

ANNEX 12

IMPLEMENTATION AND INTEGRITY OF THE AMFLORA IDENTITY PRESERVATION SYSTEM

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**IMPLEMENTATION AND INTEGRITY OF THE
AMFLORA IDENTITY PRESERVATION SYSTEM**

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General

The following provides an outline of all elements of the Amflora Identity Preservation (IP) system that are relevant in addressing the Amflora post-market monitoring plan as well as the monitoring conditions of the consent for Amflora cultivation issued by the Swedish Board of Agriculture. General surveillance as described in the Amflora monitoring plan includes the integrity of the IP system, as well as the general observations of all growers throughout the growing season. The IP system manual, version 21 May 2003, was used in the 2010 season including the field-plot card-index (Form 5) in its revised version from 2005 and is provided as Annex 1 to the 2010 monitoring report. All IP system documents were distributed to contractors and users of Amflora as applicable in Czech, German and Swedish. All records relating to the IP system are kept by BASF Plant Science.

Training

All contractors received training on the IP system by BASF Plant Science. Training and training materials were provided both in English and the respective local language. The trained managers were responsible to train all personnel handling Amflora or Amflora material. The training presentation in English is included as Annex 5 to the post-market monitoring report. An additional form, Form 112, complementing the IP system was developed to document the training participation, and is attached to this IP system report (see Document 1). The dates of the training sessions are listed in Table 1.

Table 1. IP system training dates in 2010

Date	Trainer	Country
14 April	BASF	DE
16 April	BASF	CZ
20 April	BASF	SE
28 April	Contractor	CZ
10 May	Contractor	SE
12 May	Contractor	CZ
12 May	Contractor	CZ
14 May	Contractor	CZ
17 May	Contractor	CZ
20 May	Contractor	DE
27 May	BASF	SE
5 June	Contractor	SE
9 June	Contractor	SE

This element addresses the conditions 7 and 9(a) of the Consent or Articles 3(g) and 4.1(a) of Commission Decision 2010/135/EU as they relate to informing operators and users of the legal requirements as well as informing growers and starch processors of the obligations described in the IP system. It also includes the training related to observations to be performed by the growers outlined in the field-plot card-index Form 5 of the IP system.

Transport

In order to cover all steps of transportation and shipment of Amflora tubers the IP system manual requires the use of Form 1 (Checklist for the packaging and transport of seed potatoes) and Form 2 (Checklist for the receipt and storage of seed potatoes at the farm) as checklists for all sealed seed potato transports to the farms, and Form A (Record of shipment of potatoes) and Form B (Record of receipt of shipment of potatoes) to document potato shipments accompanied by sample lists. This measure enabled to establish a complete list of all potato tuber containers moved. In addition, the forms were also used for other transports of potatoes. The checklists ensure and document that relevant IP system rules have been followed. The described process is in compliance with the condition of the consent to separate Amflora tubers during transport, storage and handling from potato tubers intended for food or feed use (Conditions 8(a) and (b) of the Consent or Articles 3(h)(i) and (ii) of Commission Decision 2010/135/EU).

Planting

The Amflora quality management as implemented by the IP system requires the use of Form 3 (Pre-planting checklist of seed potatoes at the farm) and Form 4 (Post-planting checklist of seed potatoes) as checklists before and after planting of Amflora tubers. The checklists ensure and document that all relevant IP system rules have been followed. This process is in compliance with the condition of the consent to separate Amflora tubers during planting from potato tubers intended for food or feed use (Condition 8(a) of the Consent or Article 3(h)(i) of Commission Decision 2010/135/EU).

Monitoring

As part of the Amflora quality management and as implemented by the IP system growers are required to keep records of relevant farm data and the agricultural practice that is applied to cultivating Amflora potatoes. This information is captured in

the Form 5 of the IP system manual and was completed by all growers during the growing season 2010. In addition and in a separate section, Form 5 (Field-plot card-index) also asks farmers to record observations or monitoring characters that relate to Amflora and possible effects of growing Amflora on the agro-ecosystem. In order to allow an evaluation of the information reflected in this section of Form 5, the growers were interviewed and the results of the interviews were captured in the Amflora farm questionnaire. The results of the farm questionnaire evaluation are presented in the biometrical report in **Annex 7** to the Post-market monitoring report. The implementation of Form 5 and the farm questionnaire address the requirements as outlined in the Amflora monitoring plan and address the condition of general surveillance as in Article 9(a) and (d) of the Consent or Article 4.1(a) and (d) of Commission Decision 2010/135/EU. Observations relating to volunteer management as described in Form 5 will be performed in the 2011 growing season and presented in the Amflora post-market monitoring report 2011.

Harvest

The Amflora quality management as implemented by the IP system requires the use of Form 6 (Pre-harvest checklist of potatoes) and Form 7 (Post-harvest checklist) before and after harvest of Amflora tubers, respectively. The checklists ensure and document that all relevant IP system rules have been followed. This process is in compliance with the condition of the consent to separate Amflora tubers during harvest from potato tubers intended for food or feed use (Article 8 (a) of the Consent or Article 3(h)(i) of Commission Decision 2010/135/EU).

