ANNEX 1

IDENTITY PRESERVATION SYSTEM MANUAL

BASF Plant Science

Genetically Modified Starch Potato Program

Identity Preservation System Manual

BASF Plant Science	IDENTITY PRESERVATION SYSTEM	
Title: Document Control Procedure	Original Issue Date: 21.05.03	Rev. Date:
		Approved By:

NOTATION

All **BASF** Identity Preservation System documents, including system elements, standard operating practices and work instruction, documentation procedures and forms, and training materials will be maintained on a dedicated web site. The IP system administrator will manage this site. All of the aforementioned documents will be in Portable Document Format (PDF) to provide document and data security. Also, any change(s) made to IP System contents will be made available immediately via the Internet to all participants. IP System participants will be notified of changes by one of the following methods: email, fax, post, or telephone.

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Approved: _____ Date: _____
BASF IP System Administrator

0.2 Purpose and Scope

0.2.1 General

The purpose of the Identity Preservation System Manual is to document the Identity Preservation System implemented by BASF Plant Science (hereinafter referred to as "BASF") to assure the quality of the subject product through a system of tracking and records.

0.2.2 Application

The scope of the Identity Preservation System Manual includes only the activities and materials of BASF's genetically modified starch potato production program and will be implemented for commercial production upon regulatory approval. This Identity Preservation System Manual currently applies to the production and handling of BASF's plant-based biotechnology products and related services.

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Section Title

0.3 Terms and Definitions

0.3.10 BASF – means BASF Plant Science or appointed representative.

0.3.11 (Reserved)

0.3.12 Design – The process of translating requirements into quantifiable and measurable specifications which, when achieved, assure the output will meet those requirements.

0.3.13 Design Change – A formal revision to specifications/configurations requiring review and approval by responsible function(s).

0.3.14 Design Verification – The process of proving design by testing.

0.3.15 Document – To write requirements prior to an event; or a drawing, specification, procedure, etc., which contains written requirements.

0.3.16 Grower – IP System participant.

0.3.17 Genetically modified Starch Potato – product derived from plant-based biotechnology.

0.3.18 Finding – Objective evidence that a system/product requirement or specification is missing or is not being implemented with complete reliability.

0.3.19 Label – All written, printed or graphic matter:
a) on a product or any of its containers or wrappers; or
b) accompanying a product; relating to identification, technical description and use of the product but excluding shipping documents.

0.3.20 Labeling – The process of combining labels with products.

0.3.21 Measuring Device – Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for the purpose of:
a) detection, prevention, monitoring, or treatment of grain;
b) investigation, replacement or modification of grain shipment or of a physiological process;
c) control of containment.

0.3.22 Nonconformance – A deficiency of a characteristic or a failure to adhere to documented procedures, which may render the quality of a product or service unacceptable or indeterminate.

0.3.23 Observation – Objective evidence that a system/product requirement or specification is not being implemented with complete reliability, but is not repetitive or missing. An observation may also include an audit element, which is not contrary to documented requirements, but warrants further qualification or improvement.

0.3.24 Participant Certification/Qualification **–** A written record declaring the IP System participant's adequate knowledge of and compliance with a process to a designated IP System requirement.

0.3.25 Procedure – A document that describes specifically how an activity is to be performed. It may include methods to be used, equipment to be used and sequence of operations.

0.3.26 Process – A set of interrelated resources and activities, which transforms inputs into outputs.

0.3.27 Process Control – Operational procedures designed to monitor a process with built in feedback and adjustment steps required to maintain the outcome (product or service) in conformance with requirements.

0.3.28 Product – The physical good or service that is the output of a process.

0.3.29 Qualified Auditor – An individual trained and experienced in designated audit procedures who is independent of the system or activity to be audited.

0.3.30 Quality – The totality of characteristics of a product or service that bear on its ability to satisfy stated and implied requirements or needs.

0.3.31 Quality Assurance – The activity of providing the evidence needed to establish confidence among all concerned that the quality function is being effectively performed. Dynamic planned quality systems designed with emphasis on prevention. Quality Assurance depends on tangible evidence of adequacy of such characteristics as capability, availability, reliability, operability, maintainability, durability, safety and cost.

0.3.32 Identity Preservation System Manual – An approved quality manual that describes the methods and controls for conformance of the products and services provided.

0.3.33 Quality Characteristics – Features of a product which effect performance.

0.3.34 Quality Control – Inspection, test or examination techniques used to ensure that materials, products or services conform to specified requirements.

0.3.35 Quality Plan – Specifies requirements for the quality control, documentation and traceability for a product or group of products.

0.3.36 Quality System – The organizational structure, responsibilities, procedures, processes and resources necessary to effectively manage the quality function.

0.3.37 Record – Retrievable information / data.

0.3.38 Reliability – The probability that a product or service will perform a required function under stated conditions for a given period of time.

0.3.39 Repair – An activity involving disassembly, re-assembly and testing of equipment with or without the replacement of parts.

0.3.40 Requirement – All stated and implied criteria, which must be met to satisfy market demands.

0.3.41 Review – An examination to evaluate conformance, which shall be indicated by signature, initials, seals, stamps, etc.

0.3.42 Reserved.

0.3.43 Reserved.

0.3.44 Reserved.

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Section Title

1.0 Identity Preservation System Requirements

1.1 General Requirements

BASF has implemented an Identity Preservation System (hereinafter referred to as "IP System") that is continuously maintained for effectiveness and process improvements.

1.2 Documentation Requirements

1.2.1 Documentation Levels

The IP System Documentation consists of five levels; the Company Policy (level one), the Identity Preservation System Manual (level two), Standard Operating Procedures (level three), Work Instructions (level four) and Records (level five). Supplemental to these documents are the Protocol Posting and Compliance Plans and Master Lists.

LEVEL I Company Policy – A documented Policy Statement.

LEVEL II Identity Preservation System Manual – The Identity Preservation System Manual establishes requirements and guidelines for the overall Identity Preservation System objectives. These requirements and guidelines are applicable to the operations at BASF, and limited to its genetically modified starch potato IP System and related services.

LEVEL III Standard Operating Procedures – The Standard Operating Procedures (SOP's), document conformance with, and support of the Quality Policies Manual's requirements and guidelines. The Standard Operating Procedures detail the implementation of requirements and guidelines for the operation.

LEVEL IV Work Instructions – Work Instructions are documented as necessary to support each applicable Standard Operating Procedure. They detail specific quality or inspection information and specific instructions for performance of individual tasks.

LEVEL V Records – Completed Forms provide the objective evidence of compliance.

1.2.2 IP System Manual

BASF management delegates the responsibility for the preparation, distribution and the maintenance of the IP Manual to the IP System administrator, or designated alternates.

The IP System Administrator is responsible for the communication and training required by the most recent revisions of the IP System Manual.

Initial Review and Approval – The IP System administrator approves the IP System Manual. BASF management approves the Quality Policy.

Review and Approval of Revisions – Revisions to the IP System Manual are subject to the same review and approval process as the original.

Revisions are subject to the following:
a) Manual revisions are controlled by page and only revised pages of a section have a revision level, (i.e. Rev.: 2R).
b) Revision levels are assigned in numeric order, starting with "1" for the original issue and

increasing by one with each revision.
c) Section: 0.1, (Index) is also revised to incorporate identification of the changed section/page and to document the revision status of the manual.

Change Identification – Where practical, revision to sections is indicated by using an *italic font.* If changes are extensive, the section is rewritten completely and designated by the addition of an "R" to the revision number on the page and in the index, (i.e. *2R*). Grammatical changes are not designated.

Record of Changes – The IP System administrator maintains a history of revisions and a file of superceded documents.

Manuals, SOPs, and training documents are controlled via a dedicated web site. IP System participants have permissioned access to the "official" IP System Manual, along with other "official" documents and materials necessary to perform their respective roles and responsibilities. IP System Manual and other reference materials may be downloaded as hard copies; however, they are considered to be "reference" documents for the sole purpose of assisting system participants in the proper execution of their daily duties, and therefore must be properly maintained with most current versions of "official" documents.

1.2.3 Control of Documents

BASF establishes, implements and maintains documented procedures to control all documentation and data that relate to IP System requirements.

It is the responsibility of the IP System administrator, and the assigned holders of IP System documents, to properly maintain IP System documentation.

Documents and data are reviewed and approved for adequacy by the IP System administrator and appointed IP System participants as per the documented procedures. These controls ensure that:

a) All documents, instructions and procedures are adequate for their intended purpose.
b) Correct documents, instructions and procedures are available at effected work locations and/or accessible to appropriate personnel.
c) Obsolete documents are promptly removed from the dedicated web site.
d) Revision levels of documents can be readily identified.

Document Revisions are subject to:

a) Approval – Revisions to documents are reviewed and approved by the same approval process and/or authority as the original.
b) Revision Identification – Revised documents reflect the nature of revisions, where practical.
c) Record of Revisions – Records of revisions is maintained by the issuing function where appropriate.

1.2.4 Control of Records

BASF establishes, implements and maintains documented procedures for the identification, collection, indexing, filing, storage, maintenance and disposition of quality records.

The IP System administrator is responsible for the Control of Quality Records.

