

GSPP Standard

for tomato seed and young plant production sites

Version 3.1.

Valid from 11th December 2017

Applicable from 1st January 2018

I-17-2697

CONTENTS

CONTENTS	2
HISTORY OF CHANGES	3
1 INTRODUCTION AND SCOPE OF THIS STANDARD	3
1.1 References	4
1.2 Schematical description of a GSPP site	5
2 IDENTITY	6
3 QUALITY MANAGEMENT SYSTEM (QMS)	6
3.1 Quality Policy	7
3.2 Scope	7
3.3 Organization	8
3.4 Staff	8
3.5 Quality Management Documents	9
3.6 Document Management	10
3.7 Audits	10
3.8 Management Review	11
4 RISK ANALYSIS	12
4.1 Risk Identification	12
4.2 Risk Analysis and Control Measures	13
5 CROP MONITORING FOR <i>Cmm</i>	13
6 CRISIS MANAGEMENT	14
6.1 Plants (minimum requirements)	14
6.2 Seeds (minimum requirements)	15
6.3 Facilities	15
6.4 Record the findings for both seeds and plants	16
6.5 Decision to enter in a Technical Investigation Procedure (TIP)	16
7 SALES AND SHIPMENT	17
8 TRACEABILITY	17
9 CUSTOMER RELATIONSHIP	17
10 DELIVERY DOCUMENTS & LABELS	17
10.1 Delivery documents	17
10.2 GSPP Product-Seed	18
10.3 GSPP Product-Plants	19
11 TECHNICAL REQUIREMENTS	19
12 REQUIREMENTS FOR LABORATORIES TESTING FOR THE GSPP SYSTEM	19

HISTORY OF CHANGES

Version	Chapter	Changes
3.0 & 3.0.1. (follows 2.1)	1.1	Other documents listed & wording
	1.2	Wording, new figure 1
	2	Added
	3.2.1	Wording
	3.2.2	Wording added
	3.2.4	New chapter
	3.3.3.	Chapter deleted, moved to 3.5.3.
	3.5.2	Changes & wording added
	3.5.3	Changes & wording added
	3.7	Chapter changed
	3.8	Wording
	4.1.2	Wording added
	6.	Change
	6.1	Change
	6.2	Changes & wording added
	6.3	New chapter
	6.4	Was 6.3 in V2.1
	6.5	Was 6.4 in V2.1
	10.	Information included from Annex 14.5. 10.1, 10.2 and 10.3 new chapters, no changes in content.
	12.	New chapter

1 INTRODUCTION AND SCOPE OF THIS STANDARD

GSPP is an Accreditation system based on a process approach to prevent seed- and plant-transmitted pathogens. GSPP is intended as a system for accredited companies to ensure that site(s), quality management systems, work methods and how quality information is supplied comply with the defined standard and to check their performance periodically.

The GSPP standard applies to the following crops:

- Tomato and tomato rootstock.

The GSPP standard applies to the following pathogens:

- *Clavibacter michiganensis subsp. michiganensis*(Cmm).

The GSPP standard is based on the following requirements:

- The Participant's quality management system.
- Risk assessment of defined threats in production facilities and processes.
- Technical requirements based on the listed crops and pathogen.

GSPP is a chain approach (see scope). When all applicable steps in this scope are covered and checked, thereby proving compliance with all listed requirements, the Participant

- Will receive GSPP recognition (certificate).
- Is authorized to use the collective GSPP trademark.

GSPP Participants are operators in business chain of producing tomato seeds and tomato young plants. The following GSPP Participants have been identified: Plant Raisers, Seed Companies, Seed Producers, Seed Technology Company, Sub-Contractors and independent seed Distributors. Commercial Growers and Service Suppliers are not part of the Standard, but play an important role in the final success of the Standard.

All these aspects together form an integral framework:

GSPP-standard

For tomato seed and young plant
production sites

1.1 References

The following documents are available on the GSPP website (www.gspp.eu). They must be included in the Participant's quality management system:

- GSPP Standard for tomato seed and young plant production sites latest version.

