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Eurofins IP TRUST™

Programme version 6

Contents

PART 1: CERTIFICATION PROTOCOL

1. INTRODUCTION

This document sets out the general measures for managing the Non-GMO identity of food products, derived foodstuffs and feed products for any step of the supply chain.

Formerly named Eurofins certification IP standard, the standard is now named Eurofins IP TRUST Programme and belongs to Eurofins Food Assurance. This new version applies to any audit performed after 1st July 2021.

It firstly applies to any article of raw materials, feed and food (agricultural, semi-processed and processed) for sale in European Union. However, it may apply to other destination markets if the local legislation is the actual European Union legislation or less stringent.

It is based on suitable management system and process requirements to be implemented within Non-GMO supply chains, providing an acceptable level of confidence. It includes a catalogue of requirements, specific to each actor of the supply chain, in agreement with best management practices and the relevant European legal framework. This legal framework (which is valid in 2020) is:

- Regulation (EC) n°1829/ 2003 on genetically modified food and feed and its amendments supplemented by
- Regulation (EC) n°1830/ 2003 on traceability and labelling of genetically modified organisms (GMOs) placed on the market and the traceability of food and feed products produced from GMOs and its amendments.
- Regulation (EC) n°1946/ 2003 on transboundary movements of genetically modified organisms.
- Regulation (EU) n° 619/ 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired.
- Directive 2001/ 18/ EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/ 220/ EEC and Directive (EU) 2015/ 412 amending Directive 2001/ 18/ EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.

The approach of Eurofins IP TRUST Programme is entirely consistent with the above-mentioned legislation and, considering that adventitious contamination may occur, two different thresholds are defined in the Programme:

- Legal threshold: it is legally allowed to claim the IP status of articles of food, if the GMO traces in the products are below the threshold of 0,9% and if those traces are technically unavoidable and adventitious (as stated in the Regulation (EC) n°1829/ 2003).
- Certification compliance threshold: in order to accommodate measurement uncertainty and sampling error, Eurofins Food Assurance has defined the certification compliance threshold for technically unavoidable GMO levels at 0,6%. Any product subject to the IP TRUST certification Programme shall never individually exceed this compliance threshold.

Zero tolerance is accepted for non-authorised GMOs and/ or for food and feed consisting of or produced from non-authorised GMOs, unless the applicable legislation tolerates a certain threshold (up to 0.1%).

Food and feed (or a combination of these articles of food and feed or any intermediate product or ingredient) which can claim to have an IP status are the following:

- Agricultural crops and/ or products made from them, for which there is no commercially available GM variety but for which there is a risk of GMO input (and demonstrate IP status).
- Agricultural crops and/ or products made from them, for which there is commercially available GM variety but are produced under their conventional version (and demonstrate IP status).
- Animal origin products and/ or animal-derived products, for which there is commercially available GM variety but are produced under their conventional version (and demonstrate IP status).
- Animal origin products or animal-derived products, if animals were not fed with GM feed for minimum feeding conversion periods defined by legislation, as long as the animals themselves were not produced through a GM process.

A list of GM risky inputs is provided in Appendix 1 for the purpose of reference only.

The Programme only assesses the IP status of products having GM events that can be tested (i.e. where a detection method is available on the market). Having in mind recent new genetic modification techniques and challenges for detection, this Programme currently relies on most realistic testing techniques and will be updated as further methods will become available.

This Programme is subject to third party certification audits. It is NOT a product certification but a practices/ processes/ system certification. However, correct use of the Eurofins IP TRUST seal(s) and claim(s) on product labels are checked during the audit.

2. AIM OF THE IP TRUST PROGRAMME

The Eurofins IP TRUST Programme defines appropriate measures for stakeholders to preserve non-genetically modified identity of products within a designed supply chain (seed, food and/ or feed). Compliance with these measures ensures the integrity of the supply chain, the compliance with legal requirements of regions of production/ destination, including the above-mentioned EU legislation as a baseline.

This Programme contains principles and requirements designed to provide mechanisms for evaluating the achievements of supply chains or organisations to ensure the IP integrity of their production. It also requires and fosters a culture of continuous improvement that motivates the applicants to continuously improve their systems, processes and practices.

3. SCOPE OF THE IP TRUST PROGRAMME

This Programme is applicable to all kind of supply chains or organisations, regardless of size, location or complexity of the production, manufacturing and/ or supply (including broker activities, storage, distribution and transport) of IP agricultural products and their derivatives which will be integrated to food/ feed or consumed worldwide.

The audit is specific to the site where all the processing of the product or the supply decisions (e.g. for a broker) are undertaken. Where decentralised structures exist and the audit of certain locations is insufficient to have a complete view of the applicant's activities, all other relevant facilities shall also be included in the audit. Full details shall be documented within the applicant profile in the audit report (e.g. for production sites, audit of the farms could be necessary).

The scope shall be agreed between the applicant and Eurofins Food Assurance (Certification entity) (as the certification body) before the audit takes place. This scope shall be clearly and unambiguously stated in the contract, in the audit report and on the certificate and its attachment. It shall be illustrated by a supply chain flow diagram (see Appendix 2) stating the responsibilities and positions of each site included within the scope.

This description is a requirement which helps both Eurofins Food Assurance and the applicant to efficiently prepare the audit and to carry out the risk assessment.

As operations are diverse, not all the audit requirements specified in this Programme apply to an individual site or process, that's why specific audit checklists are designed for each actor of the supply chain:

- Farmers
- Manufacturers
- Brokers
- Storage providers
- Transport providers.

If between two certification audits, new processes or products different from those included in the initial scope of the current IP audit are implemented (e.g. seasonal products), the certified company shall immediately inform Eurofins Food Assurance and perform a risk assessment so that Eurofins Food Assurance could decide whether an extension audit shall be performed or not.

In this Programme, two options of certifications and different checklists of audit requirements are possible:

- IP TRUST Site Programme: The applicant is a SINGLE site, whatever its position within the supply chain.
- IP TRUST Supply-chain Programme: The applicant is the main stakeholder of a supply chain organised as a group covering the entire supply chain from seeds to products placed on the market.

4. TYPES OF AUDITS

All types of audits shall be performed on-site. Remote audits may be performed only in case of force majeure and under specific conditions.

4.1 Initial audit

The initial audit is the company's first audit against the IP TRUST Programme. It is performed at a time and date agreed upon by the applicant and Eurofins Food Assurance.

During this audit, documentation and processes will be reviewed. All the requirements of the IP audit check-list shall be assessed by the auditor.

4.2 Recertification audit

A recertification audit is performed after the initial audit according to a defined period of time after the initial audit (at soonest twenty (20) days before anniversary date (initial audit date) + twelve (12) months). This anniversary date is mentioned on the certificate. A recertification audit involves a full and thorough audit of a company resulting in the issue of a new certificate and its attachment. During the recertification audit, all requirements of the IP audit check-list shall be assessed by the auditor as well as the non-conformities identified during the last audit.

A focus on the implementation of corrective actions and the effectiveness of measures laid down in the previous corrective actions plan will be done. If C and/ or D scorings of requirement(s) are still present from one audit to the next, or if the scorings deteriorate, the auditor should even more deteriorate the scoring, when applicable, and shall assess the situation in accordance with the chapter related to the corrective actions. The link between two (2) consecutive audits ensures a continuous improvement process.

4.3 Extension audit

In specific situations such as new products and/ or processes or new sites involved in the programme (in case of an IP TRUST Supply-chain Programme) or each time the audit scope would need to be updated on the certificate and its attachment, the main stakeholder shall inform Eurofins Food Assurance, who will assess the situation to decide whether an extension audit is required to include the change in the scope of the existing certificate and its attachment. If an extension audit is required:

- Eurofins Food Assurance will determine relevant requirements to be audited and relevant audit duration.
- The report of this extension audit will be an appendix attached to the audit report.
- Conditions for performing the extension audit will be the same as for normal one, but the scope of the extension audit will focus on specific audit requirements related to the new activity/ ies.
- The original score will not change.
- If the extension audit demonstrates compliance, the certificate and its attachment will be updated accordingly and will keep the same due date of end of validity than the current certificate.

Note: If the extension audit demonstrates serious lacks which could jeopardise the certification, decision might be made to withdraw/ suspend current certificate.

4.4 Follow-up audit

A follow-up audit shall be scheduled after an initial or recertification audit if a major non-conformity called KO (see definition in §4. Evaluation of the audit requirements) has been raised during the audit and the total score is higher or equal to 80%. The goal of this audit is to close the major non-conformity after checking the relevance and the implementation of the corresponding corrective actions.

5. CERTIFICATION PROCESS

The certification process including the time frame is described in the Appendix 3.

5.1 Preparation of the audit

5.1.1 Scope

Before being audited, the applicant shall appoint a responsible person (= main contact person) for the IP certification procedure within its organisation. They shall review all the requirements of the current version of Eurofins IP TRUST Programme and should have implemented the suitable actions for at least two (2) months before the audit date. Eurofins Food Assurance commits to provide the latest version of the Programme in an appropriate period before the initial or recertification audit.

In order to prepare for an initial audit, the applicant may carry out a pre-audit (request to be addressed to Eurofins Food Assurance). This pre-audit shall preferably be performed by an auditor different to the one who will perform the certification audit.

Beforehand, the organisation wishing to apply for the IP certification is requested to provide specific information regarding the products and the associated supply chain(s) such as:

- The list of all sites involved in the IP TRUST Programme with names, places, activities, operation level and raw materials used.
- The list of all facilities and actors (storage, transport, external suppliers, etc.) of the supply chain.
- The products range (finished products on the certificate and its attachment) and processes within the scope.
- The products and processes that the organisation would like to exclude (which are, by definition, all products and processes not in the scope).
- The other products (especially conventional or genetically modified) that are handled by the organisation (to assess the cross-contamination risk).

This shall be illustrated through a supply chain flow diagram covering the whole supply chain and showing the responsibilities and position of each site involved as well as the “hold and release” points (see Appendix 2). All raw materials and product ranges under the scope shall be specified and provided with the volumes involved, the GMO specifications (threshold for maximum content) and the criteria of compliance with specific legislation.

To this end, the applicant is required to fill the application form available upon request on iptrustcertification@eurofins.com.

On receipt of all information, Eurofins Food Assurance shall ensure that the application form is completed with all the relevant information required for the following steps of the certification process. Further conference calls or emails may be necessary to finalise the application.

Once the application form is approved, a formal application form detailing the scope, the audit duration, the applicable IP TRUST Programme and the applicable check-list of audit requirements shall be issued. At this stage, the applicant will also have to send their testing

programme, for preliminary approval (see also requirement 3.2.1 of the audit checklist, for farmers, manufacturers and brokers).

The defined audit duration is based on the applicant's experience and performance history under the IP TRUST Programme and the complexity of the organisation. Minimum audit duration is:

- One (1) day for a processing site or a broker
- 0,5 day for a farm
- 0,5 day for the headquarter, if applicable (without processing/ storage areas).

Note: The typical duration of one audit day is eight (8) hours.

This duration may be extended based on the following parameters:

- Initial audit
- Number of non-conformities identified during the previous audit
- Number of products/ processes within the audit scope
- Complexity of the supply chain
- Complexity of the processes.

Under exceptional circumstances, this duration might be reduced but this shall be thoroughly justified.

A legally enforceable contract and a quotation shall be provided with the validated application form and approved testing plan.

Once the contract and the quotation are both signed by all parties, audit dates will be suggested to the client to plan the audit.

In addition, the organisation shall fill in the table template provided by Eurofins Food Assurance with their supplier names, addresses, raw materials and certification status. This information will be kept confidential, for Eurofins Food assurance internal use only, and is aimed to understand the supply chain.

For recertification audit, application form and testing programme will be reviewed to ensure the audit scope and the testing programme are still valid and no modifications have been made on the products, processes, supply chain, testing, etc.

5.1.2 Contract agreement

A contract for acceptance of the conditions of certification services shall be in place between the applicant and Eurofins Food Assurance (certification entity) detailing the obligations of parties, the general rules, payments, limits of liability and the conditions of use of the seal(s).

One important rule is that the organisation shall notify to Eurofins Food Assurance any event/ change that may affect their ability to conform with the IP TRUST Programme requirements (see also audit requirement 1.2). This covers but is not limited to:

- Changes impacting the certification scope
- Changes of raw materials, suppliers and/ or supply chain
- Changes in site locations/ addresses

- Positive test results
- Changes of the sites/ farms involved in the audit scope.

This applies both for initial audit and during certification cycle once the organisation is certified.

The main documents required for the certification process must be written in English or in the language agreed upon with Eurofins Food Assurance. If it is not feasible, the applicant has the responsibility to provide a translation of all documents and forms relevant to the Programme. The applicant shall guarantee that the translation is identical in content and relevant details to the documents and forms used on site. The translated version shall underline the same management procedures.

5.1.3 Multi-site system: audit of centrally managed processes (for IP TRUST Site and IP TRUST Supply-chain Programmes) and site sampling (under conditions, for IP TRUST Supply-chain Programme only)

If defined processes are organised centrally in a company with several production or processing sites (e.g. suppliers' approval and monitoring, personnel training, complaint management, etc.):

- The central managing site - headquarter also called main stakeholder- shall also be audited.
- This audit shall always take place before the audit of each production or processing site in order to have a preliminary overview.
- The outcome of the relevant audited requirements shall be considered in the audit report of each production or processing site.
- Audits of sites and headquarter shall all be performed within a maximum timeframe of one (1) year.

Companies having multiple sites and headquarter may apply for IP TRUST Site or IP TRUST Supply-chain Programme. However, the audit and certification processes are managed differently.

- For the IP TRUST Site Programme, each site shall be subject to their own audit and certificate: site sampling is not possible.
- For the IP TRUST Supply chain Programme, which applies to organisations managing different steps of the supply chain, if the number of sites involved in the Programme is too large, site sampling may be possible and will be defined by Eurofins Food Assurance. The choice is made according to the regional and local constraints and situation as well as the specific nature of the crop concerned. Differences in regional aspects (e.g. climatic conditions, topography and cropping patterns as well as farm structures and crop specific GMO share in the area) are part of the criteria being considered to sample the sites to audit in priority. A focus on crops for which GM varieties are not yet approved in the European Union or in other final destination places shall be done. All sites shall be audited within a three (3)-year period.

  Note: Sampling rule is available on request to Eurofins Food Assurance.

5.1.4. Audit team

Approved by, and acting on behalf of Eurofins Food Assurance, a qualified independent auditor is in charge of preparing the audit schedule based on the information provided into the application form.

In some cases (extended factory/ activities, etc.), an audit team can be commissioned under the responsibility of a lead auditor. All the members of the audit team shall be trained against the IP TRUST Programme.

In addition, in the framework of the auditor qualification procedure:

- An assessor can be sent by Eurofins Food Assurance to shadow the lead auditor, as part of the qualification maintenance procedure. The presence of the assessor shall have no impact on the auditing process as she/ he is just required to witness the lead auditor.
- A trainee may accompany the lead auditor, as part of the training process. The lead auditor can entrust the trainee with some tasks in the auditing process, which will remain under the lead auditor's responsibility. In any other case, the trainee's role is limited to observation.

The presence of an assessor or a trainee shall have no impact on the duration of the audit and auditees should not be disadvantaged by the presence of multiple auditors.

5.2 Drawing up the audit schedule

The audit shall take place when the products included in the audit scope are being processed or when the broker activities are being carried out.

The typical duration of an audit is one (1) man day (eight (8) hours). Where necessary, the auditor may extend this audit time and shall justify the reasons in the audit report. Furthermore, in case of a recertification audit, the audit schedule shall take into consideration a review of the former corrective action plan.

The audit schedule shall be approved by the applicant (chosen responsible person for the IP certification procedure within the organisation) and Eurofins Food Assurance prior to the on-site audit. It shall contain as a minimum:

- Programme name and issue
- Audit objectives and scope
- Time of opening and closing meetings
- Time allocated for each topic
- Roles and responsibilities of auditor and other participants (e.g. in case of audit team).

A review of the audit report and action plan related to the previous audit-if one has already been performed-shall also be mentioned.

The audit will be scheduled based on the following steps (which are detailed further in the next chapter):

- The opening meeting
- An evaluation of existing product safety management system, achieved by checking documentation (quality management documentation, risk assessment, etc.)

- An on-site inspection (if presence of products on site) and interviews of the personnel from different levels of management
- The closing meeting.
- The audit schedule shall be sent to the applicant about two (2) weeks before the audit.

5.3 On-site audit

To ensure proper audit, the auditee shall:

- Ensure cooperation with Eurofins Food Assurance
- Give the auditor(s) access to the site and any other sites and/ or facilities under the scope as well as to relevant documentation for audit purposes
- Provide Eurofins Food Assurance with any other information deemed necessary for assessing compliance with this Programme
- Ensure the availability of all responsible persons at the day of the audit
- Have an open-minded behaviour concerning auditor(s) findings
- Show total transparency in their answers

In return, to guarantee the success of the audit, the auditor(s) commit to be faithful and to act under impartiality and confidentiality.

The on-site audit shall include the following steps:

- Opening meeting during which the auditor(s) shall inform the auditee about the certification process, confirm the scope of certification, agree on logistics aspects during the audit, confirm access to all relevant documents, production area(s) and various contact persons in charge of the relevant processes and detail the time required to perform the different steps of the audit.
- Verification of the management system documentation, including all the required records and procedures and all available documents related to the indicators of the IP TRUST Programme.
- Visual inspections on the ground and interviews with key personnel and workers involved in the audited activities.
- Traceability challenge: during the audit, the auditor shall sample one (1) or two (2) products to perform a traceability challenge and assess if all audit requirements are fulfilled through the sample(s) (e.g. implementation of procedures, related records, risk assessment, supplier monitoring, PCR tests, etc.). At least one (1) of the sample shall be related to a product considered as risky (e.g. if the organisation has products with and without GMO risks, sample shall be taken on a GM product).
- Preparation of the audit findings, during which the auditor summarises the identified findings and non-conformities and prepare the final conclusions for the closing meeting.
- Closing meeting with review of all the non-conformities identified during the audit. The auditor will not come up with a decision on the result of the audit, as the decision to award certification will be determined independently by Eurofins Food Assurance, following a technical review of the audit report and the closing of non-conformities in the appropriate timeframe. At the end of this process, the auditee will be informed of the certification decision.

- It is advisable that the company's senior managers are present at the opening and closing meetings.

