



TR4 BIOSECURITY STANDARD

General Regulations

ENGLISH VERSION 1.0_SEP23

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TABLE OF CONTENTS

1	INTRODUCTION	3
2	GENERAL	3
3	DOCUMENTS	4
	3.1 NORMATIVE AND OBLIGATORY DOCUMENTS	4
	3.2 NORMATIVE AND OBLIGATORY DOCUMENTS CONTROL	4
4	CERTIFICATION OPTIONS	5
	4.1 INDIVIDUAL PRODUCER	5
	4.2 MULTISITE PRODUCER WITHOUT QMS	5
	4.3 MULTISITE PRODUCER WITH QMS	5
5	PRODUCER APPLICATION REQUIREMENTS	5
6	REGISTRATION WITH THE CB/VB	5
	6.1 CB/VB	5
	6.2 REGISTRATION PROCESS	6
7	AUDIT PROCESS	8
	7.1 SELF-ASSESSMENTS	8
	7.2 CB/VB AUDITS	8
8	CERTIFICATION PROCESS	9
	8.1 REQUIREMENTS FOR ACHIEVING AND MAINTAINING TR4 BIOSECURITY STANDARD COMPLIANCE	9
	8.2 CANCELLATION	10
	8.3 LETTER OF CONFORMANCE	10
9	CB AND VB REGISTRATION RULES FOR THE TR4 BIOSECURITY STANDARD	10
	9.1 GLOBALG.A.P. FINALLY APPROVED CBS	10
	9.2 VBS	11
	9.3 CB/VB AUDITOR QUALIFICATIONS	11
	ANNEX I TR4 BIOSECURITY STANDARD CB/VB APPROVAL PROCESS	13
	ANNEX II LETTER OF CONFORMANCE TEMPLATE	14
	ANNEX III EXAMPLE OF A TR4 BIOSECURITY STANDARD LETTER OF INTENT	16

1 INTRODUCTION

Fusarium oxysporum f. sp. *cubense* is the agent that causes Fusarium wilt disease in bananas and plantains. There is currently a specific genetic lineage, the so-called Tropical Race 4 or Foc TR4 that is the most imminent threat to banana and plantain producers and to the economic livelihoods of those who depend on banana and plantain production and consumption for their subsistence, as Foc TR4 is also harmful to many local banana and plantain varieties.

There is no effective treatment to control Fusarium wilt. It cannot be controlled using fungicides or eradicated from soil using fumigants. Therefore, at this time, the only viable option is to take preventive measures.

Bananas and plantains are produced in more than 135 countries, it is a basic food security crop for more than 400 million people and an essential source of income in many developing countries (FAO, 2013).¹

The purpose of the **TR4 Biosecurity Standard** is to provide tools that can be used around the world to raise awareness among producers, consumers, and the entire supply chain about the social and economic importance of preventing the spread of Foc TR4.

The main objective of the standard is to offer a possible solution to help banana and plantain producers in the major banana- and plantain-producing countries limit the spread of Foc TR4. The aim is to cover an area big enough to prevent the mass spreading of the fungus and contamination of the soil used for banana and plantain production in the producing countries, and to provide tools that can be used around the world to raise awareness (of the threat to food security, wages, income, and employment) among producers, consumers, and the entire supply chain.

By applying the TR4 Biosecurity Standard, producers will be implementing a risk mitigation plan to prevent the introduction and/or further spread of the Foc TR4 pathogen to, within, and from their farms.

As it is integrated into the GLOBALG.A.P. system, which provides a platform for approving certification bodies (CBs) and verification bodies (VBs) and registering and the results of audits against the TR4 Biosecurity Standard in the GLOBALG.A.P. IT systems, the TR4 Biosecurity Standard is a tool that can also be used by local phytosanitary authorities, national plant protection organizations, and the market.

