



iPlanta Webinars: RNAi plant technology

28 January 2021: Honey Sweet, a RNAi based PPV resistant plum

iPlanta

The 'HoneySweet' dossier for authorization of cultivation in the EU

Introduction

Piet van der Meer

1986 – 2000: In charge of biosafety/GMO regulation in the Netherlands

2000 – 2002: Supporting EU accession countries with biosafety/GMO regulation

2002 – 2004: Leading the UNEP-GEF Biosafety Implementation Project

2004 – today: Supporting public research institutes, international organisations and governments

2006 – today: Teaching Biotechnology Regulation at various universities

HoneySweet Plum: a test case

- Since 1990, the EU rules for GMOs have changed several times, most recently with Reg. 1381/2019 on risk assessment transparency (entry into force March 2012).
- However, since 2012 there have been no submissions for cultivation.
- The HoneySweet dossier can be a good ‘test case’, because of several novelties:
 - Product developed by the public research sector
 - Perennial tree instead of an annual crop plant
 - RNAi
 - Cultivation and consumption (consumption of unprocessed product)
- The experience with the process will be shared with public sector research institutes.

Paths of dossier submission

- For placing on the market of GM crops in the EU there are various paths:
 1. Food/Feed: Regulation 1829/2003 (e.g. import)
 2. Cultivation: Directive 2001/18 (e.g. ornamental flowers)
 3. Food/Feed + cultivation:
 - a) Reg. 1829/2003 and Dir. 2001/18 via Reg. 1829 ('one door one key')
 - b) Reg. 1829/2003 and Dir. 2001/18 separately/consecutively
- For HoneySweet choice for Path 3b: first submission of the cultivation dossier via the NL CA, followed by submission of food/feed dossier via the CZ CA

Submission by an association

- International non-profit association (AISBL): “*Public Research Specialty Crops Approval Association*” (PRESCAA)
- Purpose: to collaborate on facilitating availability of regulated crops that are developed by public research institutes for the common good.
- Activities:
 - Preparing and submitting regulatory dossiers
 - Collaborating with research groups and other organizations
 - Organizing workshops, conferences, seminars etc.
 - Collecting, analysing, exchanging, comparing, and disseminating information
 - Facilitating public sector research and development of genetically modified crops

Volunteer support from many

- Scientists
- Organisations
- Companies
- Etc.

The Association thanks you warmly!