During the audit, the auditor reserves the right to take sample(s) on-site for further testing, to check continuous compliance of the organisation against IP TRUST Programme.

5.4 Evaluation of the audit requirements

During the audit, the auditor shall assess the implementation and the relevance of the requirements applied by the auditee. The auditor shall inform the auditee anytime she/ he finds a non-conformity during the audit. To determine whether compliance with an audit requirement of the IP TRUST Programme has been met, the auditor shall evaluate each audit requirement of the Programme (according to the check-list defined at the time of the preparation of the audit) with respect to the rating scale set down as follow.

For each audit requirement of the check-list (which is not a KO requirement, i.e. a pre-defined critical requirement), there are 4 scoring possibilities:

Scoring	Explanation	Points
A	Full compliance	10
B	Almost full compliance	7
C	Small part of the requirement has been implemented	3
D	Requirement has not been implemented	-10

B, C and D scorings of these requirements lead to a **minor non-conformity**.

An audit requirement can be scored "non-applicable" (NA) with appropriate justification.

For the pre-defined KO requirements of the check-list, there are 3 scoring possibilities:

Scoring	Explanation	Points
A	Full compliance	10
C	Small part of the requirement has been implemented	3
KO	Requirement has not been implemented	-15% of the final score

Note: No B scoring is possible for a KO requirement.

KO requirements are the following pre-defined critical requirements:

- Risk assessment for cross-contamination
- Traceability system
- Suppliers' approval and monitoring system (except for transport and storage providers)

- Cleaning and/ or flushing procedures (except for brokers).

In the scoring process, a failure to comply with one of those specific audit requirements is considered as a major non-conformity (called “KO”) and leads to score downgrading.

C scoring of these KO requirements leads to a **minor non-conformity** and KO is considered as a **major non-conformity.**

A KO requirement cannot be scored as NA.

The final total score is calculated (in %) as following:

Number of points awarded / Total number of possible points

5.5 Audit report

Following the audit, the auditor shall send to Eurofins Food Assurance a full report written in English, for review.

Eurofins Food Assurance will send to the auditee:

- The corrective action plan to be completed in English at latest seven (7) days after the last audit day
- The audit report at latest fourteen (14) days after last audit day.

The audit report shall contain a description of the organisation being certified and an accurate summary of its performance against the requirements of the IP TRUST Programme.

It will also provide the following information:

- The auditee’s organisation and infrastructures
- The measures implemented to ensure the IP integrity
- The non-conformities identified during the audit.

The report shall accurately reflect the findings of the auditor(s) during the audit. Audit reports shall remain the property of the organisation commissioning the audit as written in the contract.

5.6 Corrective action plan

Following the description of the non-conformities identified during the audit by the auditor(s) and according to the explanations given, the auditee commits to complete the action plan received with the report. The main contact person (if manager) identified in the application form will be responsible for proposing relevant corrective actions in this action plan. Responsibilities, implementation dates and description of the actions shall be clearly stated for each non-conformity. The completed action plan shall be sent to Eurofins Food Assurance at latest twenty-five (25) days after the last audit day.

Eurofins Food Assurance Technical Department is in charge of the technical review of the report and validation of the action plan. Within the review, as many exchanges between the Eurofins Food Assurance and the organisation main contact person as necessary are authorised until the validation of the relevance of the corrective actions. However, if the deadline (see Appendix 3) is not fulfilled, some measures (initial audit to be carried out and

withdrawal of the certificate in case of recertification audit) can be taken by Eurofins Food Assurance.

Eurofins Food Assurance reserves the right to ask for additional evidences.

5.7 Awarding the certificate

The certification decision is formalised by the issue of a certificate and its attachment thirty-five (35) days after the last audit day. This decision is dependent on both final scoring and relevance of the corrective actions submitted by the auditee.

Certification is denied in the following situations:

- If the auditee gets a total audit score lower than 80%. In this situation, a new initial audit can be scheduled if the auditee wants to reattempt the certification.
- If the auditee gets a score higher or equal to 80% and one KO. In this situation, the company is not certified or the current certificate is suspended in case of recertification audit. However, they can get the certification if they can demonstrate that the suitable corrective actions have been implemented to close the KO, through a follow-up audit performed within six (6) months after the main audit, at cost of the applicant. During this follow-up audit, the auditor shall assess the implementation of the actions taken to close the KO identified during the main audit, which may lead to a certificate awarding. If no follow-up audit is performed during this period, a full initial audit is necessary.
- If the corrective action plan is not closed in the relevant timeframe.

If decision is made to award the certificate, the certificate shall state:

- The name and address of the company being certified
- The name of the Programme
- The scope (categories of products) and the threshold (confidence level)
- The contract/ agreement number
- The date of issue
- The expiry date
- The time window during which the next recertification audit shall be conducted
- The signature of the Certification Director.

The certificate is always accompanied by a technical attachment specifying the detailed scope, the raw materials and related products, the region of production and the sites that have been audited (for sampling according to the IP TRUST Supply-chain Programme).

5.8 Certificate validity and conditions of withdrawal/ suspension

Certificate is valid for a period of twelve (12) months.

The auditee is responsible for maintaining the validity of their certificate. Ongoing certification and the related certificate are maintained where there is substantive and demonstrable evidence that the certified site(s) is/ are still compliant with the IP requirements for the products within the scope. The certification maintenance also depends on the fulfilment of the certification cycle (scheduling of the recertification audit on time). Even if the

recertification audit date changes every year, the certificate validity date shall remain the same each year. Expiry date of the certificate is defined as follow:

- Initial audit date + thirty-five (35) days (time for the audit report and corrective action plan review) + twelve (12) months
- The certificate validity starts from the date of issue stated on the certificate itself and ends after the above-defined date.

The date for the recertification audit (anniversary date) is calculated from the starting date of the initial audit and not from the date of issue of the certificate.

To avoid gaps between two consecutive certificates, the recertification audit shall be scheduled before the anniversary date. A window of twenty (20) days before the due date is deemed acceptable.

The circumstances that could trigger early withdrawal/ suspension of the certificate are the following:

- Any major change in the company's system that could jeopardise the IP certification
- Any information indicating that the process may no longer comply with the IP requirements
- Misusing of the Eurofins IP TRUST seal(s)
- Abuse in terms of communication
- KO(s) identified during the initial or recertification audit (the current certificate will be suspended until the auditee will demonstrate the implementation of suitable corrective actions through a follow-up or an initial audit, depending on the final score).

In case the information comes from external parties (final users, regional authorities, suppliers, etc.), an investigation will be conducted by Eurofins Food Assurance to determine whether or not the IP integrity is jeopardised.

5.9 Use of the seals

Two seals have been designed for the IP TRUST Programme:

One for the auditee certified under the IP TRUST Site Programme	One for the supply chain certified under the IP TRUST Supply-chain Programme
	

Seals are NOT allowed on any finished product aimed to the consumers.

Auditee under IP TRUST Supply-chain Programme can print the relevant seal on bags of products which are aimed to a business partner. The other auditees (IP TRUST Site Programme) can only use the dedicated seal on commercial/ sales/ marketing documents, brochures and websites.

The Eurofins IP TRUST seals remain the property of Eurofins Food Assurance and their use is governed by a policy for use. Eurofins Food Assurance may withdraw the use of these seals if misusing has been identified or cease certification by prior written notice to any client.

The terms and conditions for using the IP TRUST seals are set forth in the contract signed between Eurofins Food Assurance and the client. The fulfilment of these terms and conditions are checked by the auditor during the audit.

The relevant seal and the instructions for artwork are sent with the certificate.

5.10 Appealing of a decision

The decision to grant or deny certification may be appealed. Eurofins Food Assurance is responsible for providing the documented procedure for the procedure of appeal upon request.

5.11 Compliant Traceability Statement

In addition to the annual IP TRUST certificate confirming the certification of the company against the IP TRUST Programme, Eurofins Food Assurance, in cooperation with Eurofins GeneScan, can also issue, under the company's request and as an additional service, a Compliant Traceability Statement. This Statement is batch specific and confirms the traceability of a batch, from the IP certified company to the buyer.

6. REVIEW AND VERSION

The Eurofins IP TRUST Programme is subject to review every time Eurofins Food Assurance will consider it as necessary and is amended in consequence. Reasons for review are linked to experience, changes in legislation, GMO worldwide context or any reason judged relevant by Eurofins Food Assurance. This will ensure the efficiency and the credibility of the Eurofins IP TRUST requirements on an ongoing basis.

The review will be conducted by internal staff of Eurofins Food Assurance, in collaboration with relevant experts.

Any changes and/ or new version of the Eurofins IP TRUST Programme will be communicated by Eurofins Food Assurance to their clients.

PART 2: TECHNICAL IP AUDIT REQUIREMENTS

1. REQUIREMENTS APPLICABLE FOR THE IP TRUST SUPPLY-CHAIN PROGRAMME

When applying to the IP TRUST Supply-chain Programme, the main stakeholder needs to fulfil a certain number of requirements. In addition, each site of the supply chain which is under the responsibility of the main stakeholder will have to fulfil the requirements of each actor specific audit checklists of the IP TRUST Site Programme.

1. Senior management responsibilities and resources

1.0.a All the stakeholders shall be bound by contract (signed and accepted by both parties) with the main stakeholder. This contract shall mention the IP objectives, the measures to fulfil them and the responsibilities of each stakeholder. The sites included in the IP TRUST Programme shall be subject to regular audits to verify their compliance with the IP TRUST Programme requirements.

The main stakeholder shall keep records of all the stakeholders involved in the IP TRUST Programme and shall be responsible for maintaining the following records:

- List of all participating sites covered by the IP TRUST Supply-chain Programme, with their names, detailed addresses, appointed site managers and type of operations, together with the date of entry into the IP TRUST Programme
- Records of the internal audits demonstrating that all the stakeholders meet the IP TRUST Programme requirements
- Records of the management reviews
- If applicable: the date of withdrawal of any site involved in the IP TRUST Programme and reasons
- Aggregated volume summaries for all sites.

1.1.a The senior management shall draw up, sign, implement and maintain a corporate policy considering the objectives and requirements of the Eurofins IP TRUST Programme, especially the requirements related to the risk assessment, traceability, suppliers' evaluation and segregation methods. This corporate policy shall be communicated and understood by all employees of the sites involved in the IP TRUST Supply-chain Programme.

1.4.a The main stakeholder shall appoint a manager with the legal and/ or management authority and technical competences necessary to implement, oversee and maintain the IP TRUST Programme requirements in all the sites included in the scope.

1.6.a The main stakeholder (if this is not managed by the senior management of each stakeholder), shall draw-up, implement and maintain an annual training programme on IP requirements and GMO legislation/ events for all the key personnel involved in the IP TRUST Programme to keep them knowledgeable and aware about the GMO context.

2. Risk assessment

2.4.a A supply chain flow diagram showing the responsibilities for the handling of products which are in the scope of the IP TRUST certificate and its attachment and/ or have an impact on the IP finished products shall be drawn-up and maintained (see Appendix 2). It shall specify facilities, involved stakeholder's sites and type of products (raw materials, intermediate and finished products). It shall clearly identify each “hold and release” point.

2.5.a The main stakeholder shall draw-up, implement and maintain a risk assessment for all sites included in the scope of the certification, identifying the risk of adventitious presence of GMOs

4.3. Internal audits

4.3.1.a The main stakeholder shall carry out an annual internal audit of each site involved in the IP TRUST Supply-chain Programme to confirm ongoing compliance with all the requirements of the IP TRUST Programme certification.

4.5. Corrective actions

4.5.3.a The main stakeholder shall follow up and ensure that corrective actions agreed with Eurofins Food Assurance are fully implemented in the required timeframe for all involved sites.

2. REQUIREMENTS APPLICABLE FOR THE IP TRUST SITE PROGRAMME

A. AUDIT REQUIREMENTS FOR FARMERS

1. Senior management: responsibilities and resources

1.1 The senior management shall draw up, sign, implement and maintain a corporate policy considering the objectives and requirements of the Eurofins IP TRUST Programme, especially the requirements related to the risk assessment, traceability, suppliers' evaluation and segregation methods. This corporate policy shall be communicated and understood by all employees.

1.2 The senior management shall draw up, implement and maintain a dialogue procedure between their organisation and Eurofins Food Assurance to communicate on any event/ change that may affect their ability to comply with the IP TRUST Programme requirements.

1.3 The senior management shall provide the necessary resources including, where applicable, production equipment, buildings and workspace, workforce, financial and support services to meet the objectives of the IP TRUST Programme.

1.4 Competences and responsibilities, including deputation of responsibilities shall be clearly laid down for personnel identified as having authority for policy management and implementation of the IP TRUST Programme requirements. The main contact person shall show evidences of knowledge on the IP TRUST Programme.

1.5 All personnel performing work that affects the products shall have the required competences and shall be aware of their responsibilities. They shall be able to demonstrate their understanding and knowledge.

1.6 The senior management shall draw-up, implement and maintain an annual training programme on IP requirements and GMO legislation/ events for all the key personnel involved in the IP TRUST Programme to keep them knowledgeable and aware about the GMO context.

1.7 Any newcomer (including temporary personnel) shall be trained before they take charge of their duties. The training shall address the main objectives of the IP TRUST Programme, particularly: the cross-contamination risks, their impact and the related preventive and control measures.

1.8 All training/ instruction events shall be recorded (stating content, date, duration, location, trainer and participants) and such records shall be available.

1.9 Effectiveness of the training shall be verified. Refresher training shall regularly take place to ensure that personnel maintain required level of understanding and knowledge for the effective operation of the IP TRUST Programme.

1.10 The senior management shall ensure that the quality management system and risk assessment are reviewed at least annually or more frequently if significant changes occur. Such reviews shall include as a minimum:

- a review of objectives and policy concerning the IP TRUST Programme requirements
- supplier performance
- legislative, technical and industry developments relevant to the IP TRUST Programme and having an impact on the fulfilment of the IP TRUST Programme requirements
- results of audits
- complaints
- non-conformities and non-conforming products related to IP TRUST Programme requirements
- status of corrective actions.

Management review shall be documented.

2. Risk assessment

2.1 The company shall assemble a multidisciplinary team, including operational personnel and a relevant team leader, to draw-up, implement and maintain the risk assessment.

2.2 Each member of the team shall have specific knowledge of products and good handling practices and their associated cross-contamination risks and at least one person shall be knowledgeable about GMO risks and testing. Where internal expertise is not available, external expert advice shall be required.

2.3 A site flow diagram showing the operations and flows within the company shall be drawn-up and maintained for each product or product group and for all variations of the production processes and sub-processes. It shall be dated and clearly identify each critical point and “hold and release point”, where applicable.

2.4 A supply chain flow diagram showing the responsibilities for the handling of products which are in the scope of the IP TRUST certificate and its attachment and/ or have an impact on the IP finished products shall be drawn-up and maintained (see Appendix 2). It shall specify facilities and type of products and shall clearly identify each “hold and release” point.

2.5 KO N°1: A risk assessment for cross-contamination shall be drawn-up, implemented and maintained to control the likelihood of introducing a cross-contamination risk in the product and/ or the environment. It shall be based on HACCP principles or other appropriate risk assessment method.

2.6 The risk assessment shall take into consideration all grains and seeds, the different crops cultivated on the same site, the neighbouring crops as well as the differences between crop species, crop varieties and product type, crop or seed production. It shall also include storage, transport and outsourced processes.

2.7 The risk assessment shall take into account the general GMO risks of approved and unapproved GM varieties affecting the supply chain and its suppliers, including the geographic origin of raw materials. It shall be based on official documentation and

legislation from national Authorities on status of release of GMOs for planting, commercial use or import into relevant areas (production areas and destination countries).

2.8 The risk assessment shall take into account test results from the last twelve (12)-month period.

2.9 The determination of relevant critical points shall be facilitated by the application of a decision tree or other risk assessment tool(s).

2.10 The determination of relevant “hold and release” points shall be based on the supply chain flow diagram. Products at "hold and release” points shall be tested.

2.11 For each critical point, appropriate critical limits or parameters and values shall be defined, validated and implemented, according to current legislation and statistical studies based on test results, to clearly identify when the risk of jeopardising the IP integrity of the product is controlled and reduced to an acceptable level.

2.12 The critical points shall be controlled and monitored to detect any loss of control.

2.13 In the event that the monitoring of the critical points indicates that a particular critical point is not under control, adequate corrective actions shall be taken and recorded.

2.14 The risk assessment shall be reviewed at least annually and necessary changes shall be made in case of any modification made in the product, production or in legislation (such as changes in approval/ release of GM varieties, in targeted threshold tolerance levels, suppliers, etc.) to prevent any threat on the IP integrity of the product.

2.15 A procedure for regulatory surveillance related to GMO risks in both countries of production and destination (labelling, new authorisations, tolerance threshold, crisis/ event, etc.) shall be drawn-up, implemented and maintained to ensure an up-to-date risk assessment.

3. Testing and sampling plan

3.1. Sampling

3.1.1 A risk-based sampling procedure shall be drawn-up, implemented and maintained to ensure compliance with the IP TRUST Programme. This procedure shall define the following minimum criteria:

- the number of samples (primary / sub-samples, composite and laboratory, representative for the lot)
- the frequency and time interval of sampling
- sampling practices (hygiene, apparatus, etc.)
- the sample identification process
- the sample retention policy.

The sampling procedure shall take into account relevant applicable legislation, internationally recognised standards and the outputs of the risk assessment to define appropriate sampling plans.

3.1.2 The sampling shall take place at critical stages of handling (e.g. collection points, prior to shipping, post-harvest, etc.) based on risk assessment.

3.1.3 Samples shall be adequately labelled to clearly identify their origin (lot number, date and place of sampling, name of company, quality and size of sample).

3.1.4 Archive samples (of sub-samples, composite samples and laboratory samples) shall be kept on site for the timeframe during which the product would reasonably be expected to remain in the supply chain or risk based. They shall be sealed and stored under appropriate conditions to allow counter-testing and traceability test if required.

3.2 Testing

3.2.1 A risk-based testing procedure shall be drawn-up, implemented and maintained to ensure compliance with the IP TRUST Programme. This procedure shall define the following minimum criteria:

- the relevant tests to be made on the samples (the applied test/ screening scope shall cover all relevant GM events in question)
- specifications for/ with laboratories
- testing frequency (risk-based, taking into account the level of risk of inputs and geographies; for high-risk inputs and/ or geographies, testing shall be performed for each batch)
- applicable procedure in case of positive test result.

