‚HoneySweet': a RNAi based PPV resistant plum

Preparation of the dossier for cultivation in EU

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iPlanta

iPlanta Webinars: RNAi plant technology

https://www.iplantawebinars.com/

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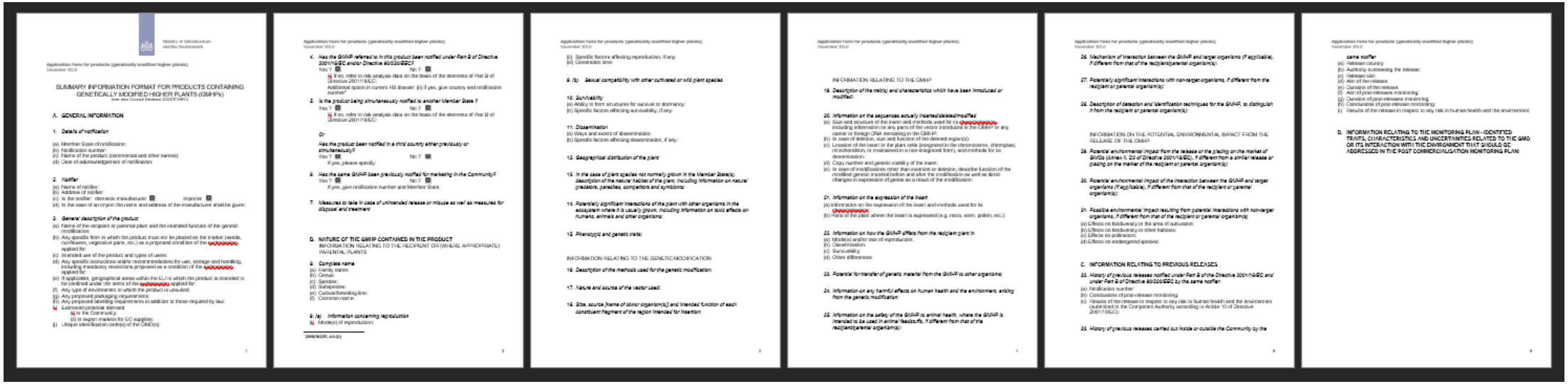
Procedure:

- **Applicant**: the Public Research Specialty Crops Approval Association (PRESCAA)
- **National Competent Authority**: The Netherlands
- Preparation of the **dossier for cultivation** of ‚HoneySweet' plum in EU

NL Application form for the GMO dossier

SUMMARY INFORMATION FORMAT FOR PRODUCTS CONTAINING

GENETICALLY MODIFIED HIGHER PLANTS (GMHPs)



https://www.ggo-vergunningverlening.nl/ma-downloads

Outline of the application form

A. General information

B. Nature of the GMHP contained in the product

C. Information relating to previous releases

D. Information relating to the monitoring plan

A. General information

1. Details of notification

(a) Member State of notification: Netherlands

(b) Notification number: To be filled in by NL CA

(c) Name of the product (commercial and other names): 'HoneySweet' plum (C5 plum)

(d) Date of acknowledgement of notification: To be filled in by NL CA

2. Notifier

(a) Name of notifier: The Public Research Specialty Crops Approval Association AISBL hereafter: "The Association".
The Association has the objective to collaborate in the facilitation of making available, in the European Union and globally, genetically modified crops that are developed by or with the contribution of public research institutes. Members of the Association include public research institutes involved in the development and/or testing of 'HoneySweet' Plum.

A. General information

Romania produces almost half of the total production volume in the EU.

European Union (EU) member states in 2018	Plum and sloe production in 2018 (tonnes)	% of total EU plum and sloe production in 2018
Romania	842132	47,61
Italy	197733	11,18
France	181947	10,29
Spain	152984	8,65
Poland	121076	6,85

(FAOSTAT database, 2018)

A. General information

- HoneySweet’ plum is **intended to be used** as conventionally produced plum trees, e.g., for cultivation, consumption and processing.

- **The type of users of ‘HoneySweet’** plum are the same as the type of users of conventionally produced plum trees.

- ‘HoneySweet’ plum is **intended to be cultivated** as conventionally produced plum trees.

- is intended to be **confined under the terms of the authorization** applied for all EU countries (in as far as not excluded in accordance with Directive 2015/412.)