Grading (Sorting)

The Amflora quality management as implemented by the IP system requires the use of Form 8 (Preparation of potatoes for grading) and Form 9 (Post-grading activities) as checklists before and after sorting of Amflora tubers, respectively. The checklists will ensure and document that all relevant IP system rules have been followed. The sorting of 2010 harvest will take place in early spring, therefore is not part of this IP system report and will be covered in the Amflora post-market monitoring report 2011.

Processing

In order to cover the steps of potato processing in the Amflora quality management the IP system manual requires the use of Form 10 (Preparation of potatoes for processing) and Form 11 (Post-processing checklist). The use of these checklists before and after processing of Amflora tubers ensures and documents that all

relevant IP System rules were followed. Form C (Record of shipment of pulp from genetically modified potatoes) and Form D (Record of receipt of shipment of pulp from genetically modified potatoes), as required by the IP system manual, document all pulp shipments and list all pulp containers moved. In 2010, a spring and an autumn campaign were conducted at the starch factory in the Czech Republic. The resulting by-product pulp was not used for animal feed. The described process is in compliance with the condition of the consent to separate the processing of Amflora tubers and processed products by time or space from potato tuber material intended for food or feed use (Article 8 (b) of the Consent or Article 3(h)(ii) of Commission Decision 2010/135/EU).

Labelling

An important element of a quality management tool such as the Amflora IP system manual is to ensure traceability and labelling. A document was developed to capture all labelling rules as applicable to seed potatoes, starch potatoes, starch, and pulp, and was included in the IP system as Document A. It is attached to this IP system report (see Document 2). This document thereby also addresses Articles 2, 5 and 6 of the Consent or Articles 3(b), 3(e) and 3(f) of Commission Decision 2010/135/EU.

Storage

In order to comply with the condition of the consent to physically separate Amflora tubers in storage from potato tubers intended for food or feed use (Articles 8(a) and (b) of the Consent or Articles 3(h)(i) and (ii) of Commission Decision 2010/135/EU) the Amflora IP system manual was complemented with Form 109 on storage. This Storage Index form is attached to this IP system report (see Document 3), and was used in the 2010 season.

Visits and Audits

According to the rules of the Amflora IP system manual a BASF Plant Science representative or delegate monitors the potato cultivation process three times throughout the vegetation period. In addition, BASF Plant Science conducts at least three audits per year: around planting time, during the growing season and around harvest time. Further, according to BASF Plant Science Quality Assurance rules, all seed potato multiplication fields are regularly visited by BASF Plant Science field personnel. Furthermore, two audits are performed per year and per field. The dates of all visits including those to the starch factory are listed in Tables 2, 3, 4 and 5, audits are presented in Table 6. A field visit is defined as a visit performed by BASF

Plant Science field personnel or delegate with the aim to monitor e.g. plant growth and development, storage facilities. An audit is conducted by the auditor with the aim to confirm compliance with applicable rules. The audit is documented in an audit report.

Table 2. Field visits Sweden in 2010

Date
9-11 May
27-28 May
4 June
9-10 June
17-18 June
23-24 June
30 June
7 July
13-14 July
28 July
4-6 August
11 August
13 August
17-18 August
24-25 August
26 August
6-9 September
19-21 September
29 September
1-3 October
5-6 October
10-15 October
1 November
16-19 November
21-24 November

Table 3. Field visits Germany in 2010

Date
7 April
19 April
29 April
11 May
17 May
1 June
2 June
8 June
10 June
15 June
22 June
23 June
24 June
28 June
29 June
8 July
9 July
13 July
14 July
27 July
28 July
9 August
11 August
13 August
16 August
23 August
26 August
27 August
30 August
31 August
10 September
15 September
20 September
28 September
29 September
30 September
1 October
2 October
4 October
5 October
21 October
12 November
24 November

Table 4. Field visits Czech Republic in 2010

Date
12 May
18 May
19 May
24 May
2 June
9 June
15 June
23 June
15 July
20 July
21 July
22 July
29 July
30 July
5 August
19 August
2 September
10 September
22 September
1 October
7 October
8 October
14 October
19 October
20 October
25 October
8 November

Table 5. Starch factory visits Czech Republic in 2010

Date
27 April
4 May
5 May
6 May
7 May
18 May
24 May
22 September
1 October
7 October
14 October
19 October
25 October
8 November
15 November
24 November
6 December
14 December

Table 6. Field audits in 2010

CZ
24-25 May
29-30 July
19-20 October
SE
10/11/27 May
11-13 May
10 June
23-24 June
13-14 July
17-18 August
24-26 August
20 September
21 September
DE
19 April
26 April
2 July
9 July
30 August
29 September

The occurrence of off-type potatoes in the Amflora potato fields was noticed during the course of field visits and audits by BASF Plant Science on August 13, 17, 18 and 25 in Sweden. The authorities were immediately informed after molecular confirmation of the identity of the off-type potatoes became available. The following provides a brief summary of the report that was handed over to the authorities by BASF Plant Science.