2 GENERAL

- a) These TR4 Biosecurity Standard general regulations supply the basis for the implementation of the TR4 Biosecurity Standard.
- b) CBs and/or VBs that want to audit producers against the TR4 Biosecurity Standard shall be formally approved by the GLOBALG.A.P. Secretariat before they may conduct any TR4 Biosecurity Standard audits. See Annex I, “TR4 Biosecurity Standard certification body/verification body approval process.”
- c) It is the responsibility of the producers to ensure that they conform to the minimum requirements of national plant protection organizations’ biosecurity measures and those of the market the producers intend to supply.

¹Food and Agriculture Organization of the United Nations 2013. Fusarium Tropical Race 4 (TR4) <https://www.fao.org/world-banana-forum/fusariumtr4/en/>

- d) The term “shall” is used throughout the GLOBALG.A.P. normative documents to indicate mandatory provisions.

3 DOCUMENTS

3.1 Normative and obligatory documents

The following normative documents (and any other documents released as normative or obligatory) are relevant to all applicants and GLOBALG.A.P. letter of conformance holders:

- a) TR4 Biosecurity Standard principles and criteria (P&Cs): a document setting out the compliance requirements for producers
 Note: Guidelines referenced in the P&Cs to guide producers to comply with the requirements are *not* normative documents.
- b) TR4 Biosecurity Standard checklist: a document based on the P&Cs and used for second- or third-party audits as well as for self-assessments and internal audits
- c) TR4 Biosecurity Standard general regulations: rules that define how the audit process works.
- d) TR4 Biosecurity Standard data access rules as a supporting document
- e) GLOBALG.A.P. sublicense and certification agreement: contract between the CB and the producer
- f) Verification body sublicense agreement: contract between the VB and the producer

3.2 Normative and obligatory documents control

- a) The latest versions of the normative documents can be downloaded free of charge from the GLOBALG.A.P. website (www.globalgap.org).
- b) Language: Original documents are in English. Normative documents are translated into selected languages and published on the GLOBALG.A.P. website. In the case of a discrepancy between translations, the English version shall prevail.
- c) Changes to documents:
 - (i) Normative documents are identified with a unique document code, version number, and date.
 - (ii) The date in the version name indicates the date of publication of the document.
 - (iii) Version number: A change in the first digit (e.g., change from 1.0 to 2.0) indicates changes in the requirements and a version change. A change in the second digit (e.g., change from 1.0 to 1.1) indicates a version update. A change in other digits (e.g., change from 1.0 to 1.0-1) indicates an edition update.
 - (iv) Updates can be made independently in the general regulations and P&C documents.
 - (v) Published updates will be sent to all TR4 Biosecurity Standard approved CBs/VBs as official communications. It is the responsibility of the CBs/VBs to inform their clients of all version and edition changes and updates.
 - (vi) Version and edition updates are summarized and indicated in the version/edition update register at the end of a document. Version changes are summarized and published separately.

4 CERTIFICATION OPTIONS

4.1 Individual producer

An individual producer (single legal entity) applies for certification to the TR4 Biosecurity Standard. The individual producer is the certificate holder once audited.

4.2 Multisite producer without QMS

An individual producer or one organization owns several production sites that do not function as separate legal entities.

For multisite producers without a quality management system (QMS) in place, all production sites shall be audited, i.e., there is no sampling of production sites. The individual producer is the certificate holder once audited.

4.3 Multisite producer with QMS

An individual producer or one organization owns several production sites that do not function as separate legal entities but where a QMS has been implemented.

For multisite producers with a QMS in place, all production sites shall be audited, i.e., there is no sampling of production sites.

The individual producer is the certificate holder once audited.

5 PRODUCER APPLICATION REQUIREMENTS

- a) Any producer responsible for the primary production of bananas and/or plantains may apply for a TR4 Biosecurity Standard audit.
- b) Producers apply as individuals, irrespective of whether they are members of a producer group (as per the GLOBALG.A.P. definition of a producer group with a quality management system) or members of a cooperative or association.
- c) Once audited as compliant, the producer shall receive a letter of conformance.
- d) Producers who have already been assigned a Global Location Number (GLN) or Global Farm Number (GFN) shall inform the CB/VB of this, if they are applying to a different CB/VB.