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B. Nature of the GMHP contained in the product

- **Information relating to the recipient**
- Information relating to the genetic modification
- Information relating to the GMHP
- Information on the potential environmental impact from the release of the GMHP

Information relating to the recipient

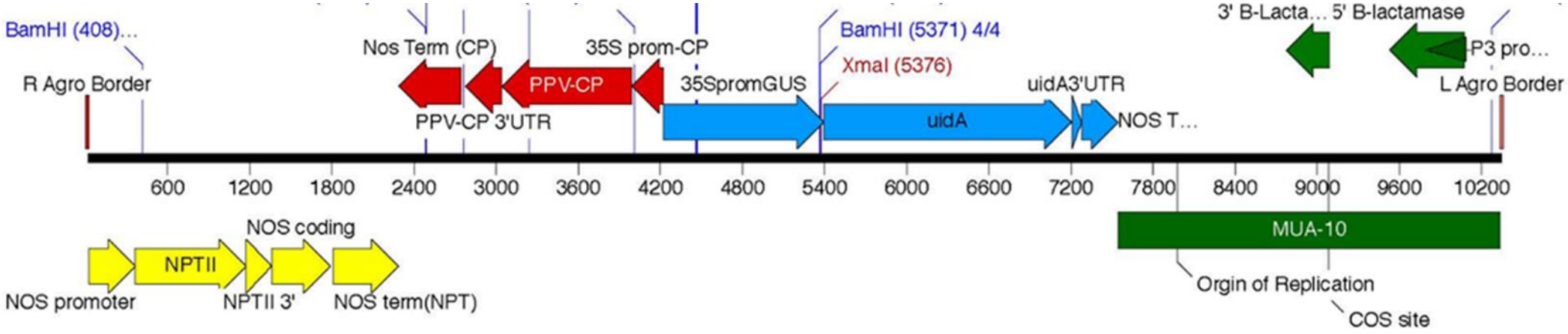
- Cultivar: ‚Bluebird' (hexaploid, self-sterile)
- Sexual compatibility between cultivated/wild species
- Survivability, dissemination, interaction with the environment
- Phenotypic and genotypic traits

B. Nature of the GMHP contained in the product

- Information relating to the recipient
- **Information relating to the genetic modification**
- Information relating to the GMHP
- Information on the potential environmental impact from the release of the GMHP

Information relating to the genetic modification

- Agrobacterium-mediated transformation
- Vector encoding *PVV-CP* gene
- Co-cultivation with hypocotyl slices, plant regeneration



B. Nature of the GMHP contained in the product

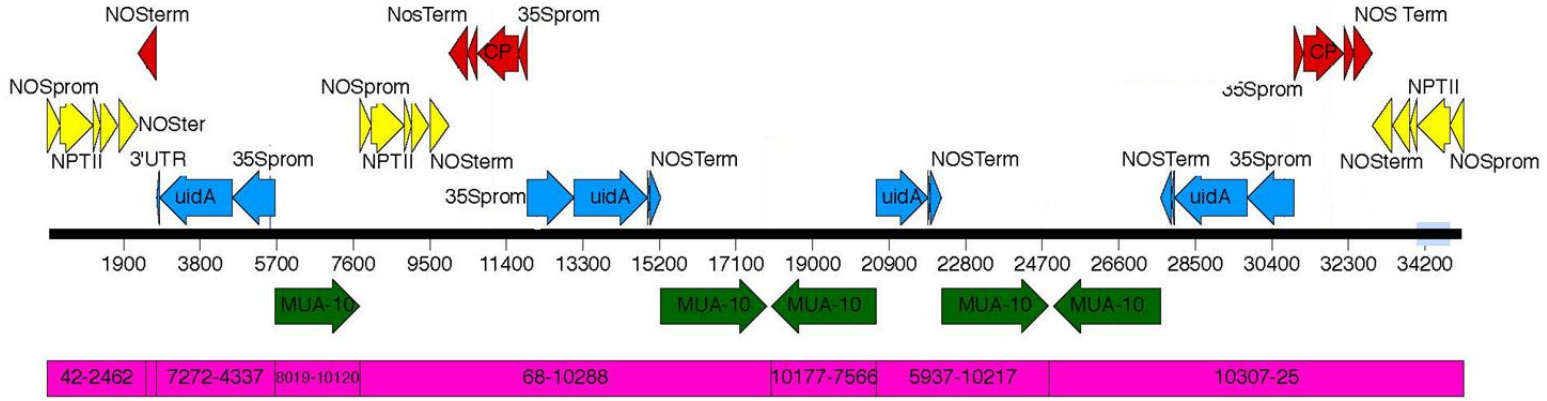
- Information relating to the recipient
- Information relating to the genetic modification
- **Information relating to the GMHP**
- Information on the potential environmental impact from the release of the GMHP