Designated IP System participants are also responsible for documentation, accumulation and maintenance of quality records.

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Section Title

2.0 Management Responsibility

2.1 Management Commitment

BASF has implemented an IP System that is continuously maintained for effectiveness and process improvements in accordance with applicable statutory or regulatory requirements.

2.2 IP System Focus

BASF establishes, implements and maintains documented procedures for contract review and for the coordination of related activities.

It is the responsibility of the IP System administrator, or designated alternates, to review all IP System requirements.

Any changes or amendments to the contract are reviewed according to the procedures established by applicable standard operating procedure(s).

2.3 Identity Preservation Policy

BASF defines and documents its Identity Preservation Policy, which provides the overall objectives for its IP System.

BASF's IP System Policy states:

BASF, a leading life sciences company seeking to discover value opportunities through plant biotechnology, exercises considerable care in the creation and delivery of its resulting products. BASF's IP System will be the quality system used to satisfy requirements related to approval for commercial production of products derived from biotechnology. BASF's IP System will assure the quality of the subject product through a system of training for participants, tracking of relevant activities, and records management in order to maintain the value of its unique products.

Approved: _____ Date: _____
[Insert Appropriate Title]

BASF Plant Science management, employees, and IP System participants are committed to assuring that this policy is implemented, understood and maintained at all levels of the organization.

2.4 Planning

2.4.1 Quality Objectives

The IP System administrator is responsible for identifying and implementing the processes; equipment and controls (including test equipment) needed to achieve the stated quality objectives.

It is the responsibility of BASF management to ensure the compatibility of all IP System components with the stated quality policy.

The IP System administrator, or designee, is responsible for validating Quality Assurance inspection and testing techniques, including the development of new techniques.

It is the responsibility of the IP administrator to identify any measurement requirement(s) involving capabilities that exceed current industry technology, in sufficient time for development.

The IP administrator is responsible for the identification of suitable verification at appropriate stages in the realization of product.

The IP System administrator is responsible for the clarification of standards of acceptability for all features and requirements, including those that contain a subjective element.

2.4.2 Identity Preservation System Planning

BASF management reviews the appropriate resource requirements for planning, provides adequate resources and assigns trained personnel to execute all functions of the IP System.

Organizational Changes – As organizational changes are implemented and responsibilities are defined (or newly created), it is the responsibility of the [insert appropriate title] to assure the timely revision of associated documentation and the proper training of associated personnel.

2.5 Responsibility, Authority and Communication

2.5.1 Responsibility and Authority

BASF management is responsible for the review of the appropriate resource requirements, providing adequate resources and assigning trained personnel to communicate and execute all functions of the IP System. (See the “Responsibility/Tasks List.”)

2.5.2 Management Representatives

BASF’s IP administrator is the Management Representative and is responsible for reporting the progress and implementation of the provisions outlined in the IP System Manual.

The Management Representative is responsible for assuring that the IP System is implemented at all levels. The Management Representative is a member of the management team with the necessary authority required to accomplish implementation. The Management Representative, or designated alternates, also acts as the liaison for third party auditors.

2.5.3 Internal Communication

BASF management ensures that appropriate communication processes are established. Thus, an IP System meeting is conducted on a regular basis to assure the effectiveness of the IP System.

2.6 Management Review

2.6.1 General

An appointed member of management, the IP System administrator, along with genetically modified starch potato project staff, conduct a Management Review of the IP System annually, (at a minimum), to assess it's continued suitability, effectiveness and future direction.

Records of Management Reviews – The IP System administrator records a summary, (minutes), of each management review.

2.6.2 Review Input

Management Review Process Inputs – BASF management, the IP System administrator, and designated genetically modified starch potato project staff review all appropriate IP System documentation.

2.6.3 Review Output

Management Review Process Outputs – BASF management, the IP System administrator, and designated genetically modified starch potato project staff provide an official outline of the IP System objectives as a result of the Management Review.

3.0 Resource Management

3.1 Provision of Resources

BASF management is responsible for determining the appropriate resource requirements and providing adequate resources for the organization. This includes assigning trained personnel to implement and maintain the IP System and continually improve its effectiveness.

3.2 Human Resources

3.2.1 General

BASF establishes, implements and maintains documented procedures for identifying training needs and for ensuring that personnel performing activities affecting quality are adequately trained, qualified and certified per established requirements or standards.

3.2.2 Competence, Awareness and Training

Designated IP System participants are responsible for defining personnel qualifications and ensuring that the appropriate personnel are trained and aware of their role affecting product quality. Accordingly, the IP System administrator is responsible for maintaining personnel training records.

Appendices A and B provide standard operating procedures (SOPs), and work instructions (WI) for executing pre-planting, planting, growing season, pre-harvest, harvest, and subsequent season activities.

3.3 Infrastructure

BASF and/or its contracted representatives or agents, establishes and maintains the facilities, utilities and all associated equipment, hardware, software and supporting services needed to achieve product quality.

3.4 Work Environment

BASF establishes and maintains the appropriate work environment needed to achieve product quality requirements.

4.0 Product Realization

4.1 Planning of Product Realization

BASF develops the processes needed for Product Realization in accordance with the requirements of other processes of the IP System.

The following is determined with output in a form according to standard methods of operation:

a) Quality objectives and requirements for the product.
b) The need to establish processes, documents, and provide resources specific to the product.
c) The required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance.
d) Records needed to provide evidence that the realization processes and resulting product meet necessary requirements.

4.2 IP System-Related Processes

4.2.1 Determination of Requirements Related to the Product

BASF determines the following:

a) The requirements specified, including the requirements for delivery and post-delivery activities.
b) The requirements not stated but necessary for specified or intended use, where such is known.
c) Statutory and regulatory requirements related to the product.
d) Any additional requirements determined to be appropriate and necessary.

4.2.2 Review of Requirements Related to the Product

BASF reviews the requirements related to the product prior to contracting with a contracted representative and/or agent and ensures that:

a) Product requirements are defined.
b) IP System requirements differing from those previously expressed are resolved.
c) The defined requirements can be achieved.

BASF maintains records of the results of reviews and actions arising from the review.

4.2.3 IP System Communication

BASF develops and implements effective methods of communicating with IP System participants in relation to product information, enquiries, contracts or order handling, including amendments and feedback.

4.3 Production and Service Provision

4.3.1 Control of Production and Service Provision

BASF establishes and maintains production and service provision under controlled conditions to include the following:

a) The availability of information that describes the characteristics of the product.
b) The availability of work instructions, as necessary.
c) The use of suitable equipment.
d) The availability of monitoring and measuring devices.

e) The implementation of monitoring and measurement.
f) The implementation of release, delivery and post-delivery activities.

4.3.2 Validation of Processes for Production and Service Provision

BASF validates processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement, to include processes where deficiencies become apparent only after the product is in use or the service has been delivered. The validation shall demonstrate the ability of these processes to achieve planned results.

BASF establishes arrangements for these processes including:

a) Defined criteria for review and approval of the processes.
b) Approval of equipment and qualification of personnel.
c) Use of specific methods and procedures.
d) Requirements for procedures.
e) Revalidation.

4.3.3 Identification and Traceability

BASF establishes, implements and maintains the appropriate documented procedures for Product Identification and Traceability, during all stages of product realization.

The IP System administrator is responsible for Product Identification and Traceability. Products are identified during all stages of production.

Traceability is provided to the extent that internal and external requirements and/or contracts specify. Traceability records are maintained for items requiring traceability.

4.3.4 Preservation of Product

BASF establishes, implements and maintains documented procedures for the preservation of product to include: handling, storage, packaging, protection and delivery of materials and products.

The Value Chain Manager or designee is responsible for handling, storage, packaging, protection and delivery of products. General methods are developed and maintained to protect materials and products from damage and/or deterioration during handling and shipping.

Secure storage areas are provided to prevent damage and/or deterioration of materials and products. General procedures for packing and marking are implemented to ensure protection and identification. Where appropriate, special packing and/or marking instructions are documented.

4.4 Control of Monitoring and Measuring Devices

BASF determines the monitoring and measurement requirements and establishes, implements and maintains documented procedures to control, calibrate and maintain inspection, measuring and test equipment used to demonstrate the conformance of product to the specified requirements.

Where necessary to ensure valid results, measuring equipment shall:

a) Be calibrated or verified at specified intervals, prior to use, against measurement standards traceable to international or national measurement standards; where no such standard exist, the basis used for calibration or verification shall be recorded.
b) Be adjusted or re-adjusted as necessary.
c) Be identified to enable the calibration status to be determined.
d) Be safeguarded from adjustment that would invalidate the measurement result.
e) Be protected from damage and deterioration during handling, maintenance and storage.

BASF implements and maintains documented procedures to ensure adequate control of inspection, measuring and test equipment and to assess the validity of previous results when the equipment is found not to conform to requirements. Records are maintained for each item of inspection, measuring and test equipment to provide supportive documentation.

When computer software is used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed prior to initial use and reconfirmed as necessary.

5.0 Measurement, Analysis, Improvement

5.1 General

BASF determines the monitoring, measurement, analysis and improvement processes, including methods such as statistical techniques that are needed to:

a) Demonstrate conformity of the product.
b) Ensure conformity of the IP System.
c) Continually improve the effectiveness of the IP System.