Unintentional comingling of Amadea type potato plants (AM04-1020 Amylopectin Potato, BPS-A1Ø2Ø-5) in field sites for seed propagation of Amflora potatoes (EH92-527-1 Amylopectin Potato, BPS-25271-9) in Northern Sweden

BASF Plant Science is submitting the attached report at the behest of the Swedish Competent Authorities. It provides the summary conclusions of BASF Plant Science' root cause analysis of the identified comingling of Amadea in two Amflora seed lots under cultivation in Northern Sweden in 2010. DG Sanco and the Competent Authorities of the cultivating countries Sweden, Czech Republic and Germany have been briefed on the progress of the root cause analysis at meetings on September 8, 2010, in Brussels, Belgium, and on September 15-16, 2010, in Gatersleben, Germany.

The reported comingling was identified through BASF Plant Science' internal quality assurance controls. BASF Plant Science self-reported the incident to the Swedish Competent Authorities on August 27, 2010, before the lots were harvested. No unapproved potatoes have entered the commercial starch production. BASF Plant Science is certain that there has been no damage to the environment and that the comingling did not endanger human or animal health. All safety assessments on Amadea have been concluded and the registration dossier was submitted to the Member State Sweden, on August 30, 2010.

Of the 15 Amflora seed lots under cultivation in 2010, only two showed comingling with Amadea. The root cause was traced back to two separate human errors during the early phases of the minituber production. One additional lot has been classified at risk by BASF Plant Science because it could have been comingled with Amadea the same way as in one of the confirmed cases. No Amadea off-type potatoes were identified during the cultivation of this seed lot. There is no evidence to suggest that the 12 remaining seed lots contain any Amadea.

Even though BASF Plant Science only found Amadea plants in 5 out of 8 fields where the affected lots were planted, BASF Plant Science is recommending to destroy the entire Amflora seed lots that proved to be comingled with Amadea and to also discard the one lot that is considered at risk. All remaining Amflora lots will be sampled and monitored to confirm the absence of Amadea in agreement with the Competent Authorities.

Document 1. Form 112 Confirmation of Employee Training

**Form 112:
Confirmation of Employee Training**

Must be used!

Company: _____

- IP System (work instructions, forms, documents, checklists)
- Handling GM material (receipt, shipment, transport, storage)
- Handling GM material (utilization, disposal)
- Compliance with the provisions of approvals (e.g. general observation)
- Labeling
- Cleaning of machinery and equipment before and after use
- Monitoring for volunteer plants
- Procedure to follow in the event of special incidents

- Name(s) and signature(s) of trained person(s):

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

- I confirm that the named individual(s) has(ve) received training prior to carrying out the above tasks.

(Date, name and signature of responsible person)

Send completed form to Amflora IP system administrator Fax: _____ E-mail: _____
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Document 2. Document A Labelling

**Document A:
Labelling**

Amflora potatoes and the products produced from them require at least the following labelling on the packaging and the relevant accompanying documents. The labelling specification results from the provisions contained in the decisions of the Commission 2010/135/EU and 2010/136/EU.

Product	Labelling
Seed potatoes	<i>This product contains genetically modified amylopectin starch potatoes. Unique identifier BPS-25271-9. Not for human consumption. Not for animal consumption.</i>
Starch potatoes	<i>This product contains genetically modified amylopectin starch potatoes. Unique identifier BPS-25271-9. Not for human consumption. Not for animal consumption.</i>
Potato tubers for disposal	<i>This product contains genetically modified amylopectin starch potatoes. Unique identifier BPS-25271-9. Not for human consumption. Not for animal consumption.</i>
Starch	<i>Produced from amylopectin starch potatoes. For industrial use only. Not for human consumption.</i>
Pulp for disposal	<i>Produced from amylopectin starch potatoes. By-product for disposal.</i>
Pulp for animal feed	<i>Produced from genetically modified amylopectin starch potatoes. Unique identifier BPS-25271-9. Not for human consumption.</i>

Additional labelling specifications may apply as a result of national seed potato legislation and other applicable legislation.

Document 3. Form 109 Storage Index

**Form 109:
Storage Index**

Must be used!

Warehouse designation: _____

Seed stock <input type="checkbox"/>	Only complete for seed stock
Starch potatoes <input type="checkbox"/>	Level:
Starch <input type="checkbox"/>	Planted out as:
<input type="checkbox"/>	
Serial number / batch number:	Land parcel:
Labelling:	
Tonnage / no. of containers:	Area in ha:
Put into storage on:	Put into storage by: surname, first name; signature
Taken from storage on: Transferred to: place	Taken from storage by: surname, first name; signature