Other documents that can be specifically mentioned are:

- Annex 14.1 Guidelines GSPP for sampling of seed lots for seed health testing latest version.
- Annex 14.2 Protocol for *Cmm* diagnosis in plant material latest version.
- Annex 14.3 ISHI protocol latest version.
- Annex 14.5 Technical requirements GSPP Standard latest version.
- Annex 14.6 Technical Investigation Procedure latest version.
- Annex 14.7 GSPP Definitions latest version.
- Annex 14.8 Requirements for laboratories testing for the GSPP system
- Annex 14.9 Overview GSPP accepted seed health test methods and validity of the results latest version.

Other documents used as reference or form in the GSPP standard, for example application and modification form, general audit regulations, Participation Letter etc...

1.2 Schematical description of a GSPP site

To understand clearly the principle of the GSPP site, a schematical description of a GSPP site is given below. This model is applicable under different practical circumstances and coloured for better understanding of the different areas (figure 1).

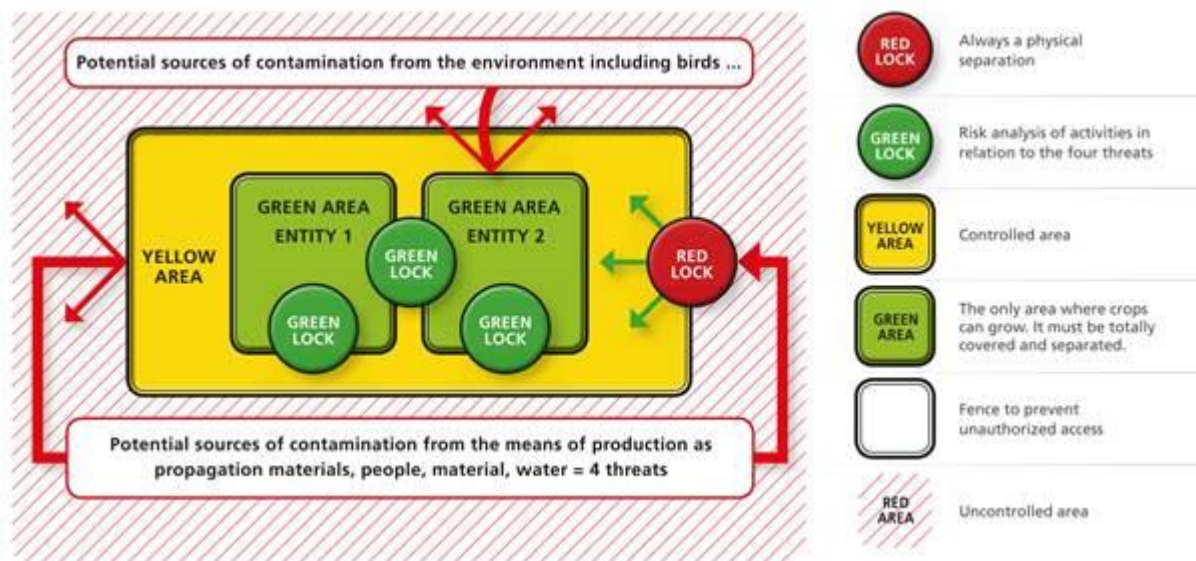


Figure 1 Schematical model of a GSPP site

A GSPP Site is a physical location where plants and/or seeds are grown and/or processed, location can be separated in several production areas. A Site is specifically named on the

certificate and/or certified list. Each site can consist of so-called Red, Yellow and Green areas.

The Red Area is an uncontrolled area and separated from a Green or Yellow Area by means of a Red Lock. GSPP assumes that *Cmm* can be present in this area. A Red Lock is always physical. A Red Lock is designed to provide access for the four Threats' (propagation material, water, people and materials (including equipment)) to the Yellow or Green Areas after sufficient disinfection and/or a risk analysis indicating that contamination with *Cmm* has been minimized. The risks of contamination between Red and Green or Yellow Area are minimized by a red lock. When entering the Yellow or Green area via the Red Lock, the boundaries (the start and end) of the Red Lock should be logic, identifiable/visible and controllable.

The Yellow Area is the part of the production site beyond the Red Lock, where all important hygiene measures are followed. This area is separated from the Red Area (by a Red Lock) and Green Area (by a Green Lock).

The Green Area is the only area where crops can grow. It must be totally covered and separated. Additional in:

- ventilation openings in Seed production (and its plant production): netting is compulsory.
- ventilation openings in Commercial Plant production: netting is not compulsory.