5.2 Monitoring and Measurement

5.2.2 Internal Audit

BASF establishes, implements and maintains documented procedures for a comprehensive system of internal audits at planned intervals to verify the effectiveness of the IP System.

The IP System administrator is responsible for administering the Internal Audit system per documented procedures. The Value Chain Manager or designee develops a schedule for internal audits according to IP System requirements and conducts unscheduled audits (internal and external) when reasons for such audits exist.

Audits are conducted utilizing documented checklists and/or audit plans. Audit results are documented in audit reports per established procedures. Copies of all audit reports including completed corrective action requests are forwarded to management of the audited area and maintained by the Value Chain Manager or designee.

Audit personnel are qualified per documented procedures and do not have direct responsibility for or control of the area to be audited.

Management personnel responsible for the audited area determine and implement timely corrective actions for any reported nonconformance and follow-up activities include verification of the corrective actions taken and reporting of the results.

5.2.3 Monitoring / Measurement of Processes

BASF implements and maintains comprehensive methods for monitoring and measuring the IP System processes, which demonstrate the ability of the processes to achieve planned results.

When planned results are not achieved, corrective actions are implemented and monitored for effectiveness.

5.2.4 Monitoring / Measurement of Product

BASF implements and maintains comprehensive methods for monitoring and measuring the characteristics of product to verify that product requirements are achieved throughout all phases of product realization in accordance with Standard Operating Procedures.

Evidence of conformity with the acceptance criteria is maintained in the records and indicates the person authorizing the release. Product release and delivery are dependant upon compliance with the appropriate SOP's set forth.

5.3 Control of Nonconformity

BASF establishes, implements and maintains documented procedures to ensure that nonconforming materials, parts or products are prevented from inadvertent use and/or additional processing without review and disposition from authorized personnel.

The IP System administrator is responsible for the Control of Nonconformity. Nonconforming inputs, materials, or products are reviewed in accordance with documented procedures and may be accepted under concession by a relevant authority, and where applicable, by the customer only if all regulatory requirements are met.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained are maintained according to quality procedures.

Product found to be nonconforming after delivery will require corrective actions.

5.4 Analysis of Data

BASF utilizes statistical techniques and methods for the analysis of appropriate data collected to demonstrate the suitability and effectiveness of the IP System.

Methods used to generate relevant data are reviewed periodically to ensure the information provided relates to:

a) Conformity to product requirements.
b) Characteristics and trends of processes and products including opportunities for preventive action.
c) Suppliers.

5.5 Improvement

5.5.1 Continual Improvement

BASF continually improves the effectiveness of its IP System through the use of the Quality Policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management reviews.

5.5.2 Corrective Action

BASF establishes, implements and maintains documented procedures to initiate corrective and preventive actions for conditions adverse to quality.

Corrective Action Procedures define the requirements for:

a) Reviewing nonconformities.
b) Determining causes of nonconformities.
c) Evaluating the need for action to ensure that nonconformities do not recur.
d) Determining and implementing the action needed.
e) Records of the results of action implemented.
f) Review of corrective action implemented.

The IP System administrator is responsible for Corrective Actions and a feedback system is used to provide early warning of quality problems and for input into the corrective action system.

5.5.3 Preventative Action

BASF establishes and maintains documented procedures to determine the appropriate preventive actions required to eliminate the causes of potential nonconformities in order to prevent their occurrence.

Preventive Action Procedures define the requirements for:

a) Determining potential nonconformities and their causes.
b) Evaluating the need for action to prevent occurrence of nonconformities.
c) Determining and implementing the action needed.
d) Records of the results of action implemented.
e) Reviewing preventive action implemented.

The IP System administrator is responsible for Preventive Action.

Reference Documents and Supportive Materials

Quality System Documentation Levels

LEVEL I Company Policy – A documented Policy Statement.

LEVEL II IP System Manual – The IP System Manual establishes requirements and guidelines for the overall IP System objectives. These requirements and guidelines are applicable to the operations at BASF, and limited to its genetically modified starch potato IP System and related services.

LEVEL III Standard Operating Procedures – The IP System Manual is a collection of Standard Operating Procedures (SOP's), which are documented in conformance with, and support of the IP System Manual's requirements and guidelines.

LEVEL IV Work Instructions – Work Instructions are documented as necessary to support each applicable Standard Operating Procedure. They detail specific quality or inspection information and specific instructions for performance of individual tasks.

LEVEL V Records – Completed Forms provide the objective evidence of compliance.

Standard Operating Procedures

SOP:	Title
A.	Seed Potato Multiplication
B.	Seed Potato Grading
C.	Production of Starch Potatoes for Processing
D.	Potato (Raw Material) Delivery
E.	Starch Production
F.	Storage of Starch in Silo After Processing
G.	Use of Potato Pulp After Production

Forms List:

Form 1 – Checklist for the Packaging and Transport of Seed Potatoes
Form 2 – Checklist for the Receipt and Storage of Seed Potatoes at the Farm
Form 3 – Pre-Planting Checklist of Seed Potatoes at the Farm
Form 4 – Post-Planting Checklist of Seed Potatoes
Form 5 – Field-Plot Card Index
Form 6 – Pre-Harvest Checklist of Seed Potatoes
Form 7 – Post-Harvest Checklist of Seed Potato
Form 8 – Preparation of Potatoes for Grading
Form 9 – Post-Processing Activities for Potatoes
Form 10 – Preparation of Potatoes for Processing
Form 11 – Post-Processing Checklist

Form A – Record of Shipment of Potatoes
Form B – Record of Receipt of Shipment of Potatoes
Form C – Record of Shipment of Pulp from genetically modified potatoes
Form D – Record of Receipt of Shipment of Pulp from genetically modified potatoes

Appendix A

Standard Operating Procedures

Appendix A: Table of Contents

Introduction

Systems Principles
(Variable Analysis and Critical Control Point)

The systems concept applies to all stages throughout the agri-food chain – growing, harvesting, processing, manufacturing, distributing – with the sole objective of managing and/or controlling the most important variables.

The basis for implementing a sustainable program is to incorporate it into prerequisite programs, including formalized good production practices and some type of validated process-monitoring program.

Process validation may also be conducted at different stages during the life cycle of a product. There are many reasons, in addition to regulatory guidelines or requirements, for validating processes. A manufacturer can assure through careful design and validation of processes, and process controls, that there is a high probability that all manufactured products will meet specifications and have uniform consistency.

Definitions

Variable Analysis – a key element in developing a plan, this is a process of collecting and evaluating information on key variables in order to decide which are significant for maintaining product value and therefore are to be addressed in the plan.

Critical Control Point – a step at which control can be applied and is essential to preventing or eliminating a variable or managing it to an acceptable level.

Analysis: Potential to Dilute Value of Genetically modified Starch Potatoes

A. Seed Potato Multiplication

1. Previous crop
2. Prove receipt and source of seed potato for multiplication
3. Segregation of Genetically modified Starch Potatoes and conventional varieties while in on-farm storage
4. All planted
5. Clean planter following planting of seed potatoes
6. Variety isolation
7. Field isolation
8. All handling in production area
9. Seed container identification
10. Unused seed disposition
11. Clean harvester following harvest of seed potatoes
12. Clean seed handling equipment
13. Following crop
14. Control of volunteer potatoes
15. Segregated storage
16. Labeling of individual lots/containers
17. Clean storage container following storage of seed potatoes
18. Clean truck following transport of seed potatoes
19. Tracking of transfer points (seed field-truck-storage-truck-grading plant)

B. Seed Potato Grading

1. Clean grading plant prior to receipt of seed potato
2. Prove receipt and source of seed potato seed for grading
3. Grading of seed potato following industry best management practices
4. Segregated storage of seed potato
5. Labeling of storage containers and/or seed bags
6. Clean facility following grading of seed potato

C. Production of Starch Potatoes for Processing

1. Previous crop
2. Validate fulfillment by checking seed bag labels to confirm correct shipment
3. Segregation of genetically modified starch potato seed from conventional potato seed during distribution
4. Tracking of transfer points (grading plant-truck-seed warehouse-truck-farm delivery)
5. Prove receipt of genetically modified starch potato seed
6. Segregation of genetically modified starch potato seed while in on-farm storage
7. All seed planted

8. Clean planter following planting
9. Variety isolation
10. Field isolation
11. All seed handled in production area
12. Seed container labeling
13. Unused seed disposition
14. Clean harvester following harvest of potatoes
15. Potato handling equipment cleaning
16. Following crop
17. Control of volunteer potatoes
18. Segregation of genetically modified starch potatoes and conventional varieties while in on-farm storage
19. Labeling of on-farm storage containers
20. Clean storage container following storage
21. Clean truck following transport
22. Tracking of transfer points (seed-field-truck-storage-truck-processing plant receipt)

D. Potato (Raw Material) Delivery

1. Prove receipt and quantity of potatoes at delivery from growers or haulers according to fixed schedule
2. Clean receiving equipment prior to delivery of potatoes
3. Clean delivery trucks before and after transport
4. Clean silo following storage
5. Disposition of materials collected during silo clean-up