The testing procedure shall take into account each product for which there is a potential GMO risk (see Appendix 1 provided for purpose of reference), all known GM events for the inputs in question, relevant applicable legislation and the outputs of the risk assessment to define appropriate testing plans.

Each testing programme shall be approved and reviewed for accuracy by Eurofins GeneScan or by an analytical expert qualified by Eurofins GeneScan, as appropriate, and at least once per year, during the application review.

3.2.2 The company shall draw up specifications with the laboratory pointing out the risks to be covered (species/ variety/ event to look for, threshold level in accordance with the country/ ies where the product is sold, methods, etc.).

3.2.3 Testing shall be performed by approved laboratories, which shall comply with the following requirements:

- ISO/ IEC 17025 accreditation for the relevant methods and tests applied, including all qualitative and quantitative GMO tests to be performed in the framework of the IP TRUST Programme as well as, if relevant, for the determination of soybean mass by PCR
- regular and successful participation in ring trials/ proficiency tests
- sufficient high testing capacities to ensure a fast-processing time even in case of seasonal peaks

- a diverse portfolio of methods for the detection of GMOs

Implementation of all essential methods, including all tests required by the IP TRUST Programme. Subcontracting may only be permitted in exceptional cases, for individual methods and over a limited period of time.

3.2.4 If tests are performed in different laboratories, the sampling and testing methods (size, species and/ or events to look for, threshold level, etc.) shall be the same to get exploitable results and to make relevant comparison and conclusions. This demonstration shall be documented.

3.2.5 1.2.1 The PCR tests shall meet the minimum following criteria:

- a duplicate DNA extraction per sample shall be performed
- controls defined in chapter 5 of ISO 24276: 2013-10 shall be used
- each DNA extract shall be subjected to the real-time PCR reactions for the detection of the target DNA sequence

results of the individual test portions shall be evaluated according to the criteria defined in chapter 6 of ISO 24276: 2013-10.

3.2.6 The test reports/ certificates of analysis for PCR tests shall fulfil the requirements defined in chapter 7 of ISO 24276: 2013-10, especially they shall include following information:

- size of the test portions used for the DNA extraction
- reference to the ISO 24276: 2013-10 standard

for quantitative tests: indication of the pLOQ, regardless of the analysed sample matrix, and the measurement uncertainty (as +/- behind the result, to represent the expanded measurement uncertainty).

3.2.7 Test results shall confirm that the GMO certification threshold of the IP TRUST Programme has been met. Both qualitative and quantitative PCR tests may be used. The scope of tests used shall in any case be sufficient to demonstrate that the products meet the requirements of the IP TRUST Programme.

3.2.8 In case of positive test results, the follow-up analyses shall take into account all relevant GMOs, subsequent testing may be performed with specific qualitative and/ or quantitative tests. Unless further investigations confirming compliance, product subject to this positive test shall be managed as a non-conforming product.

3.2.9 The testing and sampling plans shall be reviewed annually, or more frequently, based on the risk assessment and/ or on major events (for example, if there are any changes in the approval situation and / or cultivation of GMOs of plants which are in the scope of the IP TRUST certification) affecting the ability of the company to comply with the requirements of the IP TRUST Programme.

4. Quality management system

4.1 Quality manual and documentation management

4.1.1 Documents (procedures, records and any other document) related to the compliance with the IP requirements shall be drawn-up and maintained and shall be kept together, preferably in a physical and/ or electronic quality manual. They shall mention responsibility, be up to date and cover review and record keeping.

4.1.2 All documents shall be available in their latest version, clearly legible, unambiguous, comprehensive and dated if relevant. They shall be available in appropriate languages and sufficiently detailed to enable their correct application by appropriate personnel. For multi-site companies, it shall be ensured that all relevant documents are available and adapted to each site involved in the IP TRUST Programme.

4.1.3 All records shall be maintained for at least five (5) years.

4.2 Traceability

4.2.1 KO N°2: A traceability system shall be drawn-up, implemented and maintained taking into consideration every grain, seed, crop and product. Those shall be identified and labelled at all stages along the supply chain to guarantee traceability, minimum one step back and one step forward (from grains/ seeds to delivered products, and vice versa)

4.2.2 A clear relation shall be established between batches/ lots and related GMO test results. In case several locations and stakeholders are involved, the responsibility to establish this relation is with the main stakeholder.

4.2.3 Quantities of IP products shall be recorded, maintained and checked (running mass balance correlating inputs and outputs), to ensure that quantities/ volumes of IP products received are equal to volumes used/ sold. This mass balance shall include the identification of constituent batches/ lots and their proportions by batch/ lot number (new batch/ lot number or proper identification shall be defined for composite batches/ lots).

4.2.4 The traceability system shall be reviewed and tested at least once a year and each time system/ seeds/ product/ production process changes. The test shall verify upstream and downstream traceabilities. Test results shall be recorded and available for the audit.

4.3 Internal audit

4.3.1 Effective internal audits covering the IP requirements shall be conducted at least once per year. Frequency (when more often than annually) and scope shall be based on the risk assessment and documented.

4.3.2 The auditor shall be competent and independent from the audited department. Where internal expertise is not available, the company shall request an external auditor.

4.3.3 Internal audit results shall be communicated to responsible persons of concerned department and to the senior management.

4.3.4 Necessary corrective actions followed by a schedule for implementation and relevant responsibilities shall be defined and recorded, for the purpose of continuous improvement.

4.4 Management of non-conforming products and non-conformities

4.4.1 A procedure shall be drawn-up, implemented and maintained for the management of all non-conforming products and non-conformities: seeds, crops, product, production equipment and packaging materials. This shall include, as a minimum:

- defined responsibilities
- isolation/ quarantine
- cause analysis
- product identification
- decision for further use like release, rework, quarantine, disposal
- corrective actions
- specific measures for “hold and release” points to ensure that only compliant products are produced and sold

4.4.2 In particular cases when test results show detection of GMO presence:

- Eurofins Food Assurance shall be informed immediately
- if the test result is above 0.6%, affected products shall be quarantined

if the test result is positive but still below 0.6%, a root cause analysis shall be performed to ensure that the affected products will not trend to become non-compliant

4.4.3 Products in quarantine shall not be released as IP products until the deviation within the risk assessment has been fully assessed and the product verified to meet the IP requirements in terms of GMO presence threshold.

4.5 Corrective actions

4.5.1 A procedure shall be drawn-up, implemented and maintained for the management, recording and review of the non-conformities to avoid recurrence by preventive actions and/ or corrective actions.

4.5.2 Corrective actions shall be recorded. Those records shall detail the relevant responsibility and schedule for implementation.

4.5.3 The effectiveness and performance of the implemented corrective actions shall be verified and such verification shall be documented.

4.6 Management of complaints

4.6.1 A procedure shall be drawn-up, implemented and maintained to manage the complaints from authorities and customers. The complaints shall be assessed by competent personnel, reviewed and recorded.

4.6.2 If necessary, appropriate actions shall be taken, recorded and monitored to avoid the recurrence of the non-conformities.

4.7 Management of incidents, product withdrawal/ recall

4.7.1 A procedure shall be drawn-up, implemented and maintained to manage incidents and potential emergency situations that could impact the IP integrity of the products. It shall mention:

- the name of the relevant personnel (crisis team)
- an alert contact list (authorities, customers, sites and people to be informed, etc.)
- withdrawal/ recall procedure
- consideration of the dialogue procedure with Eurofins Food Assurance

In case of product recall related to IP, the company shall inform Eurofins Food Assurance within 3 working days maximum

4.7.2 The feasibility, effectiveness and timeliness of implementation of withdrawal procedure shall be tested at least once a year, or more often based on risk assessment.

4.7.3 Any event/ crisis related to GM crop or authorisation in the area of farming shall be assessed to determine the risks of adventitious presence. The results of this assessment and related actions shall be communicated to Eurofins Food Assurance.

5. Products and suppliers: approval and monitoring

5.1 Specifications shall be drawn-up, implemented and maintained for all seeds and products and shall clearly describe the non-GMO status. They shall be available to all relevant personnel and be compliant with the IP requirements.

5.2 Specifications shall be drawn-up, implemented and maintained for all packaging materials/ containers and shall clearly demonstrate that packaging materials/ containers are fit for their intended use for IP products. Where relevant, they shall describe their non-GMO status.

5.3 A procedure shall be drawn-up, implemented and maintained to check the compliance of any incoming material against the specifications at receipt. In particular, it shall include the fact that:

- delivery documents shall be clear and unambiguous, including GMO related information required by local, national and/or international regulations

- all goods shipped in bulk, where packaging or labels are not feasible, shall be duly identified with a lot or production code allowing proper identification and traceability

packaging and other product-holding vessels shall be checked and documented clean of potential GMO materials before being used for non-GMO inputs/products.

5.4 The company shall control purchasing processes to ensure that all externally sourced materials and services which have an impact on the finished products conform to the IP requirements and GMO legislation of the destination countries.

5.5 The conformity of the products with the specifications shall be regularly checked. The frequency of these controls shall take into consideration the product characteristics (variety and type of culture, country of production and destination, etc.), status of the supplier and impact on the finished products.

5.6 KO N°3: A procedure for approval and monitoring of suppliers shall be drawn-up, implemented and maintained. It shall contain clear assessment criteria such as: audits, communication on changes/ events having an impact on the IP integrity, certificates (stating GMO threshold, scope, description of the supply chain and products and physical measures), testing, supplier reliability and complaints

5.7 The procedure for approval and monitoring of suppliers shall address procurement in emergency situations to ensure that inputs are still compliant with specifications and come from an assessed supplier.

5.8 The procedure for approval and monitoring of suppliers shall include the following policy:

- the suppliers shall be certified against Eurofins IP TRUST Programme or another IP certification standard accepted by Eurofins. The company shall request the current certificate(s) and monitor the certification continuity of their suppliers

Or

- the suppliers shall be assessed through specific measures like a risk assessment review, or a second party audit covering GMO risk assessment and control measures, or the review or other relevant GMO risk management information (e.g. historical data, performance details, sampling and test results of all batches/ lots, etc.).

5.9 All external suppliers (especially in case of purchasing via a third party) shall be bound with the company. All specifications/ contracts or any agreement between the company and the supplier shall be documented, agreed and signed by relevant parties.

5.10 The contracts/ agreements between the company and the external suppliers shall require involvement from the suppliers on all the measures ensuring the IP integrity of the products, which shall include at least segregation, traceability, risk assessment and control/ testing plan.

5.11 The results of suppliers' assessment shall be reviewed regularly, based on the risk

assessment. Reviews and actions from the assessment shall be recorded.

6. Good handling practices

6.1 General good handling practices

6.1.1 Based on the risk assessment, documented requirements for protective clothing and good practices to adopt in specific areas shall be drawn-up, implemented and maintained. They shall be communicated to all personnel, contractors and visitors entering the site.

6.1.2 Based on the risk assessment, inspection schedules (for equipment, storage facilities, fields, etc.) shall be drawn-up, implemented and maintained to verify the effectiveness of the control measures implemented to ensure the IP integrity of the products.

6.2 Good growing practices

6.2.1 Based on the risk assessment, documented requirements for good growing practices shall be drawn-up, implemented and maintained. It shall mention the rules concerning the planting/ isolation distances and the crop rotation.

6.2.2 For every season of production, a map shall be drawn-up to represent the crop implantation, showing both GM and Non-GM crops.

6.2.3 The ground in which the seeds are planted shall not have been used for a GM variety of the same crop in the previous year

6.2.4 The company shall demonstrate that planting distances between Non-GM and any neighbouring crops are adequate to ensure that the cross-pollination risks are minimised.

6.2.5 A record of land use shall be drawn-up and maintained for fields used for Non-GM crops. Field records shall include type and variety of crops, lot number of used seeds and dates of planting and harvesting.

6.2.6 Fields shall be inspected during the growing period to verify any presence of volunteer crops. In case of presence of volunteer crops, relevant corrective actions shall be taken and recorded, based on the risk assessment.

6.2.7 Harvest records shall include crop weight, yield, identity of the field from which the crop was harvested, lot number assigned to the harvest, harvest date and owner's name.

6.2.8 Records of production for each crop shall be kept for at least 5 years.

6.3 Cleaning activities

6.3.1 KO N°4: Based on the risk assessment, cleaning and/ or flushing procedures and schedules shall be drawn-up, implemented and maintained to avoid any cross-contamination risk. These shall specify:

- **objectives**
- **tasks and responsibilities**
- **areas/ equipment/ containers concerned**
- **instructions, used equipment and cleaning product(s)**
- **frequency**
- **records thereof**

6.3.2 Personnel responsible for the cleaning/ flushing activities shall be trained.

6.3.3 The effectiveness of the cleaning/ flushing activities shall be verified on a regular basis, based on the risk assessment.

6.3.4 Cleaning/ flushing schedules shall be reviewed and modified in case of any changes in the product, production process, machinery or cleaning equipment.

6.3.5 If the company hires a third-party service provider for cleaning activities, all requirements specified above shall be clearly defined in the service contract.

6.3.6 Chemicals (used for cleaning, maintenance, etc.) shall not be a source of GMO cross-contamination.

6.4 Segregation

6.4.1 A procedure shall be drawn-up, implemented and maintained to ensure the IP integrity of the production. It shall describe the measures aimed to avoid mixing of controlled products with uncontrolled materials and shall include, as a minimum:

- good growing practices
- dedicated materials, when/ where possible
- labelling/ marking on packaging/ containers
- cleaning schedules
- flushing activities
- specific measures during packaging and labelling, where applicable
- dedicated storage
- dedicated transport.

Segregation measures shall be applied to any IP material within the company

6.4.2 The segregation measures shall be drawn-up, implemented, maintained and recorded at all time.

6.4.3 Effectiveness of the segregation measures shall be verified by testing

6.5 Product development/ product modification/ modification of production process

Note: this chapter may not be applicable to farmers.

6.5.1 A procedure for product development/ modification and for production process and/ or equipment modification shall be drawn-up, implemented and maintained which incorporates the risk assessment, the responsibilities for authorisation and communication to all relevant personnel. It shall include the requirement that, in case of any development/ modification, all related documents and processes shall be updated accordingly.

6.5.2 The procedure for product development/ modification and for production process and/ or equipment modification shall include criteria to ensure that packaging materials/ containers do not jeopardise IP integrity of the product.

6.5.3 Product specifications shall be drawn-up, established and maintained, clearly describing the Non-GMO status of each product the company introduces into the Non-GMO supply chain.

6.5.4 A process shall be drawn-up, implemented and maintained to ensure that labelling complies with current legislation of destination countries (tolerance threshold of adventitious presence). Any claim related to GMOs shall be compliant with legislation and shall not be misleading.

6.5.5 The Eurofins IP TRUST Programme seal(s) shall not be used on any finished product intended for the consumers and its terms and conditions for use shall be fulfilled.

6.6 Equipment

6.6.1 Equipment shall be suitably designed for intended use. It shall be checked that IP requirements are complied with.

6.7 Maintenance

6.7.1 Based on the risk assessment, an adequate system of maintenance shall be drawn-up, implemented and maintained covering all equipment to avoid any cross-contamination risk.

6.7.2 If the company hires a third-party service provider for maintenance, all relevant requirements shall be clearly defined in the service contract.

6.8 Storage

6.8.1 A procedure for storage management shall be drawn-up, implemented and maintained to ensure the segregation of Non-GM materials. This procedure shall take into account all seeds/ raw materials, semi-finished and finished products at all steps of the production including, intermediate storage.

6.8.2 Based on the risk assessment, cleaning activities and regular verification of their effectiveness, as well as other appropriate control measures, shall be drawn-up, implemented and maintained for any silo or storage facility. Appropriate measures shall be implemented for silos or facilities dedicated to the storage of non-GM products. Refilling a silo or a storage facility which is not totally empty and without specific control measures is not allowed.

6.8.3 Storage records of each silo and/ or facility containing IP products shall be documented and provided with crop type, volume and date of storage, lot number, name of supplier if relevant, cleaning records, previously stored product, remaining amount in storage as well as date and volume of removal for sale.

6.8.4 Storage silos and/ or facilities used for IP crops shall be visually identified to ensure awareness of all personnel working in this area.

6.8.5 If storage activities are managed by a third-party service provider, all good storage practices stated in this chapter shall be clearly defined in the service contract. Scope of internal audits shall include those activities to verify the effectiveness of their implementation.

6.9 Transport and loading/ unloading

6.9.1 A procedure for transport management shall be drawn-up, implemented and maintained to ensure the segregation of Non-GM materials during transport. Any transport activity along the supply chain shall be controlled to ensure that all materials sent from one stakeholder of the supply chain to another and all commodities transported for direct sales (without processing) which are under the responsibility of the certified company and have an impact on the IP finished products comply with the IP requirements and GMO legislation.

6.9.2 A procedure for approval and monitoring of transporters (external and internal) shall be drawn-up, implemented and maintained. It shall contain clear assessment criteria such as: audits, certificates, tests, transporter reliability and complaints.

6.9.3 A list of all approved transporters shall be drawn-up, implemented and maintained.

6.9.4 Loading/ unloading practices shall be drawn-up, implemented and maintained to avoid any cross-contamination risk.

6.9.5 Based on the risk assessment, cleaning and flushing activities, as well as other appropriate control measures, shall be drawn-up, implemented and maintained for facilities intended to load/ unload and transport the products. Records of achievement of these activities shall be verified before loading/ unloading to ensure that the

facilities are free from GM materials.

6.9.6 Specific practices shall be drawn-up, implemented and maintained to ensure that loading/ unloading activities are carried out from/ discharged into correct silos.

6.9.7 If transport activities are managed by a third-party service provider, all good transport practices stated in this chapter shall be clearly defined in the service contract. Scope of internal audits shall include those activities to verify the effectiveness of their implementation.

B. AUDIT REQUIREMENTS FOR MANUFACTURERS

1. Senior management: responsibilities and resources

1.1 The senior management shall draw up, sign, implement and maintain a corporate policy considering the objectives and requirements of the Eurofins IP TRUST Programme, especially the requirements related to the risk assessment, traceability, suppliers' evaluation and segregation methods. This corporate policy shall be communicated and understood by all employees.

1.2 The senior management shall draw up, implement and maintain a dialogue procedure between their organisation and Eurofins Food Assurance to communicate on any event/ change that may affect their ability to comply with the IP TRUST Programme requirements.