The Green Area is separated from the Yellow Area by a Green Lock. This is a 'physical or not physical separation', compulsory between Yellow and Green Area or between 2 entities. Entities must be recorded. A Green Lock is implemented and required if a risk analysis shows a potential risk of contamination or cross-contamination. If so, preventive measures must be written down and implemented. Risks of contamination between entities are minimized.

2 IDENTITY

The Participant must be a company duly organized and governed by the laws and regulations in force in its own country. The Participant is registered at the GSPP Secretariat through an application and/or modification form. Its authorized representatives have signed the Participation letter and which has been accepted by GSPP Board.

3 QUALITY MANAGEMENT SYSTEM (QMS)

The Participant must have a quality management system covering the items in this Standard.

3.1 Quality Policy

The Participant's management must state its wish to comply with the GSPP standard, in order to produce healthy plants/seed as required by this standard.

3.2 Scope

3.2.1 The Participant must clarify the scope for each site(s) in the Quality Manual (§ 3.5.3). Potential accreditation categories for Participants:

SCOPE #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
PROCESS	Sampling and/or testing of starting material	Interface (shipment of starting material)	Production of plants for seed production	Interface (shipment of plants)	Production of seeds	Interface (shipment of fruits)	Extraction	Interface (shipment of seeds)	Seed processing	Interface (shipment of seeds)	Seed treatment / enhancement	Interface (shipment of seeds)	Sampling and/or testing of seeds	Interface (shipment of seeds)	Trading of seeds, issue the Collection Trademark	Interface (shipment of seeds with GSPP-Collective Trademark)	Production of plants for fruit production	Interface (shipment of plants with GSPP-Collective Trademark)

Figure 2 Reference table indicating which processes are part of the scope of a GSPP-Participant

3.2.2 Steps 3, 5 and 17 are processes vulnerable to *Cmm* infection and must be conducted in the Green Area.

3.2.3 The Participant must also indicate the sub-contracted processes in the Quality Manual. He must state whether he uses sub-contractors and/or service suppliers (by process and name).

3.2.4 The explanation and boundaries of each Scope are explained in Annex 14.7.

3.3 Organization

3.3.1 The Participant must organize himself/herself to be able to constantly comply with the requirements of this standard.

3.3.2 The Participant must appoint:

- A technical manager (irrespective of title) who is directly responsible for the technical performance of the GSPP production site.
- A quality manager (irrespective of title) who is responsible for the quality management system and its implementation on the site(s), including the reports connected with this system.

3.4 Staff

3.4.1 The Participant must have enough employees to provide the labour on the production site(s), with sufficient qualifications and/or skills for their tasks.

3.4.2 The Participant must define and maintain a recorded training procedure. This procedure must cover:

- Identifying training needs.
- Planning/providing training.
- Evaluating the training dispensed.
- Keeping employee training and qualification records.

3.4.3 Staff must be informed clearly about their tasks, competencies and responsibilities assigned to them through:

- Procedures/working instructions.
- Adequate supervision.
- Qualifications/training/experience.

3.4.4 Task substitution must be arranged for key personnel.

3.4.5 They shall not be under any financial, commercial or other kind of pressure that could have a negative influence on their work efficiency.

3.4.6 The Participant's management must ensure that suitable communication processes are established within and between the departments or positions in question,

3.4.7 And that communication takes place with regard to the efficiency and effectiveness of the quality management system.

3.5 Quality Management Documents

3.5.1 The QMS must be laid down in a quality manual complying with the requirements of this standard.

3.5.2 The quality manual must be in English at least, with the provision that the Quality Manual and the procedures listed in the GSPP Standard, in France can be in French and in the Netherlands in Dutch. All other documents are allowed in the local language. If the working instructions, forms and other documents are in the local language the company should arrange an independent translator.

3.5.3 The quality manual must contain at least:

- Name of the company.
- General description of the company.
- GSPP Sites.
- Content page of the quality manual.
- Matrix: quality manual paragraphs/ GSPP standard paragraphs.
- Quality policy and scope (if applicable: per site).
- Organization organigram.
- Flow chart of processes.

3.5.4 The Participant must also provide:

- Procedures.
- Working instructions.
- Physical layout of the site(s).
- All forms.