E. Starch Production

1. Clean starch production equipment following processing
2. Disposition of by-product materials
3. Disposition of potato juice on cropland
4. Disposal of wastewater

F. Storage of Starch in Silo After Processing

1. Clean starch storage equipment prior to filling with starch from genetically modified potatoes
2. Segregate storage of starch from genetically modified potatoes from conventional starch
3. Label storage silos for starch from genetically modified potatoes
4. Validate movement of starch from genetically modified potatoes into correct storage silo
5. Track transfer points (processing plant receipt-production unit-storage silo)

G. Use of Potato Pulp After Production

1. Record receipt of pulp from processing of genetically modified potatoes

2. Track transfer points (processing plant pulp storage facility-truck-feeding location)

Work Instruction Outline

A. Seed Potato Multiplication

Element Name	Element Description	Critical Control Point
Compliance training	Cooperator has completed compliance training.	No
Previous crop	Previous crop shall not have been potatoes.	Yes
Proof of source	Receipt of seed, including source and sending location of provider, must be recorded.	Yes
Seed storage	Seed for this project is stored in an area where no other potato seed is stored.	Yes
Planter cleaned	Planter cleaned of all seed before leaving the plot area.	Yes
Variety isolation	Only one variety per field is planted.	No
5 meter Area Border	A border of at least 5 m is maintained around the entire planted area where no other potatoes are growing.	Yes
All handling in production area	All seed is loaded into planting equipment in the field.	No
Bag identification	All seed bags are labeled in accordance with standard seed industry practices.	No
Unused seed disposition	All unused and/or unusable seed and original seed container is returned to seed provider.	Yes
Final harvester cleaning	Harvester is cleaned of all tubers after finishing harvest.	Yes
Seed handling final cleanup	Seed handling equipment is cleaned of all tuber material after use.	Yes
Following crop	Following crop shall not be potatoes.	Yes
Control of volunteers	Field shall be monitored during following growing season and any volunteer potatoes shall be destroyed.	Yes

Element Name	Element Description	Critical Control Point
Segregated storage	Genetically modified starch potatoes shall be stored separately from conventional potatoes	Yes
Labeling of lots while in storage	Genetically modified starch potatoes shall be labeled with commercial and/or potato line name.	No
Clean container following storage	Storage container shall be cleaned thoroughly to remove all genetically modified potato tubers and/or pulp.	Yes
Clean truck following transport	Each truck shall be cleaned thoroughly to remove all genetically modified potato tubers and/or pulp after unloading.	Yes
Tracking of transfer points	Each transfer point – e.g., from seed container to field – shall be recorded with date of transfer, quantity transferred, sending location, and receiving location.	No

B. Seed Potato Grading

Element Name	Element Description	Critical Control Point
Compliance training	Cooperator has completed compliance training.	No
Clean grading facility	Seed grading facility shall be cleaned according to industry best management practices.	Yes
Proof of source	Receipt of seed, including source and sending location of provider, must be recorded.	No
Grading of potato seed	Seed grading according to industry best management practices.	No
Segregated storage	Genetically modified starch potatoes shall be stored separately from conventional potatoes	Yes
Labeling of lots while in storage	Genetically modified starch potatoes shall be labeled with commercial and/or potato line name.	No
Clean grading facility	Seed grading facility shall be cleaned according to industry best management practices.	Yes

C. Production of Starch Potatoes for Processing

Element Name	Element Description	Critical Control Point
Compliance training	Cooperator has completed compliance training.	No
Previous crop	Previous crop shall not have been potatoes.	Yes
Validate fulfillment	Validate shipments by comparing seed labels with shipping instructions.	Yes
Segregate genetically modified starch potato seed	Genetically modified starch potatoes shall be stored separately from conventional potatoes.	Yes
Tracking of transfer points	Each transfer point – e.g., from seed container to field – shall be recorded with date of transfer, quantity transferred, sending location, and receiving location.	No
Proof of source	Receipt of seed, including source and sending location of provider, must be recorded.	Yes
Seed storage	Seed for this project is stored in an area separate from all other potato seed.	Yes
Planter cleaned	Planter cleaned of all seed before leaving the field.	Yes
Variety isolation	Only one variety per field is planted	No
Field isolation	A border of at least 5 m is maintained around the entire planted area where no other potatoes are growing.	Yes
All handling in production area	All seed is loaded into planting equipment in production area.	No
Bag identification	All seed bags are labeled in accordance with standard seed industry practices.	No
Unused seed disposition	All unused and/or unusable seed and original seed container is returned to seed provider.	Yes
Final harvester cleaning	Harvester is cleaned of all tubers after finishing harvest.	Yes
Potato handling final cleanup	Potato handling equipment is cleaned of all tuber material after use.	Yes

Element Name	Element Description	Critical Control Point
Following crop	Following crop shall not be potatoes.	Yes
Control of volunteers	Field shall be monitored during following growing season and any volunteer potatoes shall be destroyed.	Yes
Segregated storage	Genetically modified starch potatoes shall be stored separately from conventional potatoes	Yes
Labeling of lots while in storage	Genetically modified starch potatoes in on-farm storage shall be labeled with commercial and/or potato line name.	No
Clean container following storage	Storage container shall be cleaned thoroughly to remove all genetically modified potato tubers and/or pulp.	Yes
Clean truck following transport	Each truck shall be cleaned thoroughly to remove all genetically modified potato tubers and/or pulp after unloading.	Yes
Tracking of transfer points	Each transfer point – e.g., from seed container to field – shall be recorded with date of transfer, quantity transferred, sending location, and receiving location.	No

D. Potato (Raw Material) Delivery to Starch Processor

Element Name	Element Description	Critical Control Points
Compliance training	Cooperator has completed compliance training.	No
Prove receipt	Receipt of raw material, including source and sending location of provider, must be recorded.	Yes
Clean receiving equipment	Receiving equipment is cleaned according to guidelines prior to and after handling genetically modified starch potatoes.	Yes
Truck cleaning	Trucks are cleaned before and after transporting genetically modified starch potatoes.	Yes
Clean silos	Silos are cleaned according to industry best management practices before and after genetically modified starch potatoes are stored, and before any other potatoes are stored.	Yes
Disposition of by-product	Materials collected during cleanup are disposed of according to regulatory permits.	Yes

E. Starch Production

Element Name	Element Description	Critical Control Point
Compliance training	Cooperator has completed compliance training.	No
Clean starch extraction equipment	Production equipment is cleaned following extraction process according to industry best management practices.	Yes
Disposition of by-product	Solid materials collected during cleanup are disposed of by feeding to livestock or by applying to designated cropland in accordance with current regulatory permits. Other materials (dirt, water, stones) are disposed of in accordance with current regulatory permits.	Yes
Disposition of potato juice	Potato juice water will be applied to designated cropland in accordance with current regulatory permits.	No
Disposal of wastewater	Wastewater will be disposed of in accordance with current regulatory permits.	No

F. Storage of Starch in Silo After Processing

Element Name	Element Description	Critical Control Point
Compliance training	Cooperator has completed compliance training.	No
Starch storage	Clean starch storage equipment prior to and after filling with starch from genetically modified potatoes	Yes
Storage segregation	Starch from genetically modified potatoes is stored separately from conventional starch.	Yes
Silo labeling	Starch storage silos are clearly labeled as to contents.	Yes
Storage validation	Movement of Starch from genetically modified potatoes is validated to ensure placement into proper storage silo.	Yes
Tracking of transfer points	Each transfer point – e.g., from production unit to storage silo – shall be recorded with date of transfer, quantity transferred and manufacturing batch number if applicable.	No

G. Use of Potato Pulp After Production

Element Name	Element Description	Critical Control Point
Compliance training	Cooperator has completed compliance training.	No
Receipt of pulp	Receipt of pulp material, including quantity, batch number if applicable, and processing plant location, must be recorded for validation.	Yes
Disposition of potato pulp	Potato pulp will be applied to designated cropland or used in feed in accordance with current regulatory permits.	No
Tracking of transfer points	Each transfer point – e.g., from processing plant pulp storage facility to truck to disposal location – shall be recorded with date of transfer, quantity transferred and manufacturing batch number if applicable.	No

Appendix B

Responsibilities/Task List

And

1st Level Work Instructions

Appendix B: Part I

Responsibilities/Task List

This document addresses the responsibilities of each entity within BASF's production and regulatory compliance program. These responsibilities may be modified from time to time in accordance with the provisions of Section 1.2 of this Manual.

The first table below provides a legend for describing roles and responsibilities, and each subsequent table represents a distinct phase within BASF's entire process.