6 REGISTRATION WITH THE CB/VB

6.1 CB/VB

- a) TR4 Biosecurity Standard registrations and audits may be carried out by:
 - (i) CBs with final approval for the Integrated Farm Assurance (IFA) standard versions 5 and 6 for the fruit and vegetables product category, if those CBs have applied for the scope extension and have been approved for the TR4 Biosecurity Standard
 - (ii) VBs with final GLOBALG.A.P. approval for the TR4 Biosecurity Standard
- b) Producers making use of a VB rather than a CB are responsible for ensuring that their intended customers accept the use of VBs.

- (vi) A CB/VB may not release any data to any other third party without the written consent of the applicant except the GLOBALG.A.P. Secretariat.
- f) An applicant:
- (i) May not register the same banana and/or plantain production site with more than one CB/VB
 - (ii) May not register the same banana and/or plantain production site under both the TR4 Biosecurity Standard and the TR4 Biosecurity Add-on for Bananas
 - (iii) May not register production sites in different countries with any CB/VB
- g) For the registration to be completed, the applicant shall:
- (i) Submit to the CB/VB the relevant application that shall include all the necessary information. The applicant shall make a formal commitment to comply with the obligations indicated above.
 - (ii) Sign acceptance of the GLOBALG.A.P. sublicense and certification agreement/verification body sublicense agreement in its latest version with the CB/VB. The CB/VB shall hand over a copy of the signed GLOBALG.A.P. sublicense and certification agreement/verification body sublicense agreement to the applicant
 - (iii) Be assigned a GFN if the applicant does not yet have GLN. If the applicant has a GLN, they shall provide it.
 - (iv) Pay the registration and the TR4 Biosecurity Standard fee, as specified in the current GLOBALG.A.P. fee table.
- h) Requirements for banana and plantain production sites:
- (i) For production sites that are not owned by the legal entity seeking an audit against the TR4 Biosecurity Standard, there shall be a signed document which includes a clear indication that the site owner does not have any responsibility or input or decision-making capacity regarding the production operations over the rented-out site. There shall also be written contracts in force between each production site owner and the legal entity that include the following elements:
 - Name and legal identification of the owner of the letter of conformance
 - Name and/or legal identification of the production site owner
 - Production site owner's contact address
 - Details of the individual production sites
 - Signature of both parties' representatives
 - (ii) The owner of the letter of conformance is legally responsible for all the registered production, including placing the product on the market, and ensuring that all biosecurity measures in the TR4 Biosecurity Standard have been taken.
 - (iii) A product handling unit (PHU) is defined as a facility where bananas or plantains are handled. If a producer handles bananas or plantains in one or more PHUs, all PHUs shall be identified and registered.

6.2.2 Registration with a new CB/VB

- a) The registration process shall be finalized before the CB/VB audit can take place.
- b) In the case of first registration, the CB/VB shall confirm the acceptance of the application and provide the applicant with the GFN within 28 calendar days of receiving the completed application.
- c) If a producer that has already been registered applies/changes to a new CB/VB to be audited, the producer shall communicate any relevant GLN or GFN to the new CB/VB.
- d) It is not considered an initial audit when a producer moves from one CB/VB to another CB/VB.

7 AUDIT PROCESS

In order to be successfully audited against the TR4 Biosecurity Standard, the producer shall perform a self-assessment and be audited by the chosen CB/VB.

7.1 Self-assessments

- a) The self-assessment shall:
 - (i) Cover all registered production sites, products, and processes under the TR4 Biosecurity Standard to verify compliance with the requirements defined in the applicable P&Cs
 - (ii) Be carried out by or under the responsibility of the producer
 - (iii) Be carried out before the initial CB/VB audit and thereafter at least annually before the CB/VB audit against the complete checklist. The checklist shall be available on-site for review at all times.
 - (iv) The completed self-assessment checklist shall contain comments of the evidence observed for all not applicable and non-compliant Major Must P&Cs.