Information relating to the GMHP

- **Insertion 1:**

five partial copies

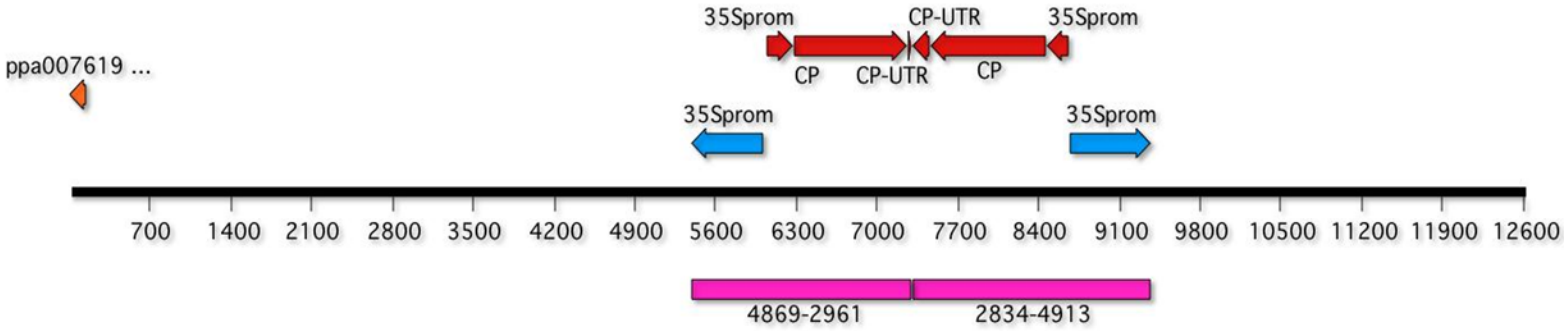
two complete copies



- **Insertion 2:**

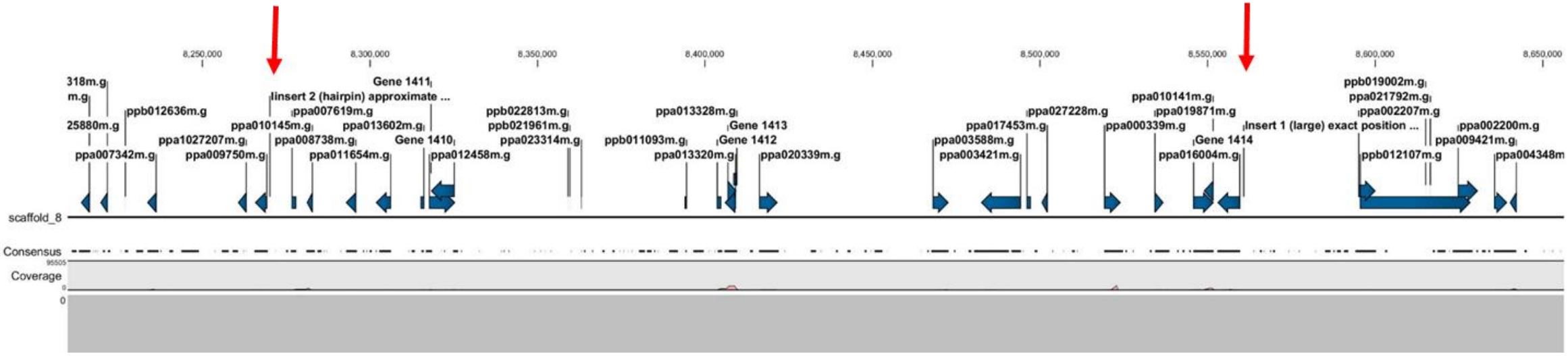
two partial copies

> Hairpin structure



Information relating to the GMHP

The two insertions do not disrupt any predicted native plum genes.