1.3 The senior management shall provide the necessary resources including, where applicable, processing equipment, buildings and workspace, workforce, financial and support services to meet the objectives of the IP TRUST Programme.

1.4 Competences and responsibilities, including deputation of responsibilities shall be clearly laid down for personnel identified as having authority for policy management and implementation of the IP TRUST Programme requirements. The main contact person shall show evidences of knowledge on the IP TRUST Programme.

1.5 All personnel performing work that affects the products shall have the required competences and shall be aware of their responsibilities. They shall be able to demonstrate their understanding and knowledge.

1.6 The senior management shall draw-up, implement and maintain an annual training programme on IP requirements and GMO legislation/ events for all the key personnel involved in the IP TRUST Programme to keep them knowledgeable and aware about the GMO context.

1.7 Any newcomer (including temporary personnel) shall be trained before they take charge of their duties. The training shall address the main objectives of the IP TRUST Programme, particularly: the cross-contamination risks, their impact and the related preventive and control measures.

1.8 All training/ instruction events shall be recorded (stating content, date, duration, location, trainer and participants) and such records shall be available.

1.9 Effectiveness of the training shall be verified. Refresher training shall regularly take place to ensure that personnel maintain required level of understanding and knowledge for the effective operation of the IP TRUST Programme.

1.10 The senior management shall ensure that the quality management system and risk assessment are reviewed at least annually or more frequently if significant changes occur. Such reviews shall include as a minimum:

- a review of objectives and policy concerning the IP TRUST Programme requirements

- supplier performance
- legislative, technical and industry developments relevant to the IP TRUST Programme and having an impact on the fulfilment of the IP TRUST Programme requirements
- results of audits
- complaints
- non-conformities and non-conforming products related to IP TRUST Programme requirements
- status of corrective actions.

Management review shall be documented.

2. Risk assessment

2.1 The company shall assemble a multidisciplinary team, including operational personnel and a relevant team leader, to draw-up, implement and maintain the risk assessment.

2.2 Each member of the team shall have specific knowledge of products and good handling practices and their associated cross-contamination risks and at least one person shall be knowledgeable about GMO risks and testing. Where internal expertise is not available, external expert advice shall be required.

2.3 A site flow diagram showing the operations and flows within the company shall be drawn-up and maintained for each product or product group and for all variations of the manufacturing processes and sub-processes. It shall be dated and clearly identify each critical point and “hold and release point”, where applicable.

2.4 A supply chain flow diagram showing the responsibilities for the handling of products which are in the scope of the IP TRUST certificate and its attachment and/ or have an impact on the IP finished products shall be drawn-up and maintained (see Appendix 2). It shall specify facilities and type of products (raw materials, intermediate and finished products). It shall clearly identify each “hold and release” point.

2.5 KO N°1: A risk assessment for cross-contamination shall be drawn-up, implemented and maintained to control the likelihood of introducing a cross-contamination risk in the product and/ or the environment. It shall be based on HACCP principles or other appropriate risk assessment method.

2.6 The risk assessment shall take into consideration the whole supply chain covering all raw materials, rework, semi-finished and finished products as well as every steps of the process from receipt to delivery of products, including storage, transport and outsourced processes.

2.7 The risk assessment shall take into account the general GMO risks of approved and unapproved GM varieties affecting the supply chain and its suppliers, including the geographic origin of raw materials. It shall be based on official documentation and legislation from national Authorities on status of release of GMOs for planting, commercial use or import into relevant areas (production/ processing areas and

destination countries).

2.8 The risk assessment shall take into account test results from the last twelve (12)-month period.

2.9 The determination of relevant critical points shall be facilitated by the application of a decision tree or other risk assessment tool(s).

2.10 The determination of relevant “hold and release” points shall be based on the supply chain flow diagram. Products at "hold and release” points shall be tested.

2.11 For each critical point, appropriate critical limits or parameters and values shall be defined, validated and implemented, according to current legislation and statistical studies based on test results, to clearly identify when the risk of jeopardising the IP integrity of the product is controlled and reduced to an acceptable level.

2.12 The critical points shall be controlled and monitored to detect any loss of control.

2.13 In the event that the monitoring of the critical points indicates that a particular critical point is not under control, adequate corrective actions shall be taken and recorded.

2.14 The risk assessment shall be reviewed at least annually and necessary changes shall be made in case of any modification made in the product, process or in legislation (such as changes in approval/ release of GM varieties, in targeted threshold tolerance levels, suppliers, etc.) to prevent any threat on the IP integrity of the product.

2.15 A procedure for regulatory surveillance related to GMO risks in both countries of production and destination (labelling, new authorisations, tolerance threshold, crisis/ event, etc.) shall be drawn-up, implemented and maintained to ensure an up-to-date risk assessment

3. Testing and sampling plan

3.1. Sampling

3.1.1 A risk-based sampling procedure shall be drawn-up, implemented and maintained to ensure compliance with the IP TRUST Programme. This procedure shall define the following minimum criteria:

- the number of samples (primary / sub-samples, composite and laboratory, representative for the lot)
- the frequency and time interval of sampling
- sampling practices (hygiene, apparatus, etc.)
- the sample identification process
- the sample retention policy.

The sampling procedure shall take into account relevant applicable legislation, internationally recognised standards and the outputs of the risk assessment to define appropriate sampling plans.

3.1.2 The sampling shall take place at critical stages of handling/ processing (e.g.

collection points, prior to shipping, post-processing, etc.) based on risk assessment.

3.1.3 Samples shall be adequately labelled to clearly identify their origin (lot number, date and place of sampling, name of company, quality and size of sample).

3.1.4 Archive samples (of sub-samples, composite samples and laboratory samples) shall be kept on site for the timeframe during which the product would reasonably be expected to remain in the supply chain or risk based. They shall be sealed and stored under appropriate conditions to allow counter-testing and traceability test if required.

3.2 Testing

3.2.1 A risk-based sampling procedure shall be drawn-up, implemented and maintained to ensure compliance with the IP TRUST Programme. This procedure shall define the following minimum criteria:

- the relevant tests to be made on the samples (the applied test/ screening scope shall cover all relevant GM events in question)
- specifications for/ with laboratories
- testing frequency (risk-based, taking into account the level of risk of inputs and geographies; for high-risk inputs and/ or geographies, testing shall be performed for each batch)
- applicable procedure in case of positive test result.

The testing procedure shall take into account each raw material, ingredient or mixed product for which there is a potential GMO risk (see Appendix 1 provided for purpose of reference), all known GM events for the inputs in question, relevant applicable legislation and the outputs of the risk assessment to define appropriate testing plans.

Each testing programme shall be approved and reviewed for accuracy by Eurofins GeneScan or by an analytical expert qualified by Eurofins GeneScan, as appropriate, and at least once per year, during the application review

3.2.2 In case PCR tests are not able to reach the level of the IP TRUST Programme, either because DNA is absent or where the DNA is degraded as to be undetectable, it shall be demonstrated that the raw materials have been derived from products or processes of IP status. In this case, unless the raw materials are coming from a supplier certified against Eurofins IP TRUST Programme or another IP certification standard accepted by Eurofins, documents stating the IP integrity of the products shall be available, with evidence of by-batch-specific traceability back to the testable inputs of the product. The requirements of the control/ testing plan shall be given as a reference to the suppliers.

- to assess whether there is still sufficient DNA in the product in question for an analytical check, whether or not the requirements of the IP TRUST Programme are met, the practical limit of quantification (pLOQ) shall be used if quantitative PCR tests have been carried out. If the pLOQ is above the relevant threshold defined in the standard, less processed levels of the product/ raw material shall

be taken into consideration

- for certain processed products, which are known to have insufficient DNA quantities, the practical limit of detection (pLOD) shall be determined. If the pLOD has been determined, it should be used to assess whether sufficient DNA amounts are still available in the material in question for a PCR control.

3.2.3 The company shall draw up specifications with the laboratory pointing out the risks to be covered (species/ variety/ event to look for, threshold level in accordance with the country/ ies where the product is sold, methods, etc.).

3.2.4 Testing shall be performed by approved laboratories, which shall comply with the following requirements:

- ISO/ IEC 17025 accreditation for the relevant methods and tests applied, including all qualitative and quantitative GMO tests to be performed in the framework of the IP TRUST Programme as well as, if relevant, for the determination of soybean mass by PCR
- regular and successful participation in ring trials/ proficiency tests
- sufficient high testing capacities to ensure a fast-processing time even in case of seasonal peaks
- a diverse portfolio of methods for the detection of GMOs
- implementation of all essential methods, including all tests required by the IP TRUST Programme. Subcontracting may only be permitted in exceptional cases, for individual methods and over a limited period of time

3.2.5 If tests are performed in different laboratories, the sampling and testing methods (size, species and/ or events to look for, threshold level, etc.) shall be the same to get exploitable results and to make relevant comparison and conclusions. This demonstration shall be documented.

3.2.6 The PCR tests shall meet the minimum following criteria:

- a duplicate DNA extraction per sample shall be performed
- controls defined in chapter 5 of ISO 24276: 2013-10 shall be used
- each DNA extract shall be subjected to the real-time PCR reactions for the detection of the target DNA sequence
- results of the individual test portions shall be evaluated according to the criteria defined in chapter 6 of ISO 24276: 2013-10

3.2.7 The test reports/ certificates of analysis for PCR tests shall fulfil the requirements defined in chapter 7 of ISO 24276: 2013-10, especially they shall include following information:

- size of the test portions used for the DNA extraction
- reference to the ISO 24276: 2013-10 standard
- for quantitative tests: indication of the pLOQ, regardless of the analysed sample matrix, and the measurement uncertainty (as +/- behind the result, to represent the expanded measurement uncertainty)
- for tests of processed raw materials, ingredients, food and/ or feed which are

known that they may have insufficient DNA quantities: indication of the pLOD, if practically available

3.2.8 Test results shall confirm that the GMO certification threshold of the IP TRUST Programme has been met. Both qualitative and quantitative PCR tests may be used. The scope of tests used shall in any case be sufficient to demonstrate that the products meet the requirements of the IP TRUST Programme.

3.2.9 In case of positive test results, the follow-up analyses shall take into account all relevant GMOs, subsequent testing may be performed with specific qualitative and/ or quantitative tests. Unless further investigations confirming compliance, product subject to this positive test shall be managed as a non-conforming product.

3.2.10 The testing and sampling plans shall be reviewed annually, or more frequently, based on the risk assessment and/ or on major events (for example, if there are any changes in the approval situation and / or cultivation of GMOs of plants of raw materials, ingredients and/ or food and feed which are in the scope of the IP TRUST certification) affecting the ability of the company to comply with the requirements of the IP TRUST Programme.

4. Quality management system

4.1 Quality manual and documentation management

4.1.1 Documents (procedures, records and any other document) related to the compliance with the IP requirements shall be drawn-up and maintained and shall be kept together, preferably in a physical and/ or electronic quality manual. They shall mention responsibility, be up to date and cover review and record keeping.

4.1.2 All documents shall be available in their latest version, clearly legible, unambiguous, comprehensive and dated if relevant. They shall be available in appropriate languages and sufficiently detailed to enable their correct application by appropriate personnel. For multi-site companies, it shall be ensured that all relevant documents are available and adapted to each site involved in the IP TRUST Programme.

4.1.3 All records shall be maintained for at least five (5) years.

4.2 Traceability

4.2.1 KO N°2: A traceability system shall be drawn-up, implemented and maintained taking into consideration every raw material, rework, semi-finished and finished product. Those shall be identified and labelled at all stages along the supply chain to guarantee traceability, minimum one step back and one step forward (from last processing step of raw materials to delivered products, and vice versa).

4.2.2 A clear relation shall be established between batches/ lots and related GMO test results. In case several locations and stakeholders are involved, the responsibility to establish this relation is with the main stakeholder.

4.2.3 Quantities of IP products (inputs and outputs) shall be recorded, maintained and checked (running mass balance correlating inputs and outputs), to ensure that

quantities/ volumes of IP products received are equal to volumes used/ sold. This mass balance shall include the use of rework, where applicable and shall include the identification of constituent batches/ lots and their proportions by batch/ lot number (new batch/ lot number or proper identification shall be defined for composite batches/ lots).

4.2.4 The traceability system shall be reviewed and tested at least once a year and each time system/ product/ process changes. The test shall verify upstream and downstream traceabilities. Test results shall be recorded and available for the audit.

4.3 Internal audit

4.3.1 Effective internal audits covering the IP requirements shall be conducted at least once per year. Frequency (when more often than annually) and scope shall be based on the risk assessment and documented.

4.3.2 The auditor shall be competent and independent from the audited department. Where internal expertise is not available, the company shall request an external auditor.

4.3.3 Internal audit results shall be communicated to responsible persons of concerned department and to the senior management.

4.3.4 Necessary corrective actions followed by a schedule for implementation and relevant responsibilities shall be defined and recorded, for the purpose of continuous improvement.

4.4 Management of non-conforming products and non-conformities

4.4.1 A procedure shall be drawn-up, implemented and maintained for the management of all non-conforming products and non-conformities: raw materials, semi-finished, finished products, rework, processing equipment and packaging materials. This shall include, as a minimum:

- defined responsibilities
- isolation/ quarantine
- cause analysis
- product identification
- decision for further use like release, rework, quarantine, disposal
- corrective actions
- specific measures for “hold and release” points to ensure that only compliant products are processed and sold.

4.4.2 In particular cases when test results show detection of GMO presence:

- Eurofins Food Assurance shall be informed immediately
- if the test result is above 0.6%, affected products shall be quarantined
- if the test result is positive but still below 0.6%, a root cause analysis shall be performed to ensure that the affected products will not trend to become non-

compliant.

4.4.3 Products in quarantine shall not be released as IP products until the deviation within the risk assessment has been fully assessed and the product verified to meet the IP requirements in terms of GMO presence threshold.

4.5 Corrective actions

4.5.1 A procedure shall be drawn-up, implemented and maintained for the management, recording and review of the non-conformities to avoid recurrence by preventive actions and/ or corrective actions.

4.5.2 Corrective actions shall be recorded. Those records shall detail the relevant responsibility and schedule for implementation.

4.5.3 The effectiveness and performance of the implemented corrective actions shall be verified and such verification shall be documented.

4.6 Management of complaints

4.6.1 A procedure shall be drawn-up, implemented and maintained to manage the complaints from authorities and customers. The complaints shall be assessed by competent personnel, reviewed and recorded.

4.6.2 If necessary, appropriate actions shall be taken, recorded and monitored to avoid the recurrence of the non-conformities.

4.7 Management of incidents, product withdrawal/ recall

4.7.1 A procedure shall be drawn-up, implemented and maintained to manage incidents and potential emergency situations that could impact the IP integrity of the products. It shall mention:

- the name of the relevant personnel (crisis team)
- an alert contact list (authorities, customers, sites and people to be informed, etc.)
- withdrawal/ recall procedure
- consideration of the dialogue procedure with Eurofins Food Assurance

In case of product recall related to IP, the company shall inform Eurofins Food Assurance within 3 working days maximum.

4.7.2 The feasibility, effectiveness and timeliness of implementation of withdrawal procedure shall be tested at least once a year, or more often based on risk assessment.

4.7.3 Any event/ crisis related to GM crop or authorisation in the area of farming shall be assessed to determine the risks of adventitious presence. The results of this

assessment and related actions shall be communicated to Eurofins Food Assurance.

5. Products and suppliers: approval and monitoring

5.1 Specifications shall be drawn-up, implemented and maintained for all seeds/ raw materials and products and shall clearly describe the non-GMO status. They shall be available to all relevant personnel and be compliant with the IP requirements.

5.2 Specifications shall be drawn-up, implemented and maintained for all packaging materials/ containers and shall clearly demonstrate that packaging materials/ containers are fit for their intended use for IP products. Where relevant, they shall describe their non-GMO status.

5.3 A procedure shall be drawn-up, implemented and maintained to check the compliance of any incoming material against the specifications at receipt. In particular, it shall include the fact that:

- delivery documents shall be clear and unambiguous, including GMO related information required by local, national and/or international regulations
- all goods shipped in bulk, where packaging or labels are not feasible, shall be duly identified with a lot or production code allowing proper identification and traceability
- packaging and other product-holding vessels shall be checked and documented clean of potential GMO materials before being used for non-GMO inputs/products.

5.4 The company shall control purchasing processes to ensure that all externally sourced materials and services which have an impact on the finished products (crops) conform to the IP requirements and GMO legislation of the destination countries.

5.5 The conformity of the products (crops) with the specifications shall be regularly checked. The frequency of these controls shall take into consideration the product characteristics (variety and type of culture, country of production and destination, etc.), status of the supplier and impact on the finished products (crops).

5.6 KO N°3: A procedure for approval and monitoring of suppliers shall be drawn-up, implemented and maintained. It shall contain clear assessment criteria such as: audits, communication on changes/ events having an impact on the IP integrity, certificates (stating GMO threshold, scope, description of the supply chain and products and physical measures), testing, supplier reliability and complaints.

5.7 The procedure for approval and monitoring of suppliers shall address procurement in emergency situations to ensure that inputs are still compliant with specifications and come from an assessed supplier.

5.8 The procedure for approval and monitoring of suppliers shall include the following policy:

- the suppliers shall be certified against Eurofins IP TRUST Programme or another

IP certification standard accepted by Eurofins. The company shall request the current certificate(s) and monitor the certification continuity of their suppliers

Or

- the suppliers shall be assessed through specific measures like a risk assessment review, or a second party audit covering GMO risk assessment and control measures, or the review or other relevant GMO risk management information (e.g. historical data, performance details, sampling and test results of all batches/ lots, etc.).

5.9 All external suppliers (especially in case of purchasing via a third party) shall be bound with the company. All specifications/ contracts or any agreement between the company and the supplier shall be documented, agreed and signed by relevant parties.

5.10 The contracts/ agreements between the company and the external suppliers shall require involvement from the suppliers on all the measures ensuring the IP integrity of the products, which shall include at least segregation, traceability, risk assessment and control/ testing plan.

5.11 The results of suppliers' assessment shall be reviewed regularly, based on the risk assessment. Reviews and actions from the assessment shall be recorded.

6. Good handling practices

6.1 General good handling practices

6.1.1 Based on the risk assessment, documented requirements for protective clothing and good practices to adopt in specific areas shall be drawn-up, implemented and maintained. They shall be communicated to all personnel, contractors and visitors entering the site.