7.2 CB/VB audits

- a) Each producer shall undergo one announced CB/VB audit per annum.
- b) The duration of CB/VB audits shall be appropriate to the size of the production site.
- c) CB/VB audits shall be conducted by a CB/VB that has been approved to conduct audits against the TR4 Biosecurity Standard.
- d) The CB/VB auditor shall conduct the audit using the complete checklist.
- e) The CB/VB 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/VB 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.

8 CERTIFICATION PROCESS

8.1 Requirements for achieving and maintaining TR4 Biosecurity Standard compliance

- 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 Standard 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.

Audit 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

Example: During the CB/VB audit, a producer complied with 23 of 37 P&Cs, 3 P&Cs were N/A. The rating is therefore calculated as follows:

Total no. of P&Cs: 37

No. of N/A P&Cs: 3

Total no. of applicable P&Cs: (37 - 3) = 34

No. of fully compliant P&Cs: 23

$$23 \times 100 / 34 =$$

67% – Some improvements required

- c) The CB/VB shall make a decision regarding the producer's result within a maximum of 28 calendar days after closure of any outstanding non-compliances.
- d) 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.
- e) Once the letter of conformance has been issued, the producer's status in the GLOBALG.A.P. IT systems shall be change from "Accepted" to "Verified".

8.2 Cancellation

- a) A cancellation of the contract shall be issued if the CB/VB finds evidence of fraud and/or lack of trust to comply with TR4 Biosecurity Standard requirements.
- b) A cancellation of the contract results in the total prohibition of the use of the TR4 Biosecurity Standard letter of conformance or any device or claim that may be linked to GLOBALG.A.P.
- c) Producers whose contract has been cancelled shall not be accepted for certification to the TR4 Biosecurity Standard within 12 months of the date of cancellation.
- d) The producer shall either resolve the issues that were communicated and led to the cancellation or appeal to the CB/VB in writing explaining the reasons for the appeal.

8.3 Letter of conformance

- a) The letter of conformance can only be issued to the legal entity.
- b) A letter of conformance is not transferable from one legal entity to another when production sites change legal entity. In this case, a complete CB/VB audit is required. The new legal entity shall receive a new GFN.
- c) The validity of the letter of conformance is 12 months.

8.3.1 Letter of conformance information

The letter of conformance issued by a CB/VB shall conform to the available template (Annex II). The format may be different, but the letter of conformance shall include at least the same information provided in the template.

8.3.2 Requirements for maintaining a valid letter of conformance

- a) The registration of the producer and the proposed products shall be confirmed with the CB/VB *annually before* the current letter of conformance expiry date.
- b) The producer shall perform the required self-assessment and be subject to external audits by the chosen CB/VB annually.

9 CB AND VB REGISTRATION RULES FOR THE TR4 BIOSECURITY STANDARD

Depending on who will conduct the TR4 Biosecurity Standard audits, the following registration rules for the CB/VB shall apply.

9.1 GLOBALG.A.P. finally approved CBs

- a) If a GLOBALG.A.P. finally approved CB uses auditors who are *already qualified* for the IFA standard and the TR4 Biosecurity Add-on for Bananas, these CB auditors shall be authorized to conduct TR4 Biosecurity Standard audits. A list of approved CB auditors for the TR4 Biosecurity Standard shall be registered in the GLOBALG.A.P. IT systems.
- b) If the CB auditors are *not yet* qualified for the IFA standard and the TR4 Biosecurity Add-on for Bananas, the CB shall audit the qualifications of those auditors (see 9.3). The CB shall evaluate and internally record evidence of their competence and qualifications before they shall be allowed to conduct any TR4 Biosecurity Standard audits. The GLOBALG.A.P. Secretariat reserves the right to inspect these records.
- c) In order to apply, the GLOBALG.A.P. finally approved CB shall:

- (i) Submit a TR4 Biosecurity Standard letter of intent to the GLOBALG.A.P. Secretariat (see Annex III)
- (ii) Pay an annual CB license fee (scope extension) according to the GLOBALG.A.P. fee table. The scope extension fee for the CB is only charged once for the first TR4 Biosecurity Standard application and includes all other extensions in any country.
- (iii) Complete a GLOBALG.A.P. IT systems training for producer registration and checklist uploading
- (iv) Register the names of the auditors who will be conducting the TR4 Biosecurity Standard audits in the GLOBALG.A.P. IT systems
- (v) Consider the clause on liability in the latest GLOBALG.A.P. sublicense and certification agreement and provide sufficient evidence, where applicable

9.2 VBs

- a) A VB may also conduct TR4 Biosecurity Standard audits only if the VB is successfully approved by the GLOBALG.A.P. Secretariat as a VB and if the applicable market accepts audits carried out by VBs.
- b) To become an approved VB, a legal entity shall first follow the application process, be successfully approved by the GLOBALG.A.P. Secretariat, and pay the relevant fees as per the latest version of the GLOBALG.A.P. fee table.
- c) To be approved as a VB for the TR4 Biosecurity Standard, the VB shall:
 - (i) Submit a TR4 Biosecurity Standard letter of intent to the GLOBALG.A.P. Secretariat (see Annex III)
 - (ii) Complete a GLOBALG.A.P. IT systems training for producer registration and checklist uploading
 - (iii) Register the names of the auditors who will be conducting the TR4 Biosecurity Standard audits in the GLOBALG.A.P. IT systems
 - (iv) Consider the clause on liability in the latest verification body sublicense agreement and provide sufficient evidence, where applicable

9.3 CB/VB auditor qualifications

- a) The audits shall be conducted by a CB/VB auditor who has been approved to conduct audits against the TR4 Biosecurity Standard. CB/VB auditors who may conduct such audits fall into three groups:
 - (i) CB auditors who have already been approved to conduct audits against accredited standards such as IFA v5 and IFA v6.
 - (ii) Auditors from GLOBALG.A.P. finally approved CBs who already conduct audits against nonaccredited products such as the TR4 Biosecurity Add-on for Bananas
 - (iii) VB auditors who have been approved to conduct audits against the TR4 Biosecurity Standard
- b) Each CB/VB auditor who conducts audits against the TR4 Biosecurity Standard shall be trained by the CB/VB 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 Standard, 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.