	Key Word	Description
T	Task	Performing the task
D	Data	Providing data about task completion
S	Supervision	On-site supervision of task completion
V	Verification	On-site verification of task completion
Q	Quality	Quality assurance regarding progress and status

Pre-Season	BASF Mgmt	Field Staff	Consultant	Grower
Grower/Site Selection	Q	TD		
Permit Application (if applicable)	TDQ			
Field Location Information	Q	TD		
Training of personnel ‡	Q	TD		
Seed Preparation ‡	Q	TD		
Seed grading/treating	Q	TD		
Bagging & Packaging	Q	TD		
Equipment cleanout	Q			TD
Determination of shrinkage	Q	TD		
Isolation Compliance ‡	Q	D		T
Seed Transport to Grower ‡	Q	TD		
Chain of Custody	Q	TD		
Seed Storage at Farm	Q	V		TD

‡ - indicates a task with overlapping or duplicate responsibilities, depending upon situation

Planting	BASF Mgmt	Field Staff	Consultant	Grower
Seed Transport to Field ‡	Q			TD
Pre-plant Checklist	Q			TD
Planting	Q			TD
Planter Cleanout (Field) ‡	Q			TD
Disposition of Unused Seed	Q	TDS		
Planter Cleanout (Final)	Q			TD

‡ - Indicates a task with overlapping or duplicate responsibilities. Responsibilities in parentheses may or may not be performed by that party depending on the situation.

In-Season	BASF	Field Staff	Consultant	Grower
Isolation Verification	Q	TD		
Field Ops/ Equipment Cleaning	Q			TD
Field Agronomic Observations	Q	S		TD
Monitoring/Maintenance of isolation distance, including volunteers ‡	Q	TD		
Auditing (if applicable)	Q		TD	
Pesticide Applications	Q	S		TD

‡ - Indicates a task with overlapping or duplicate responsibilities, depending upon situation

Harvest	BASF	Field Staff	Grower
Harvest	Q		TD
Harvester Cleanout (Field)	Q	S	TD
Disposition of Cleanout Potato Material	Q	TD	

‡ - Indicates a task with overlapping or duplicate responsibilities, depending upon situation

Subsequent Season	BASF	Field Staff	Grower
Verification of site boundaries ‡	Q	V	TD
Volunteer Monitoring ‡	Q	V	TD
Volunteer Destruction ‡	Q	VTD	
Auditing (if applicable)	Q	TD	

‡ - Indicates a task with overlapping or duplicate responsibilities, depending upon situation

Storage – Seed	BASF	Breeder
Transport to Storage	Q	TD
Transport Equipment Cleanout	Q	TD
Storage	Q	TD

Grading – Seed	BASF	Breeder
Cleaning	Q	TD
Cleanup, Cleanout	Q	TD

Storage – Potatoes	BASF	Field Staff	Starch Co.	Grower
Transport to Storage	Q	S	D	TD
Chain of Custody	Q	D	TD	
Transport Equipment Cleanout ‡	Q	S		TD
Storage	Q		TD	

‡ - Indicates a task with overlapping or duplicate responsibilities, depending upon situation

Appendix B: Part II

Work Instructions

For

Identity Preservation System Manual

A. Seed Potato Multiplication

1.1.1 Compliance Training

1.1.2 All Personnel responsible for seed potato production must attend and demonstrate sufficient knowledge of the training materials.

1. A member of BASF Plant Science Regulatory Department or a representative of BASF Plant Science will conduct training.
2. The subject covered in training will be the application of the Identity Preservation system on the seed potato production, including: regulatory compliance, standard operating procedures, work instructions, and individual responsibilities.
3. The attendants of the training will prove their attendance by signing a list.

1.2.1 Packaging and transportation of seed

1. A BASF representative or agent (e.g., farmer) who has successfully completed training must do all packaging and arrange for transport of seed. This person is also responsible for the following:
2. Packaging should have an attached label with the proof of source documents for the seed potatoes.
3. The label should clearly state the variety name and the fact that it is an Amylopectin seed potato.
4. The containers should have a semi–permanent seal with a unique serial number on the required label, and amended by a yellow identifier, attached in such a way that the bag cannot be opened without breaking the seal.
5. The proof of source documents and serial number of the semi–permanent seal should be recorded and sent to the IP System Administrator on "Record of Shipment of Potatoes" (**Form A or electronic equivalent).**
6. In the event that seed of the same origin is being shipped in multiple containers as a single shipment, each of the containers must be labelled with the information "container X of Y," with X representing the container number, and Y representing the total number of containers with the same seed being shipped as a group.
7. In the event of an accident, the driver should follow training procedures.
8. The "Checklist for Packaging and Transport of Seed Potatoes" **(Form 1 or electronic equivalent)** must be completed.

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For
Identity Preservation System Manual

1.3.1 Receiving and Storage of shipped seed potatoes at the farm.

Upon arrival of the shipped seed the grower is responsible for:
1. Verifying that the packages are physically intact and that there is no visible damage.
2. Verifying that the total number of packages for a multiple package shipment is present and accounted for.
3. Verifying that the container is labelled properly.
4. Signing for shipment and saving shipping documents.
5. Completing the "Checklist for the Receipt and Storage of Seed Potato at the Farm" **(Form 2 or electronic equivalent)** and "Record of Receipt of Shipment of Potatoes" **(Form B or electronic equivalent)**

1.3.2 Storage of shipped seed

After receipt of seed, the grower is responsible for:
1. Storing seed in a locked and secured location.
2. Storing seed separately from conventional potatoes.
3. Assuring that the semi–permanent seals on the containers are not broken until the seed has been moved to the plot area.

1.4.1 Preparing the Seed for Planting

1. The grower who stored the seed is responsible for the following:
    a. Proper shipment of seed from storage to field in a cleaned vehicle
    b. Completion of "Pre–Planting Checklist of Seed Potato at the Farm" **(Form 3 or electronic equivalent)**

1.4.2 Seed Potato Planting

1. Grower is responsible for planting of the seed.
2. The requirements for the planting are as follows:
    a. 5 meter separation distance between this field and nearest other crop
    b. All seed containers present and accounted for
    c. All seed containers have unbroken seals
    d. The planter has been cleaned of other seed potatoes
    e. The planter will be loaded or filled within the field
    f. The previous year's crop residue is from a non-potato crop
    g. The driving wheel on the planter has been turned 2 revolutions to ensure that the double feed-cup is free of conventional potatoes
    h. A sign shall be erected denoting the type of crop being grown at this site

1.4.3 Post-Planting Work Instructions

1. The grower is responsible for:
    a. Completing "Post–Planting Checklist of Seed Potatoes" **(Form 4 or electronic equivalent)**
    b. Ensuring that all potato seed has been planted or, if unplanted seed remains, that it has been returned to the seed provider.
    c. Cleaning and then verifying that the planting equipment and trucks have been properly cleaned

Work Instructions
For
Identity Preservation System Manual

1.5.1 In-Field Monitoring

1. A BASF Plant Science representative or agent who has successfully completed training shall monitor the crop progress three times during the planting season.
2. The grower shall record the following information on "Field-plot card-index, pages 1 & 2" **(Form 5 or electronic equivalent)**:
   a. Farm address
   b. Field location information
   c. Field size
   d. Soil type
   e. Valuation index of field
   f. Preceding crop, date of harvest, condition of soil, stubblefield cultivation, green manure, other culitivation prior to planting of this year's crop.
   g. Planting population of this year's crop, disinfectant used, date of planting, soil temperature when planting, date of emerge, making ridges
   h. Check for foreign varieties, irrigation
   i. Soil test results, fertilization, chemical weed control, parasites and treatment, diseases and treatment
   j. Date of harvest, yield/ha
3. The grower is responsible for providing the general agronomic services and products such as spraying, tillage, fertilizers, and crop protection products.

1.6.1 Preparing the Seed Potato for Harvest

1. The grower is responsible for completing the "Pre-Harvest Checklist of Potatoes" **(Form 6 or electronic equivalent).**
2. The grower is responsible for harvesting the potatoes and equipment clean–out, including trucks, before harvest.
3. The grower is responsible to ensure that correct labels in sufficient quantity are available to mark containers before they leave the field.

1.6.2 Harvesting the Potatoes

1. The grower is responsible for harvesting the seed potatoes, for the proper labelling of the harvested potatoes, and for forwarding harvest documents to the IP System Administrator, including "Post–Harvest Checklist" **(Form 7 or electronic equivalent).**
2. The grower shall confirm that the complete field has been harvested.
3. All containers shall have proper labelling, including harvest date, lot number, and proof of source documents.
4. All containers leaving the field shall have a uniquely numbered yellow label attached to the opening.
5. The number on the label shall be recorded on "Record of Shipment for Potatoes" **(Form A or electronic equivalent).**

1.6.3 Post–Harvest Work Instructions

1. Grower is responsible for the clean out of harvesting equipment before leaving the field.
2. Grower is also responsible for eradication with mechanical and chemical methods, including hacking as appropriate, and for completing the "Post–Harvest Checklist" **(Form 7 or electronic equivalent)** and sending the document to the IP System Administrator.

1.7.1 Following Year Crop Monitoring

1. The grower shall plant a non-potato crop.
2. The grower is responsible to follow the normal 4-year crop rotation for the cultivation of potatoes.
3. A BASF Plant Science Representative is responsible to inspect the field in the following year three times during the growing season.
4. The grower shall record the following information on “Field-plot card-index, page 1” **(Form 5 or electronic equivalent)**:
   a. Farm address
   b. Field location information
   c. Field size
   d. Soil type
   e. Valuation index of field
   f. Preceding crop, date of harvest, condition of soil, stubblefield cultivation, green manure, other culitivation prior to planting of this year’s crop.
   g. Crop name, planting population of this year’s crop, disinfectant used, date of planting, soil temperature when planting, date of emerge
   h. Check for foreign varieties

Work Instructions
For
Identity Preservation System Manual

B. Seed Grading

2.1.1 Compliance Training

2.1.2 All personnel responsible for seed grading must attend and demonstrate sufficient knowledge of the training materials.

