTER

New document	Replaced document	Date of publication	Description of modifications
240827_TR4_Biosecurity_add_on_GR_specs_v2_0_Aug24_en	170511_TR4_BioSecurity_Add-On_Bananas_Specification_Rules_V1-0_en	27 August 2024	Change in system for rating compliance. Compliance is now rated as a percentage (%) based on the achievement level demonstrated by the producer. Change of level of all P&Cs to Major Must. Addition of new overall 4-level rating for compliance with the TR4 Biosecurity add-on audit: a) Fully compliant b) Some improvements required c) Not compliant, but some steps taken d) Not compliant

If you want to receive more information on the modifications in this document, please contact the GLOBALG.A.P. Secretariat at standard_support@globalgap.org.

If the changes do not introduce new requirements to the standard, the version will remain “5.0” and an edition update shall be indicated with “5.0-x”. If the changes do affect compliance with the standard, the version name will change to “5.x”.

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