3.5.5 The quality documents must be maintained and kept up to date.

3.6 Document Management

3.6.1 Document control.

The Participant must define a system:

- To manage all documents and data referring to the requirements of the GSPP standard,
- Including, and where applicable, documents from external sources.
- This management system must:
 - Process document versions.
 - Approve documents.
 - Implement changes to documents (including removal of obsolete documents).
 - Ensure documents related to the function/task/process are available in site.

3.6.2 Records control (including electronic quality data).

The Participant must be able to demonstrate his decisions in terms of:

- Which quality records have to be kept.
- By whom and where.
- For how long,
- And how they are removed / destroyed after this period.

The reliability and stability of any electronic data processing systems must be demonstrated not to influence the accuracy of the results. Data security must be ensured, including prevention of unauthorized access and unauthorized modification of computer data.

3.7 Audits

3.7.1 Internal audits:

- The Participant must define and maintain a procedure for planning and implementing quality Internal Audits.
- The Internal Audit must be performed by the Applicant/Participant and is in line with the QMS requirements and the flow of activities. The Applicant/Participant plans Internal Audits as follows:
 - At least once every 3 years for non-vulnerable processes (processes which do not have a risk or low risk on Cmm contamination), like e.g. quality manual review, document control etc.
 - At least once per year for vulnerable processes (processes with high risks on contamination with Cmm: scopes 3, 5 and 17) like e.g. crop monitoring, sowing, grafting, harvesting, extraction etc.

- All processes are audited according to an internal audit plan. Based on the outcome of Internal and Implementation/Documentation (external) Audits, a logical Audit plan has to be made considering the processes and their importance of appraising. The logical audit plan must include:
 - The status and the significance of the audited process;
 - Internal auditors must be independent regarding the audited process;
- Internal auditors who have attended an auditor training course and/or are skilled.
- During an Internal Audit the internal auditor checks whether daily practices are carried out in accordance with:
 - The GSPP standard,
 - And the Participant's QMS.

3.7.2 The Participant must do the following after an Internal and External (Implementation/Documentation) Audit:

- The results of both an Internal and External audit must be recorded and brought to the attention of those employees responsible for the audited process.
- The Participant must undertake a root cause analysis and adequate corrective action for any non-conformity revealed during an Audit.
- The effectiveness of corrective measures must be verified and recorded.

3.8 Management Review

The Participant's management must review its processes annually to determine the effectiveness of its QMS. The management review objectives/outcome must be SMART, Specific, Measurable, Acceptable, Realistic and Time bound.

The management review must at least consider (demonstrable by minutes):

- Minutes of the previous management review.
- Results of audits (e.g. non-conformities).
- Feedback from customers.
- Control measures.
- Process indicators of the functioning of the site.
- Possible contamination.
- Status of preventive and corrective action.
- Possible changes (e.g. in GSPP standard, lay out, staff, etc.) with consequences for the Participant regarding GSPP.
- The conclusions may suggest a need to improve the QMS. If so, this must be set out in new objectives (specific, measurable, acceptable, realistic and time-bound) for the coming year(s), together with:
 - Plan of approach.
 - Possible constraints.
 - Implementation/communication with employees.

4 RISK ANALYSIS

4.1 Risk Identification

4.1.1 A procedure describes how the risks are identified (method, responsibility, frequency, etc.). The risk analysis must be updated regularly, as soon as changes occur in or with:

- All processes.
- New insights into risks.
- Organization.

4.1.2 The possible risks from the four threats have to be identified prior to any risk analysis for:

- Each process.
- On each site (including red and green locks).
- For the whole production and processing cycle.

4.1.3 This has to be carried out by a risk identification team which is competent, multi-disciplinary and expert in the requirements of the Standard, *Cmm Hygiene*.

This team, comprising representatives from both management and operators/employees, must be familiar with the interfaces between the processes involved.

4.1.4 Identifying the risks means considering each process at working instruction level by:

- Observing the process(es) applied every day for specific risks related to the four threats.
- Noting their findings (process step – risk/cause).

4.1.5 Records have to be kept.

4.2 Risk Analysis and Control Measures

Any risks identified have to be analysed individually. This has to be done by a competent and multi-disciplinary team.