6.1.2 Based on the risk assessment, inspection schedules or other methods shall be drawn-up, implemented and maintained to verify the effectiveness of the control measures implemented to ensure the IP integrity of the products.

6.2 Good processing practices

6.2.1 Based on the risk assessment, a procedure for manufacturing process schedule shall be drawn-up, implemented and maintained to avoid any cross-contamination risk. It shall take into consideration any rework or semi-finished products as well as any raw materials.

6.2.2 Process control documents shall clearly prescribe the status of the raw materials/ ingredients/ products to be processed with regard to their non-GM status. Batch/ lot identification records shall be kept at all stages of the processes.

6.2.3 Any rework (from production, after going through a foreign bodies prevention device like e.g. sieve, filter, etc.) shall be identified, recorded and appropriate measures

taken to avoid any cross-contamination risk with IP material.

6.2.4 Records of all processes shall be maintained for a minimum of 5 years.

6.3 Cleaning activities

6.3.1 KO N°4: Based on the risk assessment, cleaning and/ or flushing procedures and schedules shall be drawn-up, implemented and maintained to avoid any cross-contamination risk. These shall specify:

- **objectives**
- **tasks and responsibilities**
- **areas/ equipment/ containers concerned**
- **instructions, used equipment and cleaning product(s)**
- **frequency**
- **records thereof**

6.3.2 Personnel responsible for the cleaning/ flushing activities shall be trained.

6.3.3 The effectiveness of the cleaning/ flushing activities shall be verified on a regular basis, based on the risk assessment.

6.3.4 Cleaning/ flushing schedules shall be reviewed and modified in case of any changes in the product, process, machinery or cleaning equipment.

6.3.5 If the company hires a third-party service provider for cleaning activities, all requirements specified above shall be clearly defined in the service contract.

6.3.6 Chemicals (used for cleaning, maintenance, within the product formulation, etc.) shall not be a source of GMO cross-contamination.

6.4 Segregation

6.4.1 A procedure shall be drawn-up, implemented and maintained to ensure the IP integrity of the processed products. It shall describe the measures aimed to avoid mixing of controlled products with uncontrolled materials and shall include, as a minimum:

- good manufacturing practices
- dedicated materials and processing lines, when/ where possible
- labelling/ marking on packaging/ containers
- cleaning schedules
- flushing activities
- risks based processing schedules
- specific measures during packaging and labelling

- dedicated storage
- dedicated transport.

Segregation measures shall be applied to any IP material within the company

6.4.2 The segregation measures shall be drawn-up, implemented, maintained and recorded at all time.

6.4.3 Effectiveness of the segregation measures shall be verified by testing

6.5 Product development/ product modification/ modification of manufacturing process

6.5.1 A procedure for product development/ modification and for manufacturing process and/ or equipment modification shall be drawn-up, implemented and maintained which incorporates the risk assessment, the responsibilities for authorisation and communication to all relevant personnel. It shall include the requirement that, in case of any development/ modification, all related documents and processes shall be updated accordingly.

6.5.2 The procedure for product development/ modification and for manufacturing process and/ or equipment modification shall include criteria to ensure that packaging materials/ containers do not jeopardise IP integrity of the product.

6.5.3 Product specifications shall be drawn-up, established and maintained, clearly describing the Non-GMO status of each product the company introduces into the Non-GMO supply chain.

6.5.4 A process shall be drawn-up, implemented and maintained to ensure that labelling complies with current legislation of destination countries (tolerance threshold of adventitious presence). Any claim related to GMOs shall be compliant with legislation and shall not be misleading.

6.5.5 The Eurofins IP TRUST Programme seal(s) shall not be used on any finished product intended for the consumers and its terms and conditions for use shall be fulfilled.

6.6 Equipment

6.6.1 Equipment shall be suitably designed for intended use. It shall be checked that IP requirements are complied with.

6.7 Maintenance

6.7.1 Based on the risk assessment, an adequate system of maintenance shall be drawn-up, implemented and maintained covering all equipment to avoid any cross-contamination risk.

6.7.2 If the company hires a third-party service provider for maintenance, all relevant

requirements shall be clearly defined in the service contract.

6.8 Storage

6.8.1 A procedure for storage management shall be drawn-up, implemented and maintained to ensure the segregation of Non-GM materials. This procedure shall take into account all seeds/ raw materials, rework, semi-finished and finished products at all steps of the processing including, intermediate storage.

6.8.2 Based on the risk assessment, cleaning activities and regular verification of their effectiveness, as well as other appropriate control measures, shall be drawn-up, implemented and maintained for any silo or storage facility. Appropriate measures shall be implemented for silos or facilities dedicated to the storage of non-GM products. Refilling a silo or a storage facility which is not totally empty and without specific control measures is not allowed.

6.8.3 Storage records of each silo and/ or facility containing IP products shall be documented and provided with volume, dates of receipt, lot number, name of supplier if relevant, name of the operator who accepted the raw materials if relevant, cleaning records, previously stored product as well as date and volume of removal for sale.

6.8.4 Storage silos and/ or facilities used for IP crops shall be visually identified to ensure awareness of all personnel working in this area.

6.8.5 If storage activities are managed by a third-party service provider, all good storage practices stated in this chapter shall be clearly defined in the service contract. Scope of internal audits shall include those activities to verify the effectiveness of their implementation.

6.9 Transport and loading/ unloading

6.9.1 A procedure for transport management shall be drawn-up, implemented and maintained to ensure the segregation of Non-GM materials during transport. Any transport activity along the supply chain shall be controlled to ensure that all materials sent from one stakeholder of the supply chain to another and all commodities transported for direct sales (without processing) which are under the responsibility of the certified company and have an impact on the IP finished products comply with the IP requirements and GMO legislation.

6.9.2 A procedure for approval and monitoring of transporters (external and internal) shall be drawn-up, implemented and maintained. It shall contain clear assessment criteria such as: audits, certificates, tests, transporter reliability and complaints.

6.9.3 A list of all approved transporters shall be drawn-up, implemented and maintained.

6.9.4 Loading/ unloading practices shall be drawn-up, implemented and maintained to avoid any cross-contamination risk.

6.9.5 Based on the risk assessment, cleaning and flushing activities, as well as other appropriate control measures, shall be drawn-up, implemented and maintained for facilities intended to load/ unload and transport the products. Records of achievement

of these activities shall be verified before loading/ unloading to ensure that the facilities are free from GM materials.

6.9.6 Specific practices shall be drawn-up, implemented and maintained to ensure that loading/ unloading activities are carried out from/ discharged into correct silos.

6.9.7 If transport activities are managed by a third-party service provider, all good transport practices stated in this chapter shall be clearly defined in the service contract. Scope of internal audits shall include those activities to verify the effectiveness of their implementation.

C. AUDIT REQUIREMENTS FOR BROKERS

1. Senior management: responsibilities and resources

1.1 The senior management shall draw up, sign, implement and maintain a corporate policy considering the objectives and requirements of the Eurofins IP TRUST Programme, especially the requirements related to the risk assessment, traceability, suppliers' evaluation and segregation methods. This corporate policy shall be communicated and understood by all employees.

1.2 The senior management shall draw up, implement and maintain a dialogue procedure between their organisation and Eurofins Food Assurance to communicate on any event/ change that may affect their ability to comply with the IP TRUST Programme requirements.

1.3 The senior management shall provide the necessary resources including buildings and workspace, workforce, financial and support services to meet the objectives of the IP TRUST Programme.

1.4 Competences and responsibilities, including deputation of responsibilities shall be clearly laid down for personnel identified as having authority for policy management and implementation of the IP TRUST Programme requirements. The main contact person shall show evidences of knowledge on the IP TRUST Programme.

1.5 All personnel performing work that affects the products shall have the required competences and shall be aware of their responsibilities. They shall be able to demonstrate their understanding and knowledge.

1.6 The senior management shall draw-up, implement and maintain an annual training programme on IP requirements and GMO legislation/ events for all the key personnel involved in the IP TRUST Programme to keep them knowledgeable and aware about the GMO context.

1.7 Any newcomer (including temporary personnel) shall be trained before they take charge of their duties. The training shall address the main objectives of the IP TRUST Programme, particularly: the cross-contamination risks, their impact and the related preventive and control measures.

1.8 All training/ instruction events shall be recorded (stating content, date, duration, location, trainer and participants) and such records shall be available.

1.9 Effectiveness of the training shall be verified. Refresher training shall regularly take place to ensure that personnel maintain required level of understanding and knowledge for the effective operation of the IP TRUST Programme.

1.10 The senior management shall ensure that the quality management system and risk assessment are reviewed at least annually or more frequently if significant changes occur. Such reviews shall include as a minimum:

- a review of objectives and policy concerning the IP TRUST Programme requirements
- supplier performance

- legislative, technical and industry developments relevant to the IP TRUST Programme and having an impact on the fulfilment of the IP TRUST Programme requirements
- results of audits
- complaints
- non-conformities and non-conforming products related to IP TRUST Programme requirements
- status of corrective actions.

Management review shall be documented.

2. Risk assessment

2.1 The company shall assemble a multidisciplinary team, including operational personnel and a relevant team leader, to draw-up, implement and maintain the risk assessment.

2.2 Each member of the team shall have specific knowledge of products, their supply chain and their associated cross-contamination risks and at least one person shall be knowledgeable about GMO risks and testing. Where internal expertise is not available, external expert advice shall be required.

2.3 A site flow diagram showing the operations and flows within the company shall be drawn-up and maintained for each product or product group and for all variations of the supply chain. It shall be dated and clearly identify each critical point and “hold and release point”, where applicable.

2.4 A supply chain flow diagram showing the responsibilities for the handling of products which are in the scope of the IP TRUST certificate and its attachment and/ or have an impact on the IP finished products shall be drawn-up and maintained (see Appendix 2). It shall specify facilities and type of products and shall clearly identify each “hold and release” point.

2.5 KO N°1: A risk assessment for cross-contamination shall be drawn-up, implemented and maintained to control the likelihood of introducing a cross-contamination risk in the product. It shall be based on HACCP principles or other appropriate risk assessment method.

2.6 The risk assessment shall take into consideration the whole supply chain covering all steps of previous and further handling, including storage, transport and outsourced processes.

2.7 The risk assessment shall take into account the general GMO risks of approved and unapproved GM varieties affecting the supply chain and its suppliers, including the geographic origin of raw materials. It shall be based on official documentation and legislation from national Authorities on status of release of GMOs for planting, commercial use or import into relevant areas (production/ processing areas and destination countries).

2.8 The risk assessment shall take into account test results from the last twelve (12)-

month period.

2.9 The company shall ensure that the suppliers (or the producers/ manufacturers in case the suppliers are not producers/ manufacturers) have:

- determined relevant critical points, by the application of a decision tree or other risk assessment tool(s)
- defined, validated and implemented appropriate critical limits or parameters and values, according to current legislation and statistical studies based on test results, to clearly identify when the risk of jeopardising the IP integrity of the product is controlled and reduced to an acceptable level
- controlled and monitored the critical points to detect any loss of control
- implemented and recorded adequate corrective actions in the event that the monitoring of the critical points indicates that a particular critical point is not under control.

2.10 The determination of relevant “hold and release” points shall be based on the supply chain flow diagram. Products at "hold and release” points shall be tested.

2.11 The risk assessment shall be reviewed at least annually and necessary changes shall be made in case of any modification made in the product, supply chain or in legislation (such as changes in approval/ release of GM varieties, in targeted threshold tolerance levels, suppliers, etc.) to prevent any threat on the IP integrity of the product.

2.12 A procedure for regulatory surveillance related to GMO risks in both countries of production and destination (labelling, new authorisations, tolerance threshold, crisis/ event, etc.) shall be drawn-up, implemented and maintained to ensure an up-to-date risk assessment.

3. Testing and sampling plan

3.1. Sampling

3.1.1 A risk-based sampling procedure shall be drawn-up, implemented and maintained to ensure compliance with the IP TRUST Programme. This procedure shall define the following minimum criteria:

- the number of samples (primary / sub-samples, composite and laboratory, representative for the lot)
- the frequency and time interval of sampling
- sampling practices (hygiene, apparatus, etc.)
- the sample identification process
- the sample retention policy.

The sampling procedure shall take into account relevant applicable legislation, internationally recognised standards and the outputs of the risk assessment to define appropriate sampling plans.

3.1.2 The sampling shall take place at critical stages of handling/ processing (e.g. collection points, prior to shipping, post-processing, etc.) based on risk assessment.

3.1.3 Samples shall be adequately labelled to clearly identify their origin (lot number, date and place of sampling, name of company, quality and size of sample).

3.1.4 Archive samples (of sub-samples, composite samples and laboratory samples) shall be kept for the timeframe during which the product would reasonably be expected to remain in the supply chain or risk based. They shall be sealed and stored under appropriate conditions to allow counter-testing and traceability test if required.

3.2 Testing

3.2.1 A risk-based testing procedure shall be drawn-up, implemented and maintained to ensure compliance with the IP TRUST Programme. This procedure shall define the following minimum criteria:

- the relevant tests to be made on the samples (the applied test/ screening scope shall cover all relevant GM events in question)
- specifications for/ with laboratories
- testing frequency (risk-based, taking into account the level of risk of inputs and geographies; for high-risk inputs and/ or geographies, testing shall be performed for each batch)
- applicable procedure in case of positive test result.

The testing procedure shall take into account each product for which there is a potential GMO risk (see Appendix 1 provided for purpose of reference), all known GM events for the inputs in question, relevant applicable legislation and the outputs of the risk assessment to define appropriate testing plans.

Each testing programme shall be approved and reviewed for accuracy by Eurofins GeneScan or by an analytical expert qualified by Eurofins GeneScan, as appropriate, and at least once per year, during the application review

3.2.2 In case PCR tests are not able to reach the level of the IP TRUST Programme, either because DNA is absent or where the DNA is degraded as to be undetectable, it shall be demonstrated that the raw materials have been derived from products or processes of IP status. In this case, unless the raw materials are coming from a supplier certified against Eurofins IP TRUST Programme or another IP certification standard accepted by Eurofins, documents stating the IP integrity of the products shall be available, with evidence of by-batch-specific traceability back to the testable inputs of the product. The requirements of the control/ testing plan shall be given as a reference to the suppliers.

- to assess whether there is still sufficient DNA in the product in question for an analytical check, whether or not the requirements of the IP TRUST Programme are met, the practical limit of quantification (pLOQ) shall be used if quantitative PCR tests have been carried out. If the pLOQ is above the relevant threshold defined in the Programme, less processed levels of the product/ raw material shall be taken into consideration

- for certain processed products, which are known to have insufficient DNA quantities, the practical limit of detection (pLOD) shall be determined. If the pLOD has been determined, it should be used to assess whether sufficient DNA amounts are still available in the material in question for a PCR control.

3.2.3 The company shall draw up specifications with the laboratory pointing out the risks to be covered (species/ variety/ event to look for, threshold level in accordance with the country/ ies where the product is sold, methods, etc.).

3.2.4 Testing shall be performed by approved laboratories, which shall comply with the following requirements:

- ISO/ IEC 17025 accreditation for the relevant methods and tests applied, including all qualitative and quantitative GMO tests to be performed in the framework of the IP TRUST Programme as well as, if relevant, for the determination of soybean mass by PCR
- regular and successful participation in ring trials/ proficiency tests
- sufficient high testing capacities to ensure a fast-processing time even in case of seasonal peaks
- a diverse portfolio of methods for the detection of GMOs
- implementation of all essential methods, including all tests required by the IP TRUST Programme. Subcontracting may only be permitted in exceptional cases, for individual methods and over a limited period of time

3.2.5 If tests are performed in different laboratories, the sampling and testing methods (size, species and/ or events to look for, threshold level, etc.) shall be the same to get exploitable results and to make relevant comparison and conclusions. This demonstration shall be documented.

3.2.6 The PCR tests shall meet the minimum following criteria:

- a duplicate DNA extraction per sample shall be performed
- controls defined in chapter 5 of ISO 24276: 2013-10 shall be used
- each DNA extract shall be subjected to the real-time PCR reactions for the detection of the target DNA sequence
- results of the individual test portions shall be evaluated according to the criteria defined in chapter 6 of ISO 24276: 2013-10

3.2.7 The test reports/ certificates of analysis for PCR tests shall fulfil the requirements defined in chapter 7 of ISO 24276: 2013-10, especially they shall include following information:

- size of the test portions used for the DNA extraction
- reference to the ISO 24276: 2013-10 standard
- for quantitative tests: indication of the pLOQ, regardless of the analysed sample matrix, and the measurement uncertainty (as +/- behind the result, to represent the expanded measurement uncertainty)
- for tests of processed raw materials, ingredients, food and/ or feed which are known that they may have insufficient DNA quantities: indication of the pLOD, if

practically available.

3.2.8 Test results shall confirm that the GMO certification threshold of the IP TRUST Programme has been met. Both qualitative and quantitative PCR tests may be used. The scope of tests used shall in any case be sufficient to demonstrate that the products meet the requirements of the IP TRUST Programme.

3.2.9 In case of positive test results, the follow-up analyses shall take into account all relevant GMOs, subsequent testing may be performed with specific qualitative and/ or quantitative tests. Unless further investigations confirming compliance, product subject to this positive test shall be managed as a non-conforming product.

3.2.10 The testing and sampling plans shall be reviewed annually, or more frequently, based on the risk assessment and/ or on major events (for example, if there are any changes in the approval situation and / or cultivation of GMOs of plants of raw materials, ingredients and/ or food and feed which are in the scope of the IP TRUST certification) affecting the ability of the company to comply with the requirements of the IP TRUST Programme.

4. Quality management system

4.1 Quality manual and documentation management

4.1.1 Documents (procedures, records and any other document) related to the compliance with the IP requirements shall be drawn-up and maintained and shall be kept together, preferably in a physical and/ or electronic quality manual. They shall mention responsibility, be up to date and cover review and record keeping.

4.1.2 All documents shall be available in their latest version, clearly legible, unambiguous, comprehensive and dated if relevant. They shall be available in appropriate languages and sufficiently detailed to enable their correct application by appropriate personnel. For multi-site companies, it shall be ensured that all relevant documents are available and adapted to each site involved in the IP TRUST Programme.