1. A member of BASF Plant Science Regulatory Department or a representative of BASF Plant Science will conduct training.
2. The subject covered in training will be the application of the Identity Preservation system on the seed potato production, including: regulatory compliance, standard operating procedures, work instructions, and individual responsibilities.
3. The attendants of the training will prove their attendance by signing a list.

2.2.1 Receipt of Potatoes at Seed Grading Plant Storage

The potato breeder is responsible for the following:
1. Completing "Record of Receipt of Shipment of Potatoes" **(Form B or electronic equivalent**)
2. Storing the potatoes in a separate storage area from conventional potatoes.
3. Verifying the semi–permanent seal serial numbers.
4. Clearly labelling the storage area as to its contents and with their proof of source documents.
5. Ensuring the storage area is locked and secure when not receiving potatoes.

2.3.1 Preparing the Potatoes for Grading

1. The seed grading plant personnel are responsible for the clean–out of all equipment related to transport and grading of potatoes.
2. The potato breeder is responsible for:
   a. Completing "Preparation of Potatoes for Grading" (**Form 8 or electronic equivalent)**
   b. Verifying all equipment to be used for transport and grading of potatoes is clean.
   c. Verifying that the potatoes are stored in a locked and secured storage area.

2.3.2 Grading of Potatoes

1. The plant personnel are responsible for the proper grading of the potatoes.
2. The plant personnel are responsible for the proper storage of graded potatoes.

2.3.3 Post–Grading Activities for Seed Potatoes

1. The potato breeder is responsible for:
   a. Completing "Post-Grading Activities for Potatoes**" (Form 9 or electronic equivalent).**
   b. Verifying all equipment to be used for transport and grading of potatoes is clean.
   c. Verifying that the unusable potatoes and their cleanings, which resulted from the grading process, are properly disposed of.
   d. Verifying that the potatoes are in a locked storage area, away from conventional potatoes and labelled correctly and clearly.
2. The plant personnel are responsible for the clean–out of all equipment related to transport and grading of potatoes.

Work Instructions
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Identity Preservation System Manual

C. Production of Starch Potatoes for Processing

3.1.1 Compliance Training

1. A member of BASF Plant Science Regulatory Department or a representative of BASF Plant Science will conduct training.
2. The subject covered in training will be the application of the Identity Preservation system on the seed potato production, including: regulatory compliance, standard operating procedures, work instructions, and individual responsibilities.
3. The attendants of the training will prove their attendance by signing a list.

3.2.1 Receiving and Storage of Shipped Seed Potato at the Farm

Upon arrival of the shipped seed potato, the grower is responsible for:
1. Verifying that the packages are physically intact and that there is no visible damage.
2. Verifying that the total number of packages for a multiple package shipment is present and accounted for.
3. Verifying that the container is labelled properly.
4. Signing for shipment and saving shipping documents.
5. Storing the potatoes in a locked and secure location separate from conventional potatoes
6. Completing the "Checklist for the Receipt and Storage of Seed Potato at the Farm" **(Form 2 or electronic equivalent)** and "Record of Receipt of Shipment of Potatoes" **(Form B or electronic equivalent)**

3.2.2 Storage of Shipped Seed Potato

After receipt of seed, the grower is responsible for:
1. Storing genetically modified seed potato in a locked and secured location.
2. Storing genetically modified seed potato separately from conventional potatoes.
3. Assuring that the semi–permanent seals on the containers are not broken until the genetically modified seed potato has been moved to the plot area.

3.3.1 Genetically modified Starch Potato Planting

1. Grower is responsible for planting of the potato.
2. The requirements for the planting are as follows:
    a. 5 meter separation distance between this field and nearest other crop
    b. All seed containers present and accounted for
    c. All seed containers have unbroken seals
    d. The planter has been cleaned of other seed potatoes
    e. The planter will be loaded or filled within the field
    f. The previous year's crop residue is from a non-potato crop
    g. The driving wheel on the planter has been turned 2 revolutions to ensure that the double feed-cup is free of conventional potatoes
    h. A sign shall be erected denoting the type of crop being grown at this site

Work Instructions
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3.3.2 Post-Planting Work Instructions

1. Grower is responsible for completing the "Post Planting Checklist of Potatoes" **(Form 4 or electronic equivalent)**.
2. Grower shall:
   a. Verify that all seed has been planted or, if unplanted seed remains, that it has been returned to the seed provider.
   b. Cleaning and then verifying that the planting equipment and trucks have been properly cleaned.

3.4.1 In-Field Monitoring

1. A BASF Plant Science representative who has successfully completed training shall monitor the crop progress three times in a planting season.
2. The grower shall record the following information on "Field-plot card-index, pages 1 & 2" **(Form 5 or electronic equivalent)**:
   a. Farm address
   b. Field location information
   c. Field size
   d. Soil type
   e. Valuation index of field
   f. Preceding crop, date of harvest, condition of soil, stubblefield cultivation, green manure, other culitivation prior to planting of this year's crop.
   g. Planting population of this year's crop, disinfectant used, date of planting, soil temperature when planting, date of emerge, making ridges
   h. Check for foreign varieties, irrigation
   i. Soil test results, fertilization, chemical weed control, parasites and treatment, diseases and treatment
   j. Date of harvest, yield/ha
3. The grower is responsible for providing the general agronomic services and products such as spraying, tillage, fertilizers, and crop protection products.

3.5.1 Preparing the Potatoes for Harvest

1. The grower is responsible for completing the Pre-Harvest Checklist **(Form 6 or electronic equivalent).**
2. The grower is responsible for harvesting the potatoes and equipment clean–out, including trucks, before harvest.
3. The grower is responsible to ensure that correct labels in sufficient quantity are available to mark containers before they leave the field.

3.5.2 Harvesting the Potatoes

1. The grower is responsible for harvesting the potatoes, equipment clean–out before harvest, proper labelling of the harvested potatoes, and forwarding harvest documents, including "Post-Harvest Checklist," to the IP System Administrator **(Form 7 or electronic equivalent).**
2. The grower shall confirm that the complete field has been harvested.
3. All trucks shall have proper labelling, including harvest date, lot number, and proof of source documents.
4. All trucks leaving the field shall have a uniquely numbered yellow label attached to the opening and recorded **(Form A or electronic equivalent).**
5. All trucks shall be covered and shall have proper labelling, including harvest date, lot number, and proof of source documents.

Work Instructions
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3.5.3 Post–Harvest Work Instructions

1. Grower is responsible for the clean out of harvesting equipment and trucks before leaving the field.
2. Grower is also responsible for eradication with mechanical and chemical methods, including hacking as appropriate, and for completing the "Post–Harvest Checklist" **(Form 7 or electronic equivalent)** and sending the document to the IP System Administrator.

3.6.1 Following Year Crop Monitoring

1. The grower shall plant a non-potato crop.
2. The grower is responsible to follow the normal 4-year crop rotation for the cultivation of potatoes.
3. A BASF Plant Science Representative is responsible to inspect the field in the following year three times during the growing season. and to complete completing
4. The grower shall record the following information on "Field-plot card-index, page 1" **(Form 5 or electronic equivalent)**
   a. Farm address
   b. Field location information
   c. Field size
   d. Soil type
   e. Valuation index of field
   f. Preceding crop, date of harvest, condition of soil, stubblefield cultivation, green manure, other culitivation prior to planting of this year's crop.
   g. Crop name, planting population of this year's crop, disinfectant used, date of planting, soil temperature when planting, date of emerge
   h. Check for foreign varieties

Work Instructions
For
Identity Preservation System Manual

D. Potato (Raw Material) Delivery

4.1.1 Compliance Training

4.1.2 All Personnel responsible for starch potato processing must attend and demonstrate sufficient knowledge of the training materials.

1. A member of BASF Plant Science Regulatory Department or a representative of BASF Plant Science will conduct training.
2. The subject covered in training will be the application of the Identity Preservation system on the seed potato production, including: regulatory compliance, standard operating procedures, work instructions, and individual responsibilities.
3. The attendees of the training will prove their attendance by signing a list.

4.2.1 Receipt of Potatoes at Processing Plant Storage

1. The starch processor is responsible for the following:
    a. Completing "Record of Receipt of Shipment of Potatoes" **(Form B or electronic equivalent**)
    b. Storing the potatoes in a storage area separate from conventional potatoes.
    c. Verifying that the truck is labelled and covered.
    d. Clearly labelling the storage area as to its contents and with their proof of source documents.
    e. Ensuring the storage area is locked and secure when not receiving potatoes.