The team has to:

- Consider each risk and its possible cause(s).
- Determine the possible impact.
- Decide whether or not a control measure is required.
- Develop a new control measure or,
- Adapt an existing control measure.
- Act/manage control measures as necessary (the control measures have to be seen to be managed/monitored appropriately to reduce/minimize the risk of contamination by *Cmm*).
- Note the conclusions (process step – risk/cause/impact – conclusion/motivation. For example: no control measure required or reference to a control measure with a link to a procedure or instruction).
- Make clear which records have to be kept to monitor the control measures (to demonstrate whether or not an aspect is under control).

5 CROP MONITORING FOR *CMM*

The production site must have a crop monitoring procedure indicating:

- Responsibilities,
- Competencies,
- Frequency,
- Method,
- Forms.

The results of inspections must be recorded.

6 CRISIS MANAGEMENT

The Participant must have a Crisis Management procedure (this procedure must be applied immediately when suspicious plants or seeds are detected).

The GSPP Participant to whom the observation was made, is responsible to immediately take measures to get confirmation (or not) of suspected infection and following confirmation, to contain and limit the damage by the possible consequences of an infection by taking all reasonable precautionary measures as below.

Confirmation and initial emergency measures may thus comprise the activities, listed in 6.1 and 6.2. This list is not exhaustive but is the minimum; circumstances may require more activities.

In case there is no confirmation this procedure will be finished.

If the *Cmm* infection is confirmed, the GSPP Participant sends a copy of the written report of the confirmed *Cmm* infection to the GSPP Secretariat. The execution of the emergency plan and crisis management is the responsibility of the affected party where the *Cmm* infection is confirmed. Temporary suspension of deliveries of seeds and/or young plants from this entity is required. The emergency plan consists of the crisis measures to be taken by a Suspected *Cmm* and/or Confirmed *Cmm* company to prevent the spread of the disease. These measures have to be in line with local NPPO's regulations.

The minimum requirements are described for plants and seeds.

6.1 Plants (minimum requirements)

- Mark and isolate the plant suspected.
- Inform the management.
- Restrict access to the suspected area and adapt the working method.
- Sample and investigate the suspected plants by laboratory testing (see Annex 14.2).
- Pictures of suspected plants.

Negative outcome: carry on with the normal working procedure.

Positive outcome:

- Carry out root cause analysis to identify which entities are affected (downstream and upstream) in the process.
- Start cleaning and sanitation.
- The management must inform GSPP participants which produce beyond the same red lock in that production cycle.
- Decide whether a recall is necessary.

6.2 Seeds (minimum requirements)

- Inform the management.
- Block the lot and lots in the same green Entity.
- Confirm the suspicion.
- Make decision based on the analysis results.

Negative outcome: carry on with the normal working procedure.

Positive outcome:

- Carry out root cause analysis to identify which entities are affected (downstream and upstream) in the process and define action plan.
- Start cleaning and sanitation.
- Under no circumstances can seeds from the same green Entity be used in the GSPP system, production and delivery.
- Decide whether a recall is necessary.
- If *Cmm* has been found behind a red lock, and there was starting material present for GSPP productions, the seed company must notify all seed producers already in receipt of starting material from that entity and production cycle.
- If *Cmm* has been found behind a red lock, Seed Producer must inform all GSPP Participants that produce seeds behind this red lock in this production cycle.

6.3 Facilities

In case of a situation where the red lock is broken or fails and there is a high risk of *Cmm* entering the yellow and/or green area:

- The incident needs to be registered and risk assessment must be executed on the situation.
- If necessary a root cause analysis must be done and corrective measures related to the four threats must be taken and registered.
- Registration, risk assessment and corrective evidence need to be audited afterwards in internal audits and by the AO during an external audit (periodical, renewal or re-entry audit).

6.4 Record the findings for both seeds and plants

All relevant findings must be recorded and registered.

6.5 Decision to enter in a Technical Investigation Procedure (TIP)

In case a *Cmm* confirmed infection is found by a GSPP Participant at its GSPP Accredited Site(s) and no other companies are involved, the respective GSPP Participant does not have the obligation to initiate a TIP provided it will inform the Auditing Organization in writing before the next audit. At the presentation of the audit plan the GSPP Participant needs to brief the AO regarding the procedure it followed to solve this incident.

All *Cmm* confirmed infections where a GSPP Participant is involved, must be reported to the GSPP Secretariat. The Secretariat sends the report to the chairman of the GSPP Board. The affected GSPP Participant(s) or the chairman of the GSPP Board can decide to start a TIP, based on the report.