4.1.3 All records shall be maintained for at least five (5) years.

4.2 Traceability

4.2.1 KO N°2: A traceability system shall be drawn-up, implemented and maintained taking into consideration every purchased and sold product. Those shall be identified and labelled at all stages along the supply chain to guarantee traceability, minimum one step back and one step forward (from last processing step of the products to delivered products, and vice versa).

4.2.2 A clear relation shall be established between batches/ lots and related GMO test results. In case several locations and stakeholders are involved, the responsibility to establish this relation is with the main stakeholder.

4.2.3 Quantities of IP products (inputs and outputs) shall be recorded, maintained and checked (running mass balance correlating inputs and outputs), to ensure that quantities/ volumes of IP products received are equal to volumes used/ sold.

4.2.4 The traceability system shall be reviewed and tested at least once a year and each time system/ product/ supply chain changes. The test shall verify upstream and downstream traceabilities. Test results shall be recorded and available for the audit.

4.3 Internal audit

4.3.1 Effective internal audits covering the IP requirements shall be conducted at least once per year. Frequency (when more often than annually) and scope shall be based on the risk assessment and documented.

4.3.2 The auditor shall be competent and independent from the audited department. Where internal expertise is not available, the company shall request an external auditor.

4.3.3 Internal audit results shall be communicated to responsible persons of concerned department and to the senior management.

4.3.4 Necessary corrective actions followed by a schedule for implementation and relevant responsibilities shall be defined and recorded, for the purpose of continuous improvement.

4.4 Management of non-conforming products and non-conformities

4.4.1 A procedure shall be drawn-up, implemented and maintained for the management of all non-conforming products and non-conformities. This shall include, as a minimum:

- defined responsibilities
- isolation/ quarantine
- cause analysis
- product identification
- decision for further use like release, rework, quarantine, disposal
- corrective actions
- specific measures for “hold and release” points to ensure that only compliant products are processed and sold.

4.4.2 In particular cases when test results show detection of GMO presence:

- Eurofins Food Assurance shall be informed immediately
- if the test result is above 0.6%, affected products shall be quarantined
- if the test result is positive but still below 0.6%, a root cause analysis shall be performed to ensure that the affected products will not trend to become non-compliant.

4.4.3 Products in quarantine shall not be released as IP products until the deviation within the risk assessment has been fully assessed and the product verified to meet the IP requirements in terms of GMO presence threshold.

4.5 Corrective actions

4.5.1 A procedure shall be drawn-up, implemented and maintained for the management, recording and review of the non-conformities to avoid recurrence by preventive actions and/ or corrective actions.

4.5.2 Corrective actions shall be recorded. Those records shall detail the relevant responsibility and schedule for implementation.

4.5.3 The effectiveness and performance of the implemented corrective actions shall be verified and such verification shall be documented.

4.6 Management of complaints

4.6.1 A procedure shall be drawn-up, implemented and maintained to manage the complaints from authorities and customers. The complaints shall be assessed by competent personnel, reviewed and recorded.

4.6.2 If necessary, appropriate actions shall be taken, recorded and monitored to avoid the recurrence of the non-conformities.

4.7 Management of incidents, product withdrawal/ recall

4.7.1 A procedure shall be drawn-up, implemented and maintained to manage incidents and potential emergency situations that could impact the IP integrity of the products. It shall mention:

- the name of the relevant personnel (crisis team)
- an alert contact list (authorities, customers, sites and people to be informed, etc.)
- withdrawal/ recall procedure
- consideration of the dialogue procedure with Eurofins Food Assurance.

In case of product recall related to IP, the company shall inform Eurofins Food Assurance within 3 working days maximum

4.7.2 The feasibility, effectiveness and timeliness of implementation of withdrawal procedure shall be tested at least once a year, or more often based on risk assessment.

4.7.3 Any event/ crisis related to GM crop or authorisation in the area of farming shall be assessed to determine the risks of adventitious presence. The results of this assessment and related actions shall be communicated to Eurofins Food Assurance.

5. Products and suppliers: approval and monitoring

5.1 Specifications shall be drawn-up, implemented and maintained for all products and shall clearly describe the non-GMO status. They shall be available to all relevant

personnel and be compliant with the IP requirements.

5.2 The company shall have a process in place to ensure that packaging materials/ containers are fit for their intended use for IP products. Where relevant, they shall describe their non-GMO status.

5.3 A procedure shall be drawn-up, implemented and maintained to check the compliance of any incoming material against the specifications at the reception site. In particular, it shall include the fact that:

- delivery documents shall be clear and unambiguous, including GMO related information required by local, national and/or international regulations
- all goods shipped in bulk, where packaging or labels are not feasible, shall be duly identified with a lot or production code allowing proper identification and traceability
- packaging and other product-holding vessels shall be checked and documented clean of potential GMO materials before being used for non-GMO inputs/products.

5.4 The company shall control purchasing processes to ensure that all externally sourced materials and services which have an impact on the finished products (crops) conform to the IP requirements and GMO legislation of the destination countries.

5.5 The conformity of the products (crops) with the specifications shall be regularly checked. The frequency of these controls shall take into consideration the product characteristics (variety and type of culture, country of production and destination, etc.), status of the supplier and impact on the finished products (crops).

5.6 KO N°3: A procedure for approval and monitoring of suppliers shall be drawn-up, implemented and maintained. It shall contain clear assessment criteria such as: audits, communication on changes/ events having an impact on the IP integrity, certificates (stating GMO threshold, scope, description of the supply chain and products and physical measures), testing, supplier reliability and complaints.

5.7 The procedure for approval and monitoring of suppliers shall address procurement in emergency situations to ensure that inputs are still compliant with specifications and come from an assessed supplier.

5.8 The procedure for approval and monitoring of suppliers shall include the following policy:

- the suppliers shall be certified against Eurofins IP TRUST Programme or another IP certification standard accepted by Eurofins. The company shall request the current certificate(s) and monitor the certification continuity of their suppliers

Or

- the suppliers shall be assessed through specific measures like a risk assessment review, or a second party audit covering GMO risk assessment and control measures, or the review or other relevant GMO risk management information (e.g. historical data, performance details, sampling and test results of

all batches/ lots, etc.).

5.9 All external suppliers (especially in case of purchasing via a third party) shall be bound with the company. All specifications/ contracts or any agreement between the company and the supplier shall be documented, agreed and signed by relevant parties.

5.10 The contracts/ agreements between the company and the external suppliers shall require involvement from the suppliers on all the measures ensuring the IP integrity of the products, which shall include at least segregation, traceability, risk assessment and control/ testing plan.

5.11 The results of suppliers' assessment shall be reviewed regularly, based on the risk assessment. Reviews and actions from the assessment shall be recorded.

6. Good handling practices

6.1 Product development/ product modification/ modification of production and/ or manufacturing process

Note: this chapter may not be applicable to brokers

6.1.1 A procedure for product development/ modification and for production/ manufacturing process and/ or equipment modification shall be drawn-up, implemented and maintained which incorporates the risk assessment, the responsibilities for authorisation and communication to all relevant personnel. It shall include the requirement that, in case of any development/ modification, all related documents and processes shall be updated accordingly.

6.1.2 The procedure for product development/ modification and for production/ manufacturing process and/ or equipment modification shall include criteria to ensure that packaging materials/ containers do not jeopardise IP integrity of the product.

6.1.3 Product specifications shall be drawn-up, established and maintained, clearly describing the Non-GMO status of each product the company introduces into the Non-GMO supply chain.

6.1.4 A process shall be drawn-up, implemented and maintained to ensure that labelling complies with current legislation of destination countries (tolerance threshold of adventitious presence). Any claim related to GMOs shall be compliant with legislation and shall not be misleading.

6.1.5 The Eurofins IP TRUST Programme seal(s) shall not be used on any finished product intended for the consumers and its terms and conditions for use shall be fulfilled.

6.2 Storage

Note: this chapter may not be applicable to brokers.

6.2.1 A procedure for storage management shall be drawn-up, implemented and maintained to ensure the segregation of Non-GM materials.

6.2.2 Based on the risk assessment, cleaning activities and regular verification of their effectiveness, as well as other appropriate control measures, shall be drawn-up, implemented and maintained for any silo or storage facility. Appropriate measures shall be implemented for silos or facilities dedicated to the storage of non-GM products. Refilling a silo or a storage facility which is not totally empty and without specific control measures is not allowed.

6.2.3 Storage records of each silo and/ or facility containing IP products shall be documented and provided with volume, lot number, name of supplier if relevant, cleaning activities, previously stored product as well as date and volume of removal for sale.

6.2.4 Storage silos and/ or facilities used for IP crops shall be visually identified to ensure awareness of all personnel working in this area.

6.2.5 If storage activities are managed by a third-party service provider, all good storage practices stated in this chapter shall be clearly defined in the service contract. Scope of internal audits shall include those activities to verify the effectiveness of their implementation.

6.3 Transportation and loading/ unloading

Note: this chapter may not be applicable to brokers.

6.3.1 A procedure for transport management shall be drawn-up, implemented and maintained to ensure the segregation of Non-GM materials during transport. Any transport activity along the supply chain shall be controlled to ensure that all materials sent from one stakeholder of the supply chain to another and all commodities transported for direct sales (without processing) which are under the responsibility of the certified company and have an impact on the IP finished products comply with the IP requirements and GMO legislation.

6.3.2 A procedure for approval and monitoring of transporters (external and internal) shall be drawn-up, implemented and maintained. It shall contain clear assessment criteria such as: audits, certificates, tests, transporter reliability and complaints.

6.3.3 A list of all approved transporters shall be drawn-up, implemented and maintained.

6.3.4 Loading/ unloading practices shall be drawn-up, implemented and maintained to avoid any cross-contamination risk.

6.3.5 Based on the risk assessment, cleaning and flushing activities, as well as other appropriate control measures, shall be drawn-up, implemented and maintained for facilities intended to load/ unload and transport the products. Records of achievement of these activities shall be verified before loading/ unloading to ensure that the facilities are free from GM materials.

6.3.6 Specific practices shall be drawn-up, implemented and maintained to ensure that loading/ unloading activities are carried out from/ discharged into correct silos.

6.3.7 If transport activities are managed by a third-party service provider, all good transport practices stated in this chapter shall be clearly defined in the service contract. Scope of internal audits shall include those activities to verify the effectiveness of their implementation.

D. AUDIT REQUIREMENTS FOR STORAGE PROVIDERS

1. Senior management: responsibilities and resources

1.1 The senior management shall draw up, sign, implement and maintain a corporate policy considering the objectives and requirements of the Eurofins IP TRUST Programme, especially the requirements related to the risk assessment, traceability, suppliers' evaluation and segregation methods. This corporate policy shall be communicated and understood by all employees.

1.2 The senior management shall draw up, implement and maintain a dialogue procedure between their organisation and Eurofins Food Assurance to communicate on any event/ change that may affect their ability to comply with the IP TRUST Programme requirements.

1.3 The senior management shall provide the necessary resources including equipment, buildings and workspace, workforce, financial and support services to meet the objectives of the IP TRUST Programme.

1.4 Competences and responsibilities, including deputation of responsibilities shall be clearly laid down for personnel identified as having authority for policy management and implementation of the IP TRUST Programme requirements. The main contact person shall show evidences of knowledge on the IP TRUST Programme.

1.5 All personnel performing work that affects the products shall have the required competences and shall be aware of their responsibilities. They shall be able to demonstrate their understanding and knowledge.

1.6 The senior management shall draw-up, implement and maintain an annual training programme on IP requirements and GMO legislation/ events for all the key personnel involved in the IP TRUST Programme to keep them knowledgeable and aware about the GMO context.

1.7 Any newcomer (including temporary personnel) shall be trained before they take charge of their duties. The training shall address the main objectives of the IP TRUST Programme, particularly: the cross-contamination risks, their impact and the related preventive and control measures.

1.8 All training/ instruction events shall be recorded (stating content, date, duration, location, trainer and participants) and such records shall be available.

1.9 Effectiveness of the training shall be verified. Refresher training shall regularly take place to ensure that personnel maintain required level of understanding and knowledge for the effective operation of the IP TRUST Programme.

1.10 The senior management shall ensure that the quality management system and risk assessment are reviewed at least annually or more frequently if significant changes occur. Such reviews shall include as a minimum:

- a review of objectives and policy concerning the IP TRUST Programme requirements

- supplier performance
- legislative, technical and industry developments relevant to the IP TRUST Programme and having an impact on the fulfilment of the IP TRUST Programme requirements
- results of audits
- complaints
- non-conformities and non-conforming products related to IP TRUST Programme requirements
- status of corrective actions.

Management review shall be documented.

2. Risk assessment

2.1 The company shall assemble a multidisciplinary team, including operational personnel and a relevant team leader, to draw-up, implement and maintain the risk assessment.

2.2 Each member of the team shall have specific knowledge of products, good handling practices and their associated cross-contamination risks and at least one person shall be knowledgeable about GMO risks and testing. Where internal expertise is not available, external expert advice shall be required.

2.3 A site flow diagram showing the operations and flows within the company shall be drawn-up and maintained for each product or product group and for all variations of the storage practices. It shall be dated and clearly identify each critical point and “hold and release point”, where applicable.

2.4 A supply chain flow diagram showing the responsibilities for the handling of products which are in the scope of the IP TRUST certificate and its attachment and/ or have an impact on the IP finished products shall be drawn-up and maintained (see Appendix 2). It shall specify facilities and type of products (raw materials, intermediate and finished products). It shall clearly identify each “hold and release” point.

2.5 KO N°1: A risk assessment for cross-contamination shall be drawn-up, implemented and maintained to control the likelihood of introducing a cross-contamination risk in the product and/ or the environment. It shall be based on HACCP principles or other appropriate risk assessment method.

2.6 The risk assessment shall take into consideration the whole supply chain covering all steps of previous and further handling, including storage, transport and outsourced processes.

2.7 The risk assessment shall take into account test results from the last twelve (12)-month period.

2.8 The determination of relevant critical points shall be facilitated by the application of a decision tree or other risk assessment tool(s).

2.9 The determination of relevant “hold and release” points shall be based on the supply chain flow diagram. Products at "hold and release” points shall be tested.

2.10 For each critical point, appropriate critical limits or parameters and values shall be defined, validated and implemented, according to current legislation and statistical studies based on test results, to clearly identify when the risk of jeopardising the IP integrity of the product is controlled and reduced to an acceptable level.

2.11 The critical points shall be controlled and monitored to detect any loss of control.

2.12 In the event that the monitoring of the critical points indicates that a particular critical point is not under control, adequate corrective actions shall be taken and recorded.

2.13 The risk assessment shall be reviewed at least annually and necessary changes shall be made in case of any modification made in the product, supply chain, the storage practices or in legislation (such as changes in approval/ release of GM varieties, in targeted threshold tolerance levels, suppliers, etc.) to prevent any threat on the IP integrity of the product.

2.14 A procedure for regulatory surveillance related to GMO risks in both countries of production and destination (labelling, new authorisations, tolerance threshold, crisis/ event, etc.) shall be drawn-up, implemented and maintained to ensure an up-to-date risk assessment.

3. Testing and sampling plan

3.1. Sampling

3.1.1 The company shall implement the relevant sampling plan required by the customers

3.2 Testing

3.2.1 The company shall implement the relevant testing programme required by the customers.

4. Quality management system

4.1 Quality manual and documentation management

4.1.1 Documents (procedures, records and any other document) related to the compliance with the IP requirements shall be drawn-up and maintained and shall be kept together, preferably in a physical and/ or electronic quality manual. They shall mention responsibility, be up to date and cover review and record keeping.

4.1.2 All documents shall be available in their latest version, clearly legible, unambiguous, comprehensive and dated if relevant. They shall be available in appropriate languages and sufficiently detailed to enable their correct application by appropriate personnel. For multi-site companies, it shall be ensured that all relevant documents are available and adapted to each site involved in the IP TRUST Programme.

4.1.3 All records shall be maintained for at least five (5) years.

4.2 Traceability

4.2.1 KO N°2: A traceability system shall be drawn-up, implemented and maintained taking into consideration every received and dispatched product. Those shall be identified and labelled at all stages along the supply chain to guarantee traceability, minimum one step back and one step forward (from received to dispatched products and vice versa).

4.2.2 A clear relation shall be established between batches/ lots and related GMO test results. In case several locations and stakeholders are involved, the responsibility to establish this relation is with the main stakeholder.

4.2.3 Quantities of IP products (inputs and outputs) shall be recorded, maintained and checked (running mass balance correlating inputs and outputs), to ensure that quantities/ volumes of IP products received are equal to volumes used/ sold.

4.2.4 The traceability system shall be reviewed and tested at least once a year and each time system/ product/ storage practices changes. The test shall verify upstream and downstream traceabilities. Test results shall be recorded and available for the audit.

4.3 Internal audit

4.3.1 Effective internal audits covering the IP requirements shall be conducted at least once per year. Frequency (when more often than annually) and scope shall be based on the risk assessment and documented.

4.3.2 The auditor shall be competent and independent from the audited department. Where internal expertise is not available, the company shall request an external auditor.

4.3.3 Internal audit results shall be communicated to responsible persons of concerned department and to the senior management.

4.3.4 Necessary corrective actions followed by a schedule for implementation and relevant responsibilities shall be defined and recorded, for the purpose of continuous improvement.

4.4 Management of non-conforming products and non-conformities

4.4.1 A procedure shall be drawn-up, implemented and maintained for the management of all non-conforming products and non-conformities: raw materials, semi-finished, finished products, rework, processing equipment and packaging materials. This shall include, as a minimum:

- defined responsibilities
- isolation/ quarantine
- cause analysis
- product identification
- decision for further use like release, rework, quarantine, disposal
- corrective actions
- specific measures for “hold and release” points to ensure that only compliant

products are stored and delivered.

4.4.2 In particular cases when test results show detection of GMO presence:

- Eurofins Food Assurance shall be informed immediately
- if the test result is above 0.6%, affected products shall be quarantined
- if the test result is positive but still below 0.6%, a root cause analysis shall be performed to ensure that the affected products will not trend to become non-compliant.

4.4.3 Products in quarantine shall not be released as IP products until the deviation within the risk assessment has been fully assessed and the product verified to meet the IP requirements in terms of GMO presence threshold.

4.5 Corrective actions

4.5.1 A procedure shall be drawn-up, implemented and maintained for the management, recording and review of the non-conformities to avoid recurrence by preventive actions and/ or corrective actions.

4.5.2 Corrective actions shall be recorded. Those records shall detail the relevant responsibility and schedule for implementation.