4.3.1 Preparing the Factory for Processing of Potatoes

1. The starch processor is responsible for:
    a. Completing "Preparation of Potatoes for Processing" (**Form 10 or electronic equivalent)**
    b. Verifying all equipment to be used for transport, processing, and storage of genetically modified potatoes and starch from genetically modified potatoes is clean.
    c. Verifying the genetically modified potatoes are in a secure storage area.
    d. Taking steps to ensure that no mixing occurs.
2. The starch plant personnel are responsible for the clean–out of all equipment related to transport, processing, and storage of genetically modified potatoes and starch from genetically modified potatoes.

Work Instructions
For
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E. Starch Production

5.1.1 Processing of Potatoes

1. The processing plant personnel are responsible for the proper processing and storage of the starch from genetically modified potatoes.
2. The processing plant personnel are responsible for the proper handling or disposal of any by–products such as: potato juice, wastewater, soil, stones, and unusable potato remnants.

F. Storage of Starch After Processing

6.1.1 Post–Processing of Potatoes.

1. The starch processor is responsible for:
   a. Completing "Post-Processing Checklist" (**Form 11 or electronic equivalent).**
   b. Verifying all equipment used for transport and processing of potatoes is clean.
   c. Verifying the by–products such as: potato juice, wastewater, soil, stones, and unusable potato remnants were properly disposed of or used.
   d. Verifying the starch from genetically modified potatoes is in a locked and secured storage area.
   e. Verifying the starch from genetically modified potatoes is properly labelled.
2. The processing plant personnel are responsible for the clean–out of all equipment related to transport, processing, and storage of potatoes.

G. Use of Potato Pulp

7.1.1 Use of Potato Pulp After Processing

The starch processor is responsible for:

1. Completing "Record of Shipment of Pulp from genetically modified Potatoes" **(Form C or electronic equivalent)** for each shipment of potato pulp from starch plant.
2. Completing "Record of Receipt of Shipment of Pulp from genetically modified potatoes" **(Form D or electronic equivalent)** for receipt of each shipment of potato pulp at final destination.

Appendix C:

Forms

BASF

Genetically modified Starch Potato Program – Form 1

Checklist for the Packaging and Transport of Seed Potatoes For Identity Preservation System Manual

Printed Name: _____

Signature: _____

Title: _____ Date: _____

Total amount of seed potatoes being shipped: _____

Location and person receiving shipment: _____

This form is to be completed by an authorized and trained person. (Please, clearly circle the appropriate response.)

1. YES NO Is the label identifier used in shipping the seed potatoes of unique color?

2. YES NO Do all containers have a semi–permanent seal with serial number attached to the opening?

3. YES NO Do all containers have a label and proof of source documents attached to the container?

4. YES NO Has the driver been given specific instructions as to procedures to be followed in the event of an accident?

5. YES NO An enclosed vehicle or sealed bag is being used to transport the genetically modified seed potatoes.

6. YES NO Is the "Checklist for receiving and storage of genetically modified seed stock" (form 2) included with the shipment?

7. YES NO Were all containers and their corresponding seal serial number recorded on form A?

NOTE: If the answer to any of these questions is NO, make the required corrections or contact the IP System Administrator prior to shipment.

NOTE: If the answers to all of the previous questions are YES, forward this document to the IP System Administrator.

BASF

Genetically modified Starch Potato Program – Form 2

Checklist for the Receipt and Storage of Seed Potatoes at the Farm For Identity Preservation System Manual

Printed Name: _____

Signature: _____

Title: _____ Date: _____

Total amount of seed potatoes being accepted: _____

Location and person receiving shipment:_____

This form is to be completed by an authorized and trained grower.
(Please, clearly circle the appropriate response.)

1. YES NO Are all containers physically intact, and there is no visible damage?

2. YES NO Are all containers properly labeled with proof of source documents?

3. YES NO Are all containers present and accounted for?

4. YES NO Do all containers have a semi–permanent seal at the opening of the container that is not broken?

5. YES NO Are the seed potatoes being stored in a locked and secure location?

6. YES NO Are the seed potatoes being stored separately from conventional potatoes?

7. YES NO Were all containers and their corresponding seal serial number recorded on form B?

NOTE: If the answer to any of these questions is NO, make the required corrections or contact the IP System Administrator prior to accepting shipment.

NOTE: If the answers to all of the previous questions are YES, forward this document to the IP System Administrator.

BASF

Genetically modified Starch Potato Program – Form 3

Pre–Planting Checklist of Seed Potatoes at the Farm For Identity Preservation System Manual

Printed Name: _____

Signature: _____

Title: _____ Planting Date: _____

Total amount of seed potatoes being planted:_____

This form is to be completed by an authorized and trained person. (Please, clearly circle the appropriate response.)

1. YES NO Has the vehicle used for transporting the seed potatoes to the field been adequately cleaned prior to making delivery to the field?

2. YES NO Is there a 5-meter wide fallow area surrounding the intended planting area?

3. YES NO Are all containers present and accounted for?

4. YES NO Do all seed potato containers have a semi–permanent seal at the opening of the container that is not broken?

5. YES NO Has the planter been adequately cleaned of any other seed potatoes?

6. YES NO Are the seed potatoes being stored separately from conventional potatoes?

7. YES NO Will the planter be loaded or filled within the field?

8. YES NO Is the previous year's plant residue a non–potato crop?

9. YES NO Has the driving wheel on the planter been turned 2 revolutions to ensure that the double feed–cup is free of conventional potatoes?

NOTE: If the answer to any of these questions is NO, make the required corrections or contact the IP System Administrator prior to planting.

NOTE: If the answers to all of the previous questions are YES, forward this document to the IP System Administrator.

BASF

Genetically modified Starch Potato Program – Form 4

Post–Planting Checklist of Seed Potatoes For Identity Preservation System Manual

Printed Name: _____

Signature: _____

Title: _____ Planting Date: _____

Hectares planted: _____ Planted by: _____

This form is to be completed by an authorized and trained person. (Please, clearly circle the appropriate response.)

1. YES NO Is there a 5-meter wide fallow area surrounding the intended planting area?

2. YES NO Has the planting area been appropriately signed?

3. YES NO Was all the potato seed planted or, if seed remained, was it returned to the seed provider?

4. YES NO Has the driving wheel on the planter been turned 2 revolutions to ensure that the double feed–cup is free of genetically modified seed stock?

5. YES NO Has the planter been adequately cleaned of all seed potatoes?

6. YES NO Has the truck that delivered the seed potatoes to the field been adequately cleaned?

NOTE: If the answer to any of these questions is NO, make the required corrections or contact the IP System Administrator prior to harvest.

NOTE: If the answers to all of the previous questions are YES, forward this document to the IP System Administrator.

[INTENTIONALLY BLANK]

Field-plot card-index (Form 5)(Version 2, 04.01.06)

This form is to be completed by an authorized and trained person.

Field-plot card-index for potatoes in 20.....

Variety: ..... Kind of utilization ..... Field (extract from land register) .....

Farm (address):..... Size:..... ha (10,000m^2)

Soiltype (nature of the soil) ..... Valuation index of field:..... Annual rainfall (mm):……

Cultivation, Starting after harvest of the Precrop

Preceding crop: .....

Date of harvest: .....

Condition of soil: .....

Stubblefield cultivation: .....

Green manure: .....

Further cultivation till planting: .....

.....

.....

Declaration concerning Seed Potatoes

Check of the sealing: .....

Category: .....

Calibration: .....

Chitting: .....

Desinfectant: .....

Quantity of seed potatoes/ha:.....

Remarks:.....

.....

.....

Planting / Cultivation

Check of planting machine and and transport trucks: .....

Date of planting: .....

Soil temperature when planting: .....

Date of emerge: .....

Making ridges: .....

Check for foreign varieties:

First date: .....

Second date: .....

Irrigation: .....

Observations (see also page 59) during the season (e.g. weather): .....

.....

Results Soil test from 20:..... pH..... mg P_2O_5..... K_2O..... MgO..... Mn.....

$N\text{-}_{min:}$ date..... kg NO_3 –N/ha ..... checking for nematodes.....

.....

Fertilization

Organic manure:.....

Date :.....

Quantity: ……

Expected nutrients:

N	P_2O_5	K_2O	MgO
.....	.....	.....	.....

Mineral nutrients/ha

Date	N	P_2O_5	K_2O	MgO
.....	.....	.....	.....	.....
.....	.....	.....	.....	.....
.....	.....	.....	.....	.....
Total amount	.....	.....	.....	.....

Tradename of the fertilizers:

.....

.

Chemical weed control

Kind of weeds:.....

Date of application: .....

Trade name: .....

Effectiveness: .....

Remaining weeds: .....

Observations (see also page 59):.....

Parasites

Parasite:.....

Treatment.....

Insecticides: .....

Observations (see also page 59):.....

Treatment against Phytophthora (Potato blight)

Treatment, trade name, date, quantity:

1. .....
2. .....
3. .....
4. .....

Other diseases:.....

Observations (see also page 59):.....…

Harvest

Info to factory: .....

Date of lifting: .....

Disposal from soil and potatoes:.....

Yield/ha:.....

Observations (see also page 59):.....