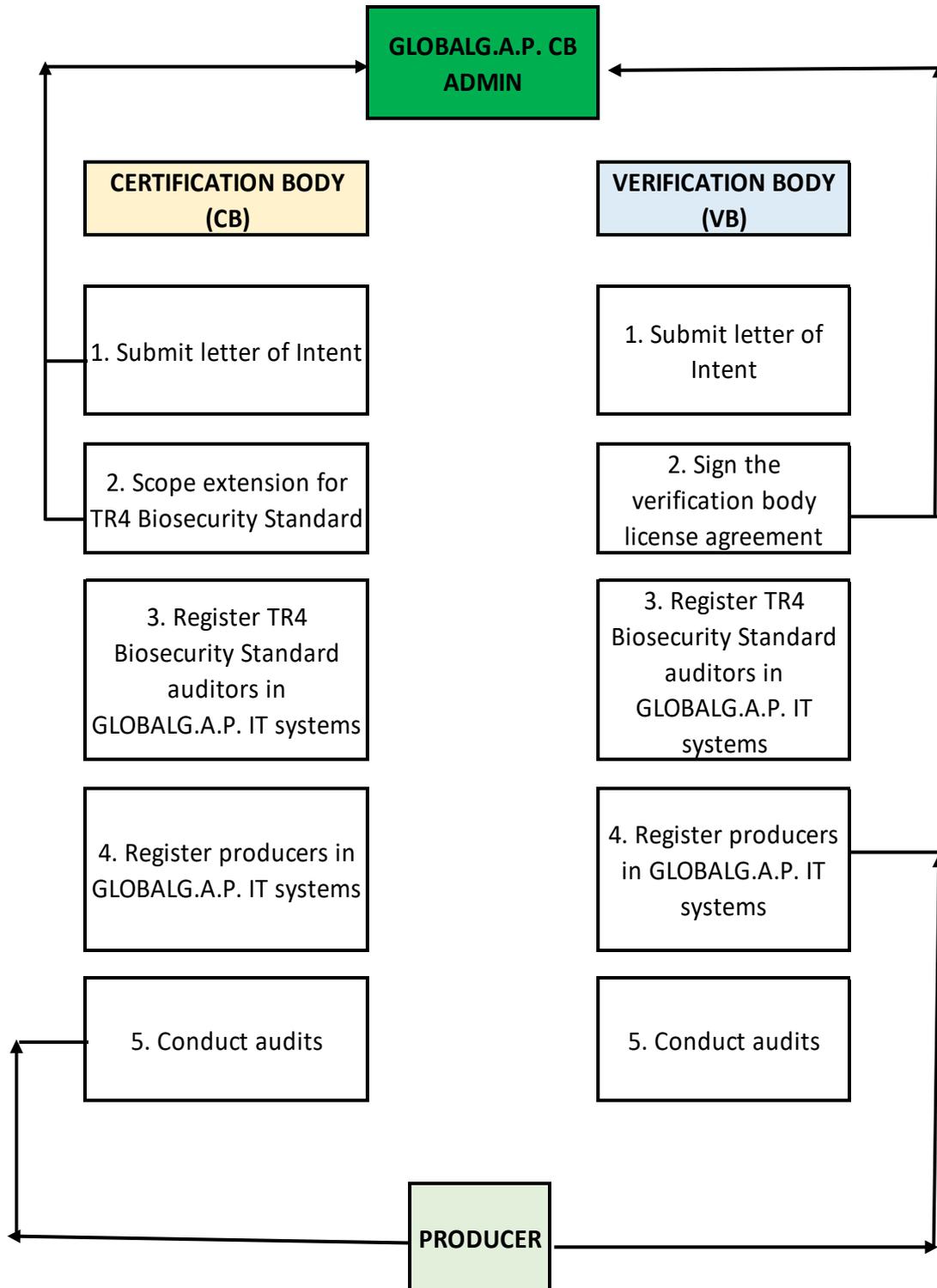
- c) CB/VB auditors shall pass a TR4 Biosecurity Standard online test once it becomes available.
- d) CB/VB auditors shall be aware of the current list of countries with a confirmed presence of Foc TR4. The CB/VB shall keep this country list updated.
- e) The CB/VB shall maintain records of each auditor's travel log and ensure that they are not transmitting Foc TR4. These records shall be kept for each CB/VB 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/VB auditor conducting the audit against the TR4 Biosecurity Standard
 - (ii) List of the countries visited (where the CB/VB auditor visited banana or plantain production sites) in chronological order
 - (iii) List of the GFNs of the producers visited by this CB/VB auditor prior to the audit
 - (iv) List of the GFNs for production sites where the Foc TR4 pathogen has been identified, including the date of the visit
- f) The CB/VB 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/VB 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.

*A disinfection kit shall include the necessary disinfecting agents and items for ensuring that all the CB/VB 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).

ANNEX I TR4 BIOSECURITY STANDARD CB/VB APPROVAL PROCESS



230922_TR4_Biosecurity_GR_v1_0_Sep23_en

ANNEX II LETTER OF CONFORMANCE TEMPLATE

LETTER OF CONFORMANCE TEMPLATE FOR THE GLOBALG.A.P.

TR4 BIOSECURITY STANDARD



Global Farm Number (GFN): **GFN_XXXXXXXXXXXXXXXXXXXXX**²
 Registration number of company (from CB/VB) **XXXXXXXXXX**³

Letter of Conformance

According to **the TR4 Biosecurity Standard**
 Version **xx**⁴

Issued to

Company/Producer
 Company name, address⁵

Option⁶

Country of production/Company location⁷

The certification body [company name] declares that the company has been audited against the TR4 Biosecurity Standard version **xx**, for the following products:

Crop – area (ha) ⁸		
Plantain ID 141	Banana ID 9	Banana PPM ID 501
Baby Banana ID 126		

