

ANNEX 11

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 2011 season including the field-plot card-index (Form 5) in its revised version from 2005 and is provided as Annex 1 to the 2011 monitoring report. All IP system documents were distributed to contractors and users of Amflora. 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 in 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 2011

Date	Trainer	Country
26.04.	BASF	SE
28.04.	BASF	DE
05.05.	Contractor	SE
07.05.	BASF	DE
26.05.	BASF	SE
27.05.	BASF	SE
08.06.	Contractor	SE
12.06.	Contractor	SE
31.08.	BASF	DE
16.09.	Contractor	SE
27.09.	BASF	SE
30.09.	Contractor	SE
28.11.	Contractor	SE
30.11.	BASF	SE

These trainings address 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. They also referred 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 Amflora 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 2011. 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, all growers filled an additional questionnaire (Amflora farm questionnaire, Annex 6 to the Post-Market Monitoring Report). These Amflora farm questionnaires were analyzed and evaluated. 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 have been performed in the 2011 growing season three times during the vegetation period by the grower who cultivated Amflora in 2010 (Table 2). In addition, BASF Plant Science personnel has conducted several controls to ensure that the volunteer monitoring has been done appropriately.

Table 2. Volunteer Monitoring at fields cultivated 2010 conducted by the grower in 2011

Field	Dates [dd.mm.]	Potato volunteer plants found [yes/no]
SE		
10Amflora-JB1	28.06., 14.07., 23.08.	no
10Amflora-JB2	28.06., 14.07., 23.08., 05.09.	no
10Amflora-LBS1	28.06., 14.07., 16.09., 23.09.	yes
10Amflora-LBS2	28.06., 14.07., 16.09., 23.09.	yes
10Amflora-LBS3	28.06., 14.07., 05.09., 16.09.	yes
10Amflora-EH1	28.06., 14.07., 05.09.	no
10Amflora-EH2	28.06., 14.07., 05.09.	yes
10Amflora-ML2	18.07., 03.08., 29.08.	yes
10Amflora-ML3	18.07., 03.08., 29.08.	no
10Amflora-ML4	18.07., 03.08., 29.08.	no
10Amflora-ML5	18.07., 03.08., 29.08.	yes
10Amflora-ML6	18.07., 03.08., 29.08.	no
10Amflora-ML7	18.07., 03.08., 29.08.	yes
10Amflora-ML8	18.07., 03.08., 29.08.	no
10Amflora-RN1	19.07., 05.08., 30.08.	no
10Amflora-RN2	19.07., 05.08., 30.08.	no
10Amflora-RN3	19.07., 05.08., 30.08.	no
10Amflora-RN4	19.07., 05.08., 30.08.	no
DE		
10Amflora-N1&N2	09.05., 24.05., 15.06., 12.07., 22.08., 26.09.	no
CZ		
CZ01-5502	08.06., 13.07., 24.08., 28.09.	no
CZ02-4601/1	08.06., 13.07., 24.08., 28.09.	no
CZ03-7703/1	30.05., 29.07., 30.09.	no
CZ04-7705/6	30.05., 29.07., 30.09.	no
CZ05-7705/2	30.05., 29.07., 30.09.	no
CZ06-0402/11	30.04., 31.07., 30.09.	no
CZ07-0402/1	30.04., 31.07., 30.09.	no

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 ensure and document that all relevant IP system rules have been followed. The sorting of 2010 harvest material took place in early spring 2011.

Processing

In 2011, no processing of Amflora potatoes took place.

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 added to 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 2011 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 Stewardship 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 are listed in Tables 3 and 4, audits are presented in Table 5. 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 3. Field visits Sweden in 2011

Date [dd.mm.]
07.05. + 08.05.
13.05.
18.05.
03.06.
10.06. – 13.06.
20.06.
28.06.
04.07. – 07.07.
11.07. – 14.07.
18.07. – 20.07.
25.07. – 29.07.
03.08. – 04.08.
08.08. – 09.08.
13.08.
16.08. – 17.08.
22.08. – 23.08.
29.08. – 30.08.
05.09. – 07.09.
15.09. – 17.09.
25.09. - 27.09.

Table 4. Field visits Germany in 2011

Date [dd.mm.]
25.03.
08.04.
07.05.
02.06.
08.06.
17.06.
21.06.
22.06.
29.06.
06.07.
11.07.
18.07.
25.07.
03.08.
10.08.
19.08.
24.08.
26.08.
31.08.

Table 5. Field audits in 2011

Date [dd.mm.]	Country
06.05.	DE
13.05.	SE
09.06.	SE
29.06.	DE
14.07.	SE
31.08.	DE
16.09. + 17.09.	SE
30.09. + 01.10.	SE

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)
- Labelling
- 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