4.5.3 The effectiveness and performance of the implemented corrective actions shall be verified and such verification shall be documented.

4.6 Management of complaints

4.6.1 A procedure shall be drawn-up, implemented and maintained to manage the complaints from authorities and customers. The complaints shall be assessed by competent personnel, reviewed and recorded.

4.6.2 If necessary, appropriate actions shall be taken, recorded and monitored to avoid the recurrence of the non-conformities.

4.7 Management of incidents, product withdrawal/ recall

4.7.1 A procedure shall be drawn-up, implemented and maintained to manage incidents and potential emergency situations that could impact the IP integrity of the products. It shall mention:

- the name of the relevant personnel (crisis team)
- an alert contact list (authorities, customers, sites and people to be informed, etc.)
- withdrawal/ recall procedure
- consideration of the dialogue procedure with Eurofins Food Assurance

In case of product recall related to IP, the company shall inform Eurofins Food

Assurance within 3 working days maximum.

4.7.2 The feasibility, effectiveness and timeliness of implementation of withdrawal procedure shall be tested at least once a year, or more often based on risk assessment.

5. Good handling practices

5.1 General good handling practices

5.1.1 Based on the risk assessment, documented requirements for protective clothing and good practices to adopt in specific areas shall be drawn-up, implemented and maintained. They shall be communicated to all personnel, contractors and visitors entering the site.

5.1.2 Based on the risk assessment, inspection schedules or other methods shall be drawn-up, implemented and maintained to verify the effectiveness of the control measures implemented to ensure the IP integrity of the products.

5.2 Cleaning activities

5.2.1 KO N°3: Based on the risk assessment, cleaning and/ or flushing procedures and schedules shall be drawn-up, implemented and maintained to avoid any cross-contamination risk. These shall specify:

- **objectives**
- **tasks and responsibilities**
- **areas/ equipment/ containers concerned**
- **instructions, used equipment and cleaning product(s)**
- **frequency**
- **records thereof**

5.2.2 Personnel responsible for the cleaning/ flushing activities shall be trained.

5.2.3 The effectiveness of the cleaning/ flushing activities shall be verified on a regular basis, based on the risk assessment.

5.2.4 Cleaning/ flushing schedules shall be reviewed and modified in case of any changes in the product, storage practices, machinery or cleaning equipment.

5.2.5 If the company hires a third-party service provider for cleaning activities, all requirements specified above shall be clearly defined in the service contract.

5.2.6 Chemicals (used for cleaning, maintenance, within the product formulation, etc.) shall not be a source of GMO cross-contamination.

5.3 Segregation

5.3.1 A procedure shall be drawn-up, implemented and maintained to ensure the IP integrity of the products. It shall describe the measures aimed to avoid mixing of controlled products with uncontrolled materials and shall include, as a minimum:

- good storage practices
- dedicated storage
- labelling/ marking on packaging/ containers
- cleaning schedules
- flushing activities
- Risks based processing schedules
- Specific measures during packaging and labelling
- Dedicated transport

Segregation measures shall be applied to any IP material within the company.

5.3.2 The segregation measures shall be drawn-up, implemented, maintained and recorded at all time.

5.3.4 Effectiveness of the segregation measures shall be verified by testing.

5.4 Equipment

5.4.1 Equipment shall be suitably designed for intended use. It shall be checked that IP requirements are complied with.

5.5 Maintenance

5.5.1 Based on the risk assessment, an adequate system of maintenance shall be drawn-up, implemented and maintained covering all equipment to avoid any cross-contamination risk.

5.5.2 If the company hires a third-party service provider for maintenance, all relevant requirements shall be clearly defined in the service contract.

5.6 Storage

5.6.1 A procedure for storage management shall be drawn-up, implemented and maintained to ensure the segregation of Non-GM materials. This procedure shall take into account all seeds/ raw materials, rework, semi-finished and finished products at all steps of the processing including, intermediate storage.

5.6.2 Based on the risk assessment, cleaning activities and regular verification of their effectiveness, as well as other appropriate control measures, shall be drawn-up, implemented and maintained for any silo or storage facility. Appropriate measures shall be implemented for silos or facilities dedicated to the storage of non-GM

products. Refilling a silo or a storage facility which is not totally empty and without specific control measures is not allowed.

5.6.3 Storage records of each silo and/ or facility containing IP products shall be documented and provided with volume, lot number, name of supplier if relevant, cleaning activities, previously stored product as well as date and volume of removal for sale.

5.6.4 Storage silos and/ or facilities used for IP crops shall be visually identified to ensure awareness of all personnel working in this area.

5.6.5 If storage activities are managed by a third-party service provider, all good storage practices stated in this chapter shall be clearly defined in the service contract. Scope of internal audits shall include those activities to verify the effectiveness of their implementation.

E. AUDIT REQUIREMENTS FOR TRANSPORT PROVIDERS

1. Senior management: responsibilities and resources

1.1 The senior management shall draw up, sign, implement and maintain a corporate policy considering the objectives and requirements of the Eurofins IP TRUST Programme, especially the requirements related to the risk assessment, traceability, suppliers' evaluation and segregation methods. This corporate policy shall be communicated and understood by all employees.

1.2 The senior management shall draw up, implement and maintain a dialogue procedure between their organisation and Eurofins Food Assurance to communicate on any event/ change that may affect their ability to comply with the IP TRUST Programme requirements.

1.3 The senior management shall provide the necessary resources including equipment, buildings and workspace, workforce, financial and support services to meet the objectives of the IP TRUST Programme.

1.4 Competences and responsibilities, including deputation of responsibilities shall be clearly laid down for personnel identified as having authority for policy management and implementation of the IP TRUST Programme requirements. The main contact person shall show evidences of knowledge on the IP TRUST Programme.

1.5 All personnel performing work that affects the products shall have the required competences and shall be aware of their responsibilities. They shall be able to demonstrate their understanding and knowledge.

1.6 The senior management shall draw-up, implement and maintain an annual training programme on IP requirements and GMO legislation/ events for all the key personnel involved in the IP TRUST Programme to keep them knowledgeable and aware about the GMO context.

1.7 Any newcomer (including temporary personnel) shall be trained before they take charge of their duties. The training shall address the main objectives of the IP TRUST Programme, particularly: the cross-contamination risks, their impact and the related preventive and control measures.

1.8 All training/ instruction events shall be recorded (stating content, date, duration, location, trainer and participants) and such records shall be available.

1.9 Effectiveness of the training shall be verified. Refresher training shall regularly take place to ensure that personnel maintain required level of understanding and knowledge for the effective operation of the IP TRUST Programme.

1.10 The senior management shall ensure that the quality management system and risk assessment are reviewed at least annually or more frequently if significant changes occur. Such reviews shall include as a minimum:

- a review of objectives and policy concerning the IP TRUST Programme requirements

- supplier performance
- legislative, technical and industry developments relevant to the IP TRUST Programme and having an impact on the fulfilment of the IP TRUST Programme requirements
- results of audits
- complaints
- non-conformities and non-conforming products related to IP TRUST Programme requirements
- status of corrective actions.

Management review shall be documented.

2. Risk assessment

2.1 The company shall assemble a multidisciplinary team, including operational personnel and a relevant team leader, to draw-up, implement and maintain the risk assessment.

2.2 Each member of the team shall have specific knowledge of products, good handling practices and their associated cross-contamination risks and at least one person shall be knowledgeable about GMO risks and testing. Where internal expertise is not available, external expert advice shall be required.

2.3 A site flow diagram showing the operations and flows within the company shall be drawn-up and maintained for each product or product group and for all variations of the transport practices. It shall be dated and clearly identify each critical point and “hold and release point”, where applicable.

2.4 A supply chain flow diagram showing the responsibilities for the handling of products which are in the scope of the IP TRUST certificate and its attachment and/ or have an impact on the IP finished products shall be drawn-up and maintained (see Appendix 2). It shall specify facilities and type of products (raw materials, intermediate and finished products). It shall clearly identify each “hold and release” point.

2.5 KO N°1: A risk assessment for cross-contamination shall be drawn-up, implemented and maintained to control the likelihood of introducing a cross-contamination risk in the product and/ or the environment. It shall be based on HACCP principles or other appropriate risk assessment method.

2.6 The risk assessment shall take into consideration the whole supply chain covering all steps of previous and further handling, including storage, transport and outsourced processes.

2.7 The risk assessment shall take into account test results from the last twelve (12)-month period.

2.8 letermination of relevant critical points shall be facilitated by the application of a decision tree or other risk assessment tool(s).

2.9 The determination of relevant “hold and release” points shall be based on the supply

chain flow diagram. Products at "hold and release" points shall be tested.

2.10 For each critical point, appropriate critical limits or parameters and values shall be defined, validated and implemented, according to current legislation and statistical studies based on test results, to clearly identify when the risk of jeopardising the IP integrity of the product is controlled and reduced to an acceptable level.

2.11 The critical points shall be controlled and monitored to detect any loss of control.

2.12 In the event that the monitoring of the critical points indicates that a particular critical point is not under control, adequate corrective actions shall be taken and recorded.

2.13 The risk assessment shall be reviewed at least annually and necessary changes shall be made in case of any modification made in the product, supply chain, the transport practices or in legislation (such as changes in approval/ release of GM varieties, in targeted threshold tolerance levels, suppliers, etc.) to prevent any threat on the IP integrity of the product.

2.14 A procedure for regulatory surveillance related to GMO risks in both countries of production and destination (labelling, new authorisations, tolerance threshold, crisis/ event, etc.) shall be drawn-up, implemented and maintained to ensure an up-to-date risk assessment.

3. Testing and sampling plan

3.1. Sampling

3.1.1 The company shall implement the relevant sampling plan required by the customers

3.2 Testing

3.2.1 The company shall implement the relevant testing programme required by the customers

4. Quality management system

4.1 Quality manual and documentation management

4.1.1 Documents (procedures, records and any other document) related to the compliance with the IP requirements shall be drawn-up and maintained and shall be kept together, preferably in a physical and/ or electronic quality manual. They shall mention responsibility, be up to date and cover review and record keeping.

4.1.2 All documents shall be available in their latest version, clearly legible, unambiguous, comprehensive and dated if relevant. They shall be available in appropriate languages and sufficiently detailed to enable their correct application by appropriate personnel. For multi-site companies, it shall be ensured that all relevant documents are available and adapted to each site involved in the IP TRUST Programme.

4.1.3 All records shall be maintained for at least five (5) years.

4.2 Traceability

4.2.1 KO N°2: A traceability system shall be drawn-up, implemented and maintained taking into consideration every loaded and unloaded product. Those shall be identified and labelled at all stages along the supply chain to guarantee traceability, minimum one step back and one step forward (from loaded to unloaded products, and vice versa).

4.2.2 A clear relation shall be established between batches/ lots and related GMO test results. In case several locations and stakeholders are involved, the responsibility to establish this relation is with the main stakeholder.

4.2.3 Quantities of IP products (inputs and outputs) shall be recorded, maintained and checked (running mass balance correlating inputs and outputs), to ensure that quantities/ volumes of IP products received are equal to volumes used/ sold.

4.2.4 The traceability system shall be reviewed and tested at least once a year and each time system/ product/ transport practices changes. The test shall verify upstream and downstream traceabilities. Test results shall be recorded and available for the audit.

4.3 Internal audit

4.3.1 Effective internal audits covering the IP requirements shall be conducted at least once per year. Frequency (when more often than annually) and scope shall be based on the risk assessment and documented.

4.3.2 The auditor shall be competent and independent from the audited department. Where internal expertise is not available, the company shall request an external auditor.

4.3.3 Internal audit results shall be communicated to responsible persons of concerned department and to the senior management.

4.3.4 Necessary corrective actions followed by a schedule for implementation and relevant responsibilities shall be defined and recorded, for the purpose of continuous improvement.

4.4 Management of non-conforming products and non-conformities

4.4.1 A procedure shall be drawn-up, implemented and maintained for the management of all non-conforming products and non-conformities: raw materials, semi-finished, finished products, rework, processing equipment and packaging materials. This shall include, as a minimum:

- defined responsibilities
- isolation/ quarantine
- cause analysis
- product identification
- decision for further use like release, rework, quarantine, disposal
- corrective actions
- specific measures for “hold and release” points to ensure that only compliant

products are transported and delivered

4.4.2 In particular cases when test results show detection of GMO presence:

- Eurofins Food Assurance shall be informed immediately
- if the test result is above 0.6%, affected products shall be quarantined
- if the test result is positive but still below 0.6%, a root cause analysis shall be performed to ensure that the affected products will not trend to become non-compliant.

4.4.3 Products in quarantine shall not be released as IP products until the deviation within the risk assessment has been fully assessed and the product verified to meet the IP requirements in terms of GMO presence threshold.

4.5 Corrective actions

4.5.1 A procedure shall be drawn-up, implemented and maintained for the management, recording and review of the non-conformities to avoid recurrence by preventive actions and/ or corrective actions.

4.5.2 Corrective actions shall be recorded. Those records shall detail the relevant responsibility and schedule for implementation.

4.5.3 The effectiveness and performance of the implemented corrective actions shall be verified and such verification shall be documented.

4.6 Management of complaints

4.6.1 A procedure shall be drawn-up, implemented and maintained to manage the complaints from authorities and customers. The complaints shall be assessed by competent personnel, reviewed and recorded.

4.6.2 If necessary, appropriate actions shall be taken, recorded and monitored to avoid the recurrence of the non-conformities.

4.7 Management of incidents, product withdrawal/ recall

4.7.1 A procedure shall be drawn-up, implemented and maintained to manage incidents and potential emergency situations that could impact the IP integrity of the products. It shall mention:

- the name of the relevant personnel (crisis team)
- an alert contact list (authorities, customers, sites and people to be informed, etc.)
- withdrawal/ recall procedure
- consideration of the dialogue procedure with Eurofins Food Assurance

In case of product recall related to IP, the company shall inform Eurofins Food

Assurance within 3 working days maximum.

4.7.2 The feasibility, effectiveness and timeliness of implementation of withdrawal procedure shall be tested at least once a year, or more often based on risk assessment.

5. Good handling practices

5.1 General good handling practices

5.1.1 Based on the risk assessment, documented requirements for protective clothing and good practices to adopt in specific areas shall be drawn-up, implemented and maintained. They shall be communicated to all personnel, contractors and visitors entering the site.

5.1.2 Based on the risk assessment, inspection schedules or other methods shall be drawn-up, implemented and maintained to verify the effectiveness of the control measures implemented to ensure the IP integrity of the products.

5.2 Cleaning activities

5.2.1 KO N°3: Based on the risk assessment, cleaning and/ or flushing procedures and schedules shall be drawn-up, implemented and maintained to avoid any cross-contamination risk. These shall specify:

- **objectives**
- **tasks and responsibilities**
- **areas/ equipment/ containers concerned**
- **instructions, used equipment and cleaning product(s)**
- **frequency**
- **records thereof**

5.2.2 Personnel responsible for the cleaning/ flushing activities shall be trained.

5.2.3 The effectiveness of the cleaning/ flushing activities shall be verified on a regular basis, based on the risk assessment.

5.2.4 Cleaning/ flushing schedules shall be reviewed and modified in case of any changes in the product, transport practices, machinery or cleaning equipment.

5.2.5 If the company hires a third-party service provider for cleaning activities, all requirements specified above shall be clearly defined in the service contract.

5.2.6 Chemicals (used for cleaning, maintenance, within the product formulation, etc.) shall not be a source of GMO cross-contamination.

5.3 Segregation

5.3.1 A procedure shall be drawn-up, implemented and maintained to ensure the IP integrity of the products. It shall describe the measures aimed to avoid mixing of controlled products with uncontrolled materials and shall include, as a minimum:

- good transport practices
- dedicated transport
- labelling/ marking on packaging/ containers
- cleaning schedules
- flushing activities
- risks based processing schedules
- specific measures during packaging and labelling
- dedicated storage.

Segregation measures shall be applied to any IP material within the company

5.3.2 The segregation measures shall be drawn-up, implemented, maintained and recorded at all time.

5.3.3 Effectiveness of the segregation measures shall be verified by testing.

5.4 Equipment

5.4.1 Equipment shall be suitably designed for intended use. It shall be checked that IP requirements are complied with.

5.5 Maintenance

5.5.1 Based on the risk assessment, an adequate system of maintenance shall be drawn-up, implemented and maintained covering all equipment to avoid any cross-contamination risk.

5.5.2 If the company hires a third-party service provider for maintenance, all relevant requirements shall be clearly defined in the service contract.

5.6 Transport and loading/ unloading

5.6.1 A procedure for transport management shall be drawn-up, implemented and maintained to ensure the segregation of Non-GM materials during transport. Any transport activity along the supply chain shall be controlled to ensure that all materials sent from one stakeholder of the supply chain to another and all commodities transported for direct sales (without processing) which are under the responsibility of the certified company and have an impact on the IP finished products comply with the

IP requirements and GMO legislation.

5.6.2 A procedure for approval and monitoring of transporters (external and internal) shall be drawn-up, implemented and maintained. It shall contain clear assessment criteria such as: audits, certificates, tests, transporter reliability and complaints.

5.6.3 A list of all approved transporters shall be drawn-up, implemented and maintained.

5.6.4 Loading/ unloading practices shall be drawn-up, implemented and maintained to avoid any cross-contamination risk.

5.6.5 Based on the risk assessment, cleaning and flushing activities, as well as other appropriate control measures, shall be drawn-up, implemented and maintained for facilities intended to load/ unload and transport the products. Records of achievement of these activities shall be verified before loading/ unloading to ensure that the facilities are free from GM materials.

5.6.6 Specific practices shall be drawn-up, implemented and maintained to ensure that loading/ unloading activities are carried out from/ discharged into correct silos.

5.6.7 If transport activities are managed by a third-party service provider, all good transport practices stated in this chapter shall be clearly defined in the service contract. Scope of internal audits shall include those activities to verify the effectiveness of their implementation.

APPENDIX 1: LIST OF GM RISKY INPUTS

This list of GM risky inputs is provided with the IP TRUST Programme for the purpose of reference only and includes those plant species:

- having commercial planting, or
- not having commercial planting, but being present by accidental release, or
- not having commercial planting, but with risks of GMO inputs by botanical impurities.

As this list may evolve quickly, the responsibility to ensure that relevant and up-to-date risky inputs are addressed within the risk assessment remains at the audited company.