Evaluated 00%¹⁵

Date of issuing (printing date of letter):
xx/xx/xxxx⁹

Valid from: xx/xx/xxxx¹⁰

Valid to: xx/xx/xxxx¹¹

Authorized by¹²

Date of approval decision: xx/xx/xxxx¹³

“The current status of this letter of conformance is always displayed at:
<http://www.globalgap.org/search>”¹⁴

230922_TR4_Biosecurity_GR_v1_0_Sep23_en

Notes

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

- 1) The certification body (CB)/verification body (VB) logo shall appear on all LoCs.
- 2) The Global Farm Number (GFN) shall appear on all LoCs. If an LoC holder owns a Global Location Number (GLN), this number shall replace the GFN.
- 3) The CB- or VB-assigned registration number of a company/producer may (voluntarily) appear on all LoCs. It consists of the CB/VB initials and a number (with exactly one space character between, [CB initials] xxxxxxxxxxxx)
- 4) Please enter “TR4 Biosecurity Standard, version x.x.” Always mention the version used.
- 5) The name of the LoC holder and the address shall be printed on the paper LoC.
- 6) The applicable option shall always appear on the LoC as one of the following:
Individual producer, Individual multisite producer, Individual multisite producer with QMS.
- 7) Country of production/Company location
- 8) For the TR4 Biosecurity Standard, the crop could be any of the following products: Banana ID 9 (FV); Baby banana ID 126 (FV); Plantain ID 141 (FV); Banana PPM (ID 501). Hectares shall be aggregated for each product.
- 9) Date of issuing (printing date of LoC): Day/Month/Year. The date of issuing is the printing date of the paper LoC. It shall be added to the first page of the LoC and to the annex to connect them to each other.
- 10) The LoC “valid from” date defines the beginning of an audit cycle.
- 11) The LoC “valid to” date is the expiry date of the LoC.
- 12) The first and the last name of the person who has authorized the LoC, written in block letters. This person shall sign the LoC.
- 13) “Date of approval decisions” shall appear on all LoCs.
- 14) The note “The current status of this letter of conformance is always displayed at: <http://www.globalgap.org/search>” shall be added to all paper LoCs in order to point out that only a validation in the GLOBALG.A.P. IT systems proves the current status of the LoC.
- 15) Percentage (%) result of the evaluation

ANNEX III EXAMPLE OF A TR4 BIOSECURITY STANDARD LETTER OF INTENT

(NOTE: This letter of intent shall be completed by any CB/VB that wants to conduct TR4 Biosecurity Standard audits.)

[Applicant company]’s

TR4 Biosecurity Standard Letter of Intent

Attention: GLOBALG.A.P. CB Administration

Date: _____

RE: Letter of intent to audit against the TR4 Biosecurity Standard

Please accept the intention of **[COMPANY NAME]** to participate in the TR4 Biosecurity Standard audits for the following products:

1. We hereby commit to paying all fees as per the current GLOBALG.A.P. fee table on time.

2. We are a: **[choose whichever is applicable]**

GLOBALG.A.P. finally approved certification body

Verification body

3. We appoint Mr./Mrs./Ms./Dr. _____ as the **contact person** for the TR4 Biosecurity Standard.

The contact details of the contact person(s) is/are as follows:

Telephone number: _____

Mobile number: _____

Email address: _____

4. Please find attached the list of the names of the auditors approved to conduct the audits (with the relevant qualification records).

Kind regards,

[Signature]

[LAST NAME, FIRST NAME, and TITLE]

VERSION/EDITION UPDATE REGISTER

New document	Replaced document	Date of publication	Description of modifications
230922_TR4_Biosecurity_GR_v1_0_Sep23_en	230703_TR4_Biosecurity_GR_v1_0_Jul23_en	22 September 2023	8.1 clarification of the number ranges in the table

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

When 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”. When the changes do affect compliance with the standard, the version name will change to “5.x”. A new version e.g.: v6.0, v7., etc., will always affect the accreditation of the standard.

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