The TIP is described in Annex 14.6 TIP procedure.

The objective of this procedure is to achieve technical conclusions in situations where a *Cmm* incident has occurred. The TIP describes the necessary steps and information in order to:

- Limit the damage.
- Reveal all the technical facts.
- Reach a sound technical conclusion.
- Recommend adaptations of the GSPP Standard.

7 SALES AND SHIPMENT

Plants and seeds are packed and handled in such a way during the sales and shipment phase that risks are negligible.

8 TRACEABILITY

The Participant must have a system to:

- Track and trace the entire history of a lot (seeds, plants, pollen or plant parts) throughout the whole GSPP process chain and possible Entities (in terms of participant responsibility).

9 CUSTOMER RELATIONSHIP

The Participant must have:

- A complaint handling procedure.
- A logical recall procedure, which complies with NPPO regulations.

10 DELIVERY DOCUMENTS & LABELS

10.1 Delivery documents

Delivery documents must be clear and unambiguous.

All rights and obligations concerning the Collective Trademark are laid down in "REGULATIONS ON THE USE AND SUPERVISION OF THE GSPP COLLECTIVE TRADEMARK". In case of any contradiction between the interpretation document and the Regulations, the Regulations shall prevail.

Use of the Collective Trademark is only permitted by GSPP Participants:

- provided it is not included in another logo or mark to form a new combination;
- provided the size allows evident and easy reading of the letters "GSPP" in the Collective Trademark;
- provided the Collective Trademark does not surpass the attention value of the Product, trade mark and/or trade name. The Collective Trademark must always be

communicated and presented as a Collective Trademark. It may not be used as a brand name or presented in such a way that suggests this is the case.

Use of the Logo is only permitted:

- in the mock-up and typographical design as specified and available for GSPP participants on the website www.gspp.eu;
- in black/white or in the registered colour combination, as below:



Participant has to prove that GSPP accreditation was in place during the production period and sales of the GSPP products.

10.2 GSPP Product-Seed

The participant must ensure that the:

- GSPP accreditation for all Scopes 1-16.
- Identification of batches of seed production plants produced according to GSPP Standard (method: track and trace system, not labelling).
- Identification of batches of seed produced according to GSPP Standard (method: track and trace system, not labelling).
- Commercialization of GSPP seed (method: track and trace system, invoices and/or waybill (shipping document) of GSPP seed, whereby on the invoices and/or waybill the GSPP logo and/or a reference to GSPP is made linked with the seed product description).
- Demonstration of the seed packaging material with affixed GSPP logo.

Or for a seed distributor:

- GSPP accreditation for all Scopes 15-16.
- Identification of batches of seed produced according to GSPP Standard (method: track and trace system, not labelling).
- Commercialization of GSPP seed (method: track and trace system, invoices and/or waybill (shipping document) of GSPP seed, whereby on the invoices and/or waybill the GSPP logo and/or a reference to GSPP is made linked with the seed product description).
- Demonstration of the seed packaging material with affixed GSPP logo.

Seed producers should demonstrate through their track and trace system the production of seeds according to the GSPP Standard. The seed, produced by a seed producer, must be identifiable for the seed company as GSPP seed. No visible GSPP-logo is allowed on the seed packaging. Seed companies should have in their contracts with a seed producer that any disruption of GSPP accreditation is communicated to them.

10.3 GSPP Product-Plants

The participant must ensure that the:

- GSPP accreditation for Scope 17 and 18.
- Identification of batches of plants produced according to GSPP Standard (method: track and trace system, not labelling).
- Commercialisation of GSPP plants (method: track and trace system, invoices and/or waybill (shipping document) of plants, whereby on these documents a reference sentence, like for example "Produced according to GSPP Standard" is added, optionally the GSPP logo can be placed on the documents).

11 TECHNICAL REQUIREMENTS

The technical requirements for the GSPP standard are stated in Annex 14.5.

12 REQUIREMENTS FOR LABORATORIES TESTING FOR THE GSPP SYSTEM

The requirements for laboratories for GSPP both for seed testing and for the testing of suspected plants are stated in Annex 14.8. An overview of GSPP accepted seed health test methods and validity of the results are mentioned in Annex 14.9.