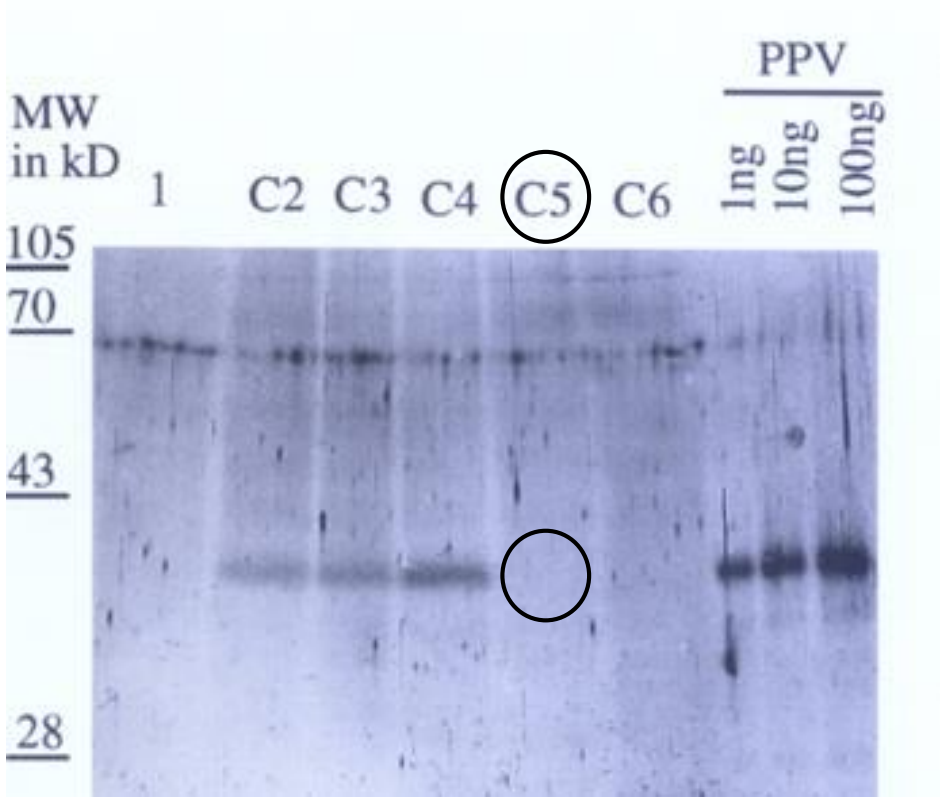
Information relating to the GMHP

Gene	**Expression level (mRNA)**
UidA (GUS)	moderate
NPTII	low
PPV-CP	low
pBR322-MAU-10	none

> The lack of *PPV-CP* expression has been maintained for over 15 years of field trials with HoneySweet clones!

Information relating to the GMHP

No PVV-CP protein detected in HoneySweet (or C5)



„The HoneySweet plum does not express the coat protein from PPV at detectable levels, which **eliminates concern of protein exposure to non-target organisms**.”