Species	
Alfalfa	Plum
Apple	Poplar
Canola (rapeseed)	Potato
Carnation	Rice
Chicory	Salmon
Corn (maize)	Soybean
Cotton	Squash
Creeping bent grass	Sunflower
Eggplant	Sugar beet
Linseed (flax)	Sugar cane
Mustard	Sweet pepper
Papaya	Tobacco
Petunia	Tomato
Pineapple	

APPENDIX 2: SUPPLY CHAIN FLOW DIAGRAM

To identify the different stakeholders involved in the supply chain and the steps followed to obtain the products, the applicant shall draw a supply chain flow diagram.

The supply chain flow diagram shall address the following elements:

- The status of the different stakeholders: production site, production centre and/ or processing site.
- The identification of the site which is the main stakeholder (i.e. the headquarters or the site which is responsible for managing and controlling the other stakeholders of the supply chain).
- The different steps under the responsibilities of the audited site/ company along the supply chain (e.g. transport, processing, storage, etc.).
- The “hold and release” points, to enlighten where controls (by PCR tests) need to be performed before the product can go to the next step.
- The different steps followed to obtain the finished products: from seeds to crops, from raw materials to finished products as well as the transfer of intermediate products if relevant.

Through this supply chain flow diagram, any reader shall be able to identify the responsibilities, especially those concerning transport, storage and management of the IP system.

Example 1: supply chain flow diagram for a processing company applying for **IP TRUST Site Programme** (note that this example is simplified for the purpose of the example and actual supply chain flow diagram may be more complex, taking into account the various raw materials, suppliers, processes, etc.):

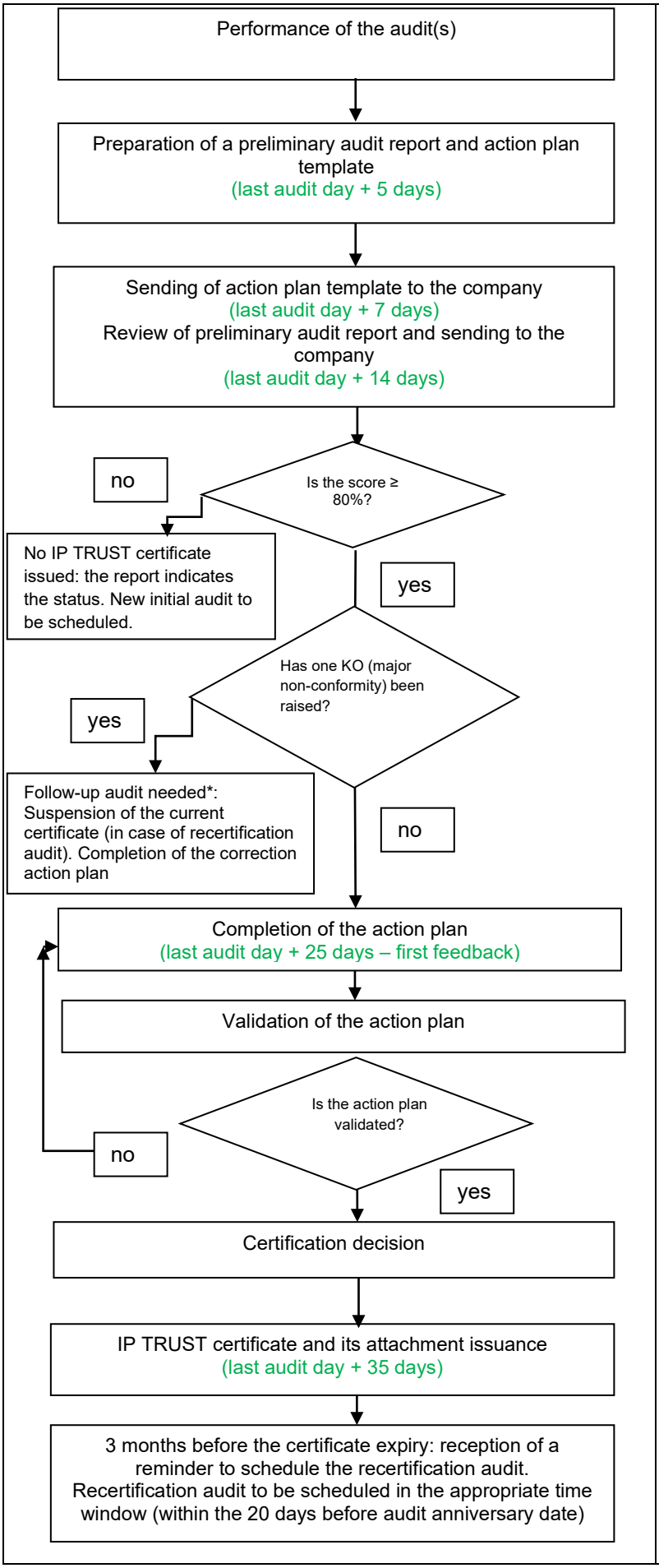
Step	Responsible	Comments/ actions (from the company applicant)
Growing or processing of the raw material	**Supplier 1** in the Country A **Supplier 2** in the country B	- Product specifications - Suppliers approval and monitoring
Transport by road by Supplier 1 Transport by boat, then by road by Supplier 2	**Supplier 1** **Supplier 2**	- Product specifications - Suppliers approval and monitoring
Processing site: reception of raw material (detailed description of the different steps, including, where relevant, intermediate storage)	**Company (applicant)**	**Hold and release point:** - If sampling and testing is possible: negative PCR result - If sampling and testing is not possible (e.g. if the material is too refined to perform a PCR analysis): evidence to prove the IP identity of the material **If OK, go to next step**
Processing site: storage	**Company (applicant)**	Good storage practices (including cleaning and segregation)
Processing site: processing	**Company (applicant)**	Good manufacturing practices (including cleaning, segregation and traceability)
Processing site Storage area for product dispatch **Service provider** Transport to off-site storage area Storage area (off-site) for product dispatch	**Company (applicant)** **Or** **Service provider**	**Hold and release point:** - If sampling and testing is possible: negative PCR result - If sampling and testing is not possible (e.g. if the material is too refined to perform a PCR analysis): evidence to prove the IP identity of the material - Contracts with service providers **If OK, go to next step**
Dispatch to customer	**Company (applicant)**	

Example 2: supply chain flow diagram for a company applying for **IP TRUST Supply-chain Programme,** from seeds to finished products (note that this example is simplified for the purpose of the example and actual supply chain flow diagram may be more complex, taking into account the complexity of the supply chain):

Step	Responsible	Comments/ actions (from the company applicant)
Supplier of seeds	**Supplier**	- Product specifications - Suppliers approval and monitoring **Hold and release point:** **If negative PCR result, go to next step**
Production site 1 Planting Growing Harvesting Storage **Production site 2** Planting Growing Harvesting Storage	**Company (applicant)**	- Specifications on good planting, growing, harvesting and storage practices (including cleaning, segregation and traceability)
Service provider Transport by road **Service provider** Transport by road	**Company (applicant)**	- Contracts with service providers
Processing site: reception of raw material	**Company (applicant)**	- Checks at receipt **Hold and release point:** **If negative PCR result, go to next step**
Processing site: storage	**Company (applicant)**	- Good storage practices (including cleaning and segregation)
Processing site: processing (detailed description of the different steps, including, where relevant, intermediate storage)	**Company (applicant)**	- Good manufacturing practices (including cleaning, segregation and traceability)
Processing site: storage area (on site) for product dispatch	**Company (applicant)**	**Hold and release point:** - If sampling and testing is possible: negative PCR result - If sampling and testing is not possible (e.g. if the material is too refined to perform a PCR analysis): evidence to prove the IP identity of the material
Dispatch to customer	**Company (applicant)**	

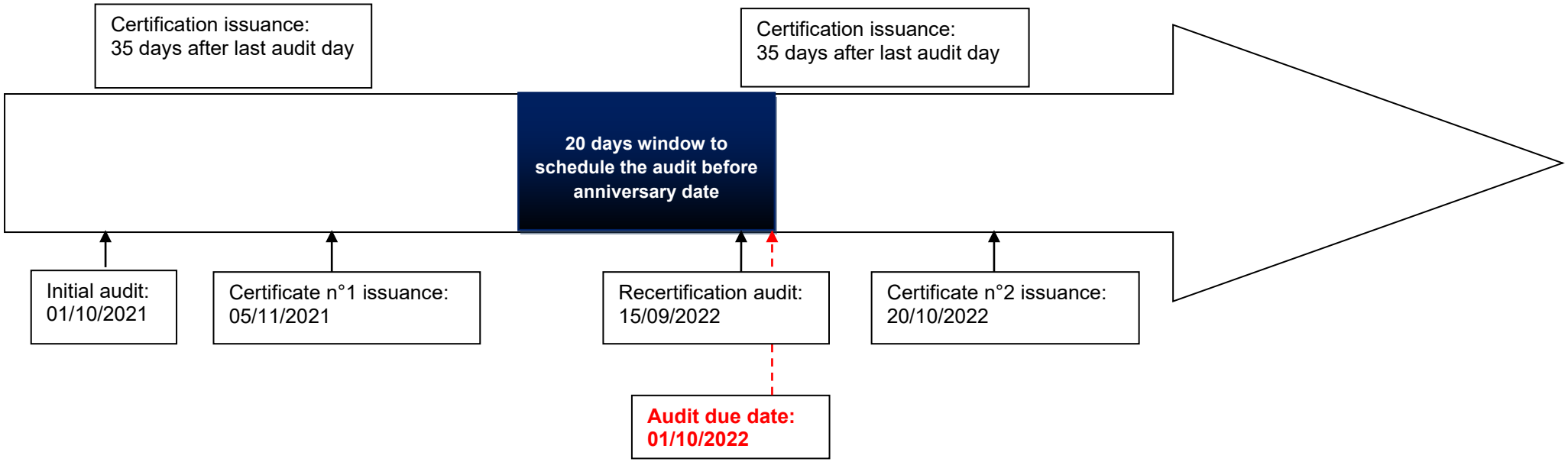
APPENDIX 3: IP TRUST PROGRAMME CERTIFICATION PROCESS

Step	Responsible	Comments/ actions
Decision to apply for an IP certification	Company (applicant)	
Contact with Eurofins Food Assurance (certification entity) or the local approved office to get the IP TRUST Programme	Company (applicant)	
Self-assessment of the current status of compliance of the company against the IP TRUST Programme requirements.	Company (applicant)	Where relevant, implementation of the necessary measures/ procedures to comply with the IP TRUST Programme (implemented at latest 2 months before the certification audit)
Does the company apply for an IP TRUST Supply-chain Programme? (no / yes)		
Contact with the different companies involved in the supply chain and definition of responsibilities	Company (applicant)	
Appointment of a main contact person (for the IP certification procedure within the organisation and for contacts with Eurofins Food Assurance)	Company (applicant)	
Definition of the certification scope with Eurofins Food Assurance and sending of testing programme, for preliminary review	Company (applicant)	
Submission of a quotation and contract	Eurofins Food Assurance	
Optional: realisation of a pre-audit	Company/ Eurofins Food assurance and/ or auditor	
Scheduling of the audit (8 weeks before the audit date)	Company/ Eurofins Food assurance and/ or auditor	
Sending of the audit schedule (about 2 weeks before the audit date)	Auditor	



Auditor	In all sites included in the audit scope: opening meeting, documentation evaluation, on-site assessment including interviews with employees, preparation of the audit conclusion and closing meeting
Auditor	
Eurofins Food Assurance	
	* Completion of the correction action plan by the company, for the auditor to check if the KO (major non-conformity) is solved. Then, validation of the action plan by Eurofins Food Assurance. If the KO is solved: certification decision made by Eurofins Food Assurance
Company	if the company does not send the completed action plan in due time (i.e. between 25 and 35 days after last audit day), some measures (initial audit to be carried out and withdrawal of the certificate in case of recertification audit) can be taken by Eurofins Food Assurance.
Eurofins Food Assurance and/ or auditor	
Eurofins Food Assurance	Relevance of the corrective actions and deadlines for implementation
Eurofins Food Assurance	
Company	

APPENDIX 4: CERTIFICATION CYCLE



Year 1:
Certificate n°1 issuance date: 05/11/2021
Certificate n°1 expiry date: 05/11/2022
Re-certification audit time window: from 11/09 to 01/10/2022

Year 2:
Certificate n°2 issuance date: 20/10/2022
Certificate n°2 start of validity date: 05/11/2022
Certificate n°2 expiry date: 05/11/2023
Re-certification audit time window: from 11/09 to 01/10/2023

APPENDIX 5: DEFINITIONS

Term	Definition
Annually	Every 12 months. Any postponement shall be justified, risk based, and documented.
Applicant	Main stakeholder who asks for the IP certification.
Audit	Systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit requirements are fulfilled.
Auditee	Applicant under the process of being audited.
Auditor	Qualified person who conducts the audit.
Audit requirements/ criteria	Set of policies, procedures and requirements used as a reference against which objective evidence is compared during the audit.
Broker	Applicant who sells products but does not physically handle them. They work with service providers for transport, storage, etc. They can manage some steps of the supply chain such as seeds selection, suppliers and/ or processors monitoring.
Commodities	Manufactured goods or raw materials that are virtually handled by the organisation (applicable for a broker).
Conformity/ compliance	Fulfilment of the requirements/ policies/ procedures.
Conventional products	Products processed without the help of genetic modification and for which there is a well-established history of safe use.
Corrective action	Action to eliminate the cause of a non-conformity and to prevent recurrence.
Corrective action plan	Plan sent by Eurofins Food Assurance to address the non-conformities and to be completed by the auditee with appropriate corrective actions.
Critical point	Identified by the risk assessment as essential to control the likelihood of introducing a cross-contamination risk in the product and/ or environment. A control shall be implemented at this step to prevent/ eliminate/ reduce to an acceptable level any risk of jeopardising the IP integrity of the product. Critical points may cover “hold and release” points.
Cross contamination	Crossing over of genetically modified genes into Non-GM plants. This contamination can occur at any stage of the supply chain.
Evidence	Records, statements of fact or other information which are relevant to the audit requirement/ criteria and verifiable.
Farmer	Worker responsible for the farming of the crops (planting, growing, harvesting, etc.). They depend on the production site (main farm).

Flow diagram	Systematic representation of the sequence of steps, operations and actors that the product(s) follow(s). In the IP TRUST Programme, deux (2) flow diagrams are required: - The supply chain flow diagram, showing the responsibilities of the audited site/ company along the supply chain and an overall vision of inputs and outputs which lead to the products within the scope of the certification. - The site flow diagram, showing the detailed operations and flows within the site.
Flushing	Measure of segregation to avoid the cross-contamination risk. In practice, a defined quantity of Non-GM products (defined according to test results and the risk assessment) shall be processed to eliminate the residues of GM products in the flow before starting the Non-GMO production. The quantity used as flushing material is identified as GM products.
GM	Genetically Modified. Term used for any material in which the genetic material has been modified otherwise than by natural multiplication or natural recombination.
GMO	Genetically Modified Organism. Organism in which the genetic material has been modified otherwise than by natural multiplication or natural recombination.
Hold and release point	Point/ step where product testing (by PCR test) shall be implemented before the product can go to the next step, to prevent/ eliminate/ reduce to an acceptable level any risk of jeopardising the IP integrity of the product. Hold and release points are identified by the risk assessment and contribute to control the likelihood of introducing a cross-contamination risk in the product and/ or environment.
Identity Preserved (IP)	Depending on the context where they're used, these terms have the two (2) following meanings: - Product which has a defined origin or purity characteristic (here absence of GMOs) which needs to be retained throughout the supply chain (e.g. through traceability and segregation measures to avoid cross-contamination). - Tracking system of crop and processing management that preserves the identity of the source or nature of the materials along a supply chain. Here, this system shall be implemented according to the general objectives of the Eurofins IP TRUST Programme.
Internal audit	Audit conducted by or on behalf of the auditee for internal purposes. It helps the organisation to accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk assessment, control and processes. This concept is included in the continuous improvement.
KO	Major non-conformity, which corresponds to a failure to comply with one of the pre-defined critical KO requirements (see details in §6. *Evaluation of audit requirements*).
Non-conformity	Non-fulfilment of an audit requirement. This non-fulfilment is assessed is scored by the auditor. In this Programme: - Minor non-conformities are related to B, C or D scoring of "regular" audit requirements and to C scoring of KO requirements. - Major non-conformities are related to the non-compliance of KO requirements (=KO, D scoring of KO requirements).
Positive test result	Test result showing detected presence of GMO.

Procedure	Specified way to carry out an activity or a process. Procedures shall be implemented and documented by documents or process descriptions.
Processing site	Organisation responsible for undertaking the activities of manufacturing of the supplied products to process intermediate or finished products. In the Programme, the term “manufacturing” is used equivalently as “processing”.
Production site	Main farm where all the products are stored and handled (first step of the transformation like washing, etc.) before sending to the processing site(s). They can be a company collecting all the crops at the end of the harvesting season from many small farmers. In that case, they are responsible for managing them.
Record	Document stating results achieved or providing evidence of activities performed.
Regulation (EC) n°1829/ 2003	Regulation of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.
Regulation (EC) n°1830/ 2003	Regulation of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/ 18/ EC.
Review	Determination of the suitability, adequacy or effectiveness of an object to achieve established objectives.
Rework	Reused products (e.g. returned materials/ non-conforming products) which are suitable for reprocessing (e.g. pellet fines, screenings, etc.).
Risk	A function or the probability of an adventitious presence and the severity of that effect consequential to a hazard in the product.
Risk assessment	Process of risk identification, risk analysis and risk evaluation (e.g. risk of cross-contamination) to determine control measures to preserve the IP integrity.
Scope	Range of activities and products which are the focus of the audit.
Segregation	Measure(s) to avoid the cross-contamination according to the risk assessment. It often consists in a separation between two kinds of products (for IP TRUST Programme: separation of GM from Non-GM production).
Service provider	Company that provides another organisation with activities such as transport, storage, processing, etc.
Traceability	Ability to trace and follow a raw material or a product through all stages of production, processing and distribution. It can be upstream or downstream traceability.
Volunteer crop	crop that grows on his own rather than being deliberately planted by a farmer.

The IP TRUST Programme is a Eurofins Food Assurance Programme

Email: iptrust@eurofins.com

English is the original and official language of this programme.

For more information about Eurofins Food Assurance certification entity, please contact:

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