General observations during the vegetation period

Rain fall	☐ average	☐ above or below average	☐ no comment
If deviating from average specify the difference observed	……..		
Temperature	☐ average	☐ above or below average	☐ no comment
If deviating from average specify the difference observed	……..		
Soil fertility	☐ as usual	☐ different	☐ no comment
If deviating from usual specify the difference observed	……..		
Weed management	☐ as usual	☐ different	☐ no comment
If deviating from usual specify the difference observed	……..		
Treatment against *Phytophthora infestans*	☐ as usual	☐ different	☐ no comment
If deviating from usual specify the difference observed	……..		
Parasites	☐ as usual	☐ different	☐ no comment
If deviating from usual specify the difference observed	……..		
Plant growth and development (e.g. emergence, flower development)	☐ as usual	☐ different	☐ no comment
If deviating from usual specify the difference observed	……..		

General observations after harvest

Volunteer management ☐ as usual ☐ different ☐ no comment

If deviating from usual specify the difference observed ……..

Volunteers outside the managed field ☐ as usual ☐ different ☐ no comment

If deviating from usual specify the difference observed ……..

Other unusual field observations (note any observations not described above e.g. on differences in susceptibility to pests and disease, on differences in the occurrence of beneficials, etc.)

……

……

……

……

……

……

BASF

Genetically modified Starch Potato Program – Form 6

Pre-Harvest Checklist of Potatoes
For
Identity Preservation System Manual

Printed Name:_____

Signature:_____

Title:_____ Possible Harvest Date:_____

Hectares to be harvested:_____

This form is to be completed by an authorized and trained person. (Please, clearly circle the appropriate response.)

1. YES NO Has the IP System Administrator been notified of date of harvest?

2. YES NO Has the potato harvester been adequately cleaned of conventional potatoes?

3. YES NO Have all trucks that are going to be used in the harvest been properly cleaned?

4. YES NO On the potato harvester, have the space of the webs, the picking table, and moving–floor hopper been adequately cleaned?

5. YES NO Are there correct labels in sufficient quantity to mark the containers before they leave the field?

6. YES NO Has the storage building and storage equipment been adequately cleaned?

7. YES NO Are there enough semi–permanent seals available to seal all containers leaving the field?

NOTE: If the answer to any of these questions is NO, make the required corrections or contact the IP System Administrator prior to harvest.

NOTE: If the answers to all of the previous questions are YES, forward this document to the IP System Administrator.

BASF

Genetically modified Starch Potato Program – Form 7

Post–Harvest Checklist
For
Identity Preservation System Manual

Printed Name: _____

Signature: _____

Title: _____ Harvest Date: _____

Hectares Harvested: _____ Harvested by:_____

This form is to be completed by an authorized and trained person. (Please, clearly circle the appropriate response.)

1. YES NO Was the entire field harvested?

2. YES NO Has the potato harvester been adequately cleaned of potatoes?

3. YES NO Have all trucks that have been used for harvest been properly cleaned?

4. YES NO On the potato harvester, have the space of the webs, the picking table, and moving–floor hopper been adequately cleaned?

5. YES NO Were all containers leaving the field correctly labeled?

7. YES NO Did all containers leaving the field have a semi–permanent seal attached to the opening?

7. YES NO Were all containers and their corresponding seal serial number recorded on form A?

NOTE: If the answer to any of these questions is NO, make the required corrections or contact the IP System Administrator prior to leaving the plot area.

NOTE: If the answers to all of the previous questions are YES, forward this document to the IP System Administrator.

BASF

Genetically modified Starch Potato Program – Form 8

Preparation of Potatoes for Grading
For
Identity Preservation System Manual

Printed Name:_____

Signature:_____

Title:_____ Date:_____

This form is to be completed by an authorized and trained person. (Please, clearly circle the appropriate response.)

1. YES NO Are the potatoes in a locked and secured storage area?

2. YES NO Has the potato transport equipment been adequately cleaned of potatoes?

3. YES NO Has the grading equipment been adequately cleaned of potatoes?

NOTE: If the answer to any of these questions is NO, make the required corrections or contact the IP System Administrator prior to leaving potato grading storage area.

NOTE: If the answers to all of the previous questions are YES, forward this document to the IP System Administrator.

BASF

Genetically modified Starch Potato Program – Form 9

Post-Grading Activities
For
Identity Preservation System Manual

Printed Name: _____

Signature: _____

Title: _____ Date: _____

This form is to be completed by an authorized and trained person. (Please, clearly circle the appropriate response.)

1. YES NO Are the potatoes in a locked and secured storage area?

2. YES NO Are the potatoes stored in a separate area away from conventional potatoes?

3. YES NO Are the potatoes labeled correctly and clearly?

4. YES NO Has the potato transport equipment been adequately cleaned of potatoes?

5. YES NO Has the grading equipment been adequately cleaned of potatoes?

6. YES NO Were the unusable potatoes and their cleanings, which resulted from processing, properly disposed of?

_____

_____

_____

_____

_____

NOTE: If the answer to any of these questions is NO, make the required corrections or contact the IP System Administrator prior to leaving potato grading storage area.

NOTE: If the answers to all of the previous questions are YES, forward this document to the IP System Administrator.

BASF

Genetically modified Starch Potato Program – Form 10

Preparation of Potatoes for Processing
For
Identity Preservation System Manual

Printed Name: _____

Signature: _____

Title: _____ Date: _____

This form is to be completed by an authorized and trained person. (Please, clearly circle the appropriate response.)

1. YES NO Are the potatoes in a locked and secured storage area?
2. YES NO Have the factory storage bins been adequately cleaned of potatoes?
3. YES NO Has the wet–processing part of the factory been adequately cleaned of potatoes?
4. YES NO Has the factory vacuum filter been adequately cleaned of potatoes?
5. YES NO Has the dry–processing part of the factory been adequately cleaned of potatoes?
6. YES NO Has the potato transportation equipment been adequately cleaned of potatoes?
7. YES NO Have appropriate steps been taken to ensure that no mixing occurs?

NOTE: If the answer to any of these questions is NO, make the required corrections or contact the IP System Administrator prior to leaving potato grading storage area.

NOTE: If the answers to all of the previous questions are YES, forward this document to the IP System Administrator.

BASF

Genetically modified Starch Potato Program – Form 11

Post–Processing Checklist
For
Identity Preservation System Manual

Printed Name: _____

Signature: _____

Title: _____ Date: _____

This form is to be completed by an authorized and trained person. (Please, clearly circle the appropriate response.)

1. YES NO Is the starch from genetically modified potatoes in a locked and secured storage area?

2. YES NO Is the starch from genetically modified potatoes properly labeled?

3. YES NO Has the wet–processing part of the factory been adequately cleaned of genetically modified potatoes?

4. YES NO Has the factory vacuum filter been adequately cleaned of genetically modified potatoes?

5. YES NO Has the dry–processing part of the factory been adequately cleaned of genetically modified potatoes?

6. YES NO Has the potato transportation equipment been adequately cleaned of genetically modified potatoes?

7. YES NO Have appropriate steps been taken to ensure that no mixing will occur?

8. YES NO Have the unusable by–products such as potato juice, wastewater, soil, stones, and unusable potato remnants been properly disposed of?

NOTE: If the answer to any of these questions is NO, make the required corrections or contact the IP System Administrator prior to leaving potato grading storage area.

NOTE: If the answers to all of the previous questions are YES, forward this document to the IP System Administrator.

BASF

Genetically modified Starch Potato Program – Form A

Record of Shipment of Potatoes
For
Identity Preservation System Manual

Printed Name: _____

Signature: _____

Title: _____ Shipment Date: _____

Shipping to: _____

Total amount of containers on truck: _____

Truck ID: _____ Driver: _____

This form is to be completed by an authorized and trained person.

Container ID Number	Number of Semi – Permanent Seal or Label

When this document is full or complete forward immediately to IP System Administrator.

BASF

Genetically modified Starch Potato Program – Form B

Record of Receipt of Shipment of Potatoes
For
Identity Preservation System Manual

Printed Name: _____

Signature: _____

Title: _____ Receiving Date: _____

Receiving from: _____

Total amount of containers on truck: _____

Truck ID: _____ Driver: _____

Location of Storage: _____

This form is to be completed by an authorized and trained person.

Container ID Number	Number of Semi – Permanent Seal or Label

When this document is full or complete forward immediately to IP System Administrator.

BASF

Genetically modified Starch Potato Program – Form C

Record of Shipment of pulp from Genetically modified potatoes For Identity Preservation System Manual

Printed Name: _____

Signature: _____

Title: _____ Shipment Date: _____

Shipping to: _____

Total amount of containers on truck: _____

Truck ID: _____ Driver: _____

This form is to be completed by an authorized and trained person.

Container ID Number

When this document is full or complete forward immediately to IP System Administrator.

BASF

Genetically modified Starch Potato Program – Form D

Record of Receipt of Shipment of Pulp from genetically modified Potatoes For Identity Preservation System Manual

Printed Name: _____

Signature: _____

Title: _____ Receiving Date: _____

Receiving from: _____

Total amount of containers on truck: _____

Truck ID: _____ Driver: _____

Location of Storage: _____

This form is to be completed by an authorized and trained person.

Container ID Number

When this document is full or complete forward immediately to IP System Administrator.

Appendix D - Index of Records

[to be completed during implementation]

Appendix E

BASF IP System Grower Participation Agreement