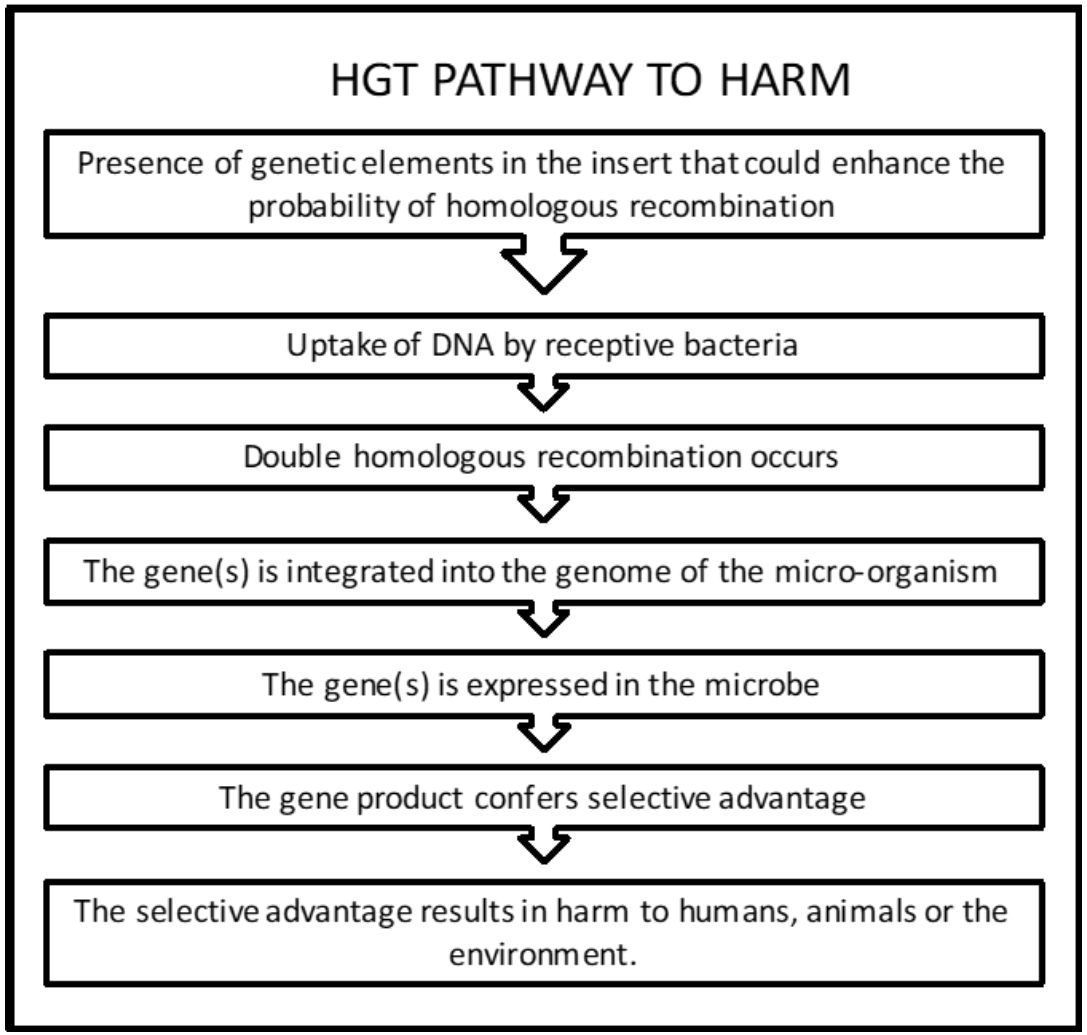
Information relating to the GMHP

- Information on how the GMHP **differs from the recipient plant**
- Potential for **transfer of genetic material** from the GMHP to other organisms?

> **Gene transfer to naturalized *Prunus* species** in the EU is limited because of ploidy differences and the limited success of interspecific hybrids.

> There is no evidence of gene flow from HoneySweet plum **to microorganisms.**

Information relating to the GMHP



„The likelihood that the cultivation of HoneySweet plum in the EU will result in harmful effects in human or animal health or the environment **as a consequence of HGT is negligible**."

B. Nature of the GMHP contained in the product

- Information relating to the recipient
- Information relating to the genetic modification
- Information relating to the GMHP
- **Information on the potential environmental impact from the release of the GMHP**

Information on the potential environmental impact from the release of the GMHP

Risk assessment is required: indicate for each of the 9 areas of concern as given in D. 2 of Annex II why this there is a concern or not.

9 areas:

1. Likelihood of the GMHP becoming **more persistent** than the recipient or parental plants in agricultural habitats or **more invasive** in natural habitats?

2. Any **selective advantage or disadvantagee** conferred to the GMHP?

Etc.

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C. Information relating to previous releases

- **USA**:

- first field testing in 1995
- Unregulated cultivation since 2007

- Field testing in **EU**: Czech Republic, Romania, Poland and Spain

„**No immediate or delayed adverse effects** as a result of the direct and indirect interaction of the genetically modified plum with the environment have been identified.”

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D. Information relating to the monitoring plan

- A **general** surveillance plan is mandatory: e.g., in the occurrence of unforeseen adverse effects
- A **case-specific** monitoring plan is not considered necessary.

EFSA Transparency Regulation

Regulation (EU) 1381/2019, the ‘Transparency Regulation’: regulation on the transparency and sustainability of the EU risk assessment in the food chain:

- ensuring more transparency
- increasing the independence of studies
- strengtening scientific cooperation
- deverloping comprehensive risk communication

> into application in March 2021

https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation

I would like to thank the Association for all their support! Contact: nvgheluw@gmail.com