MS11 – how to risk assess?

PART II

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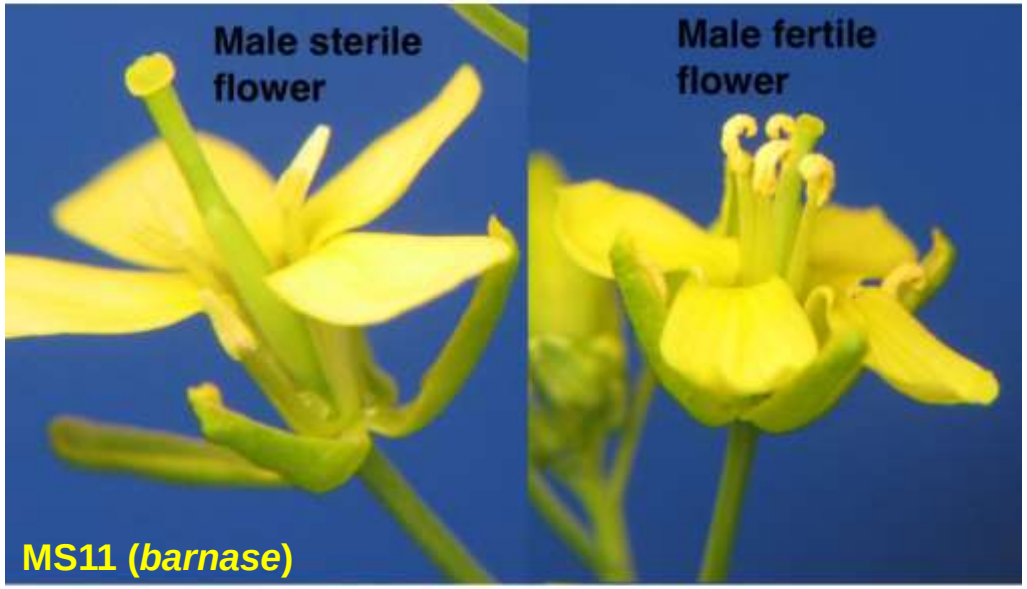
BACKGROUND - EVENT MS11

- GM oilseed rape (MS = Male Sterile)
- Part of breeding system to produce hybrid seed (MS11 x RF3)
- HT (glufosinate-ammonium tolerant)
- Is not placed on the EU market as single event, but as mixture of MS11 x RF3, MS11, RF3



BACKGROUND - RISK ASSESSMENT MS11 (EFSA)

Request by COM to assess as a single event to be imported as food/feed

Difficulties:

- Lack of MS11 material for the comparative analyses, in particular compositional analysis of MS11
- Evaluation of toxicity, allergenicity & nutritional value could not be completed

⇒ Inconclusive for 'food/feed' safety (hypothetical import scenario);

⇒ Accidental import does not raise safety issues (true import scenario)

BACKGROUND – STEPS TAKEN BY BELGIUM

- **2nd of April 2020** Publication of Scientific opinion of EFSA on MS11
- **1st of July 2020** Publication Advice of Biosafety Advisory Council
  - Agreement with EFSA that assessment of full feed/feed is not possible
  - Notes OSR M11 is not intended to be commercialized
  - Questions the scientific relevance of assessing a 'hypothetical product' not to be marketed
  - Seen as example of unnecessary workload & waste of time and money
- **15th of Sept 2020** Presentation of EFSA at SCOPAFF meeting
- **2nd of Oct 2020** Mail sent to COM on Belgian's viewpoint on handling of MS11
- **10th of Oct 2020** Belgium explained it's viewpoint at SCOPAFF meeting
- **19th of April 2021** First discussion at SCOPAFF meeting
- **8th of June 2021** Asked for update on MS11

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RISK ASSESSMENT MS11 APPROACHES

Approach followed: **MS11 is assessed for its full food/feed use in separate application**

- Reasons (are vague):
  - MS11 needs to be evaluated first, thus separate dossier is needed
  - Full food/feed RA of the single is needed as descendants stack contain MS11

- Full food/feed risk assessment according to IR is not possible, due to an incomplete compositional data set.

Q: Where in IR 503/2003 is stated a separate dossier is needed?

Q: Is assessment of single separately best option to achieve a full food/feed RA?

RISK ASSESSMENT MS11 APPROACHES

- Comparative compositional analysis:
  - (Hypothetical) cultivation conditions for food/feed were followed
  - MS11 seed lot = 50:50 mixture containing/not-containing the traits
  - MS11 non GLU-treated: analysis is adequate

    MS11 GLU-treated: analysis is inadequate

    (reason: *the genetic background of the plants treated with the herbicide is heterogeneous and they are therefore not considered adequate for comparative analysis*)

Q: What is scientific relevance of assessing hypothetical production scenario's?

RISK ASSESSMENT MS11 APPROACHES

***2nd approach followed:* MS11 is assessed for its intended use**

- Intended use assessment also done by EFSA
- Risk assessment of accidental import is possible.

Q: One of the principles of a risk assessment is that the 'intended use' should be taken into account. Why was this not (solely) followed for MS11 not to be imported as food/feed per se?

RISK ASSESSMENT MS11 APPROACHES

***Other scenario:* MS11 is assessed making use of the information on MS11 x RF3 – one dossier for MS11 & MS11 x RF3**

- Comparative compositional analysis:
  - True cultivation conditions for food/feed can be followed (MS11 x RF3 stack is grown)
  - Treatment with GLU will not result in a (too) heterogeneous background
  - F2 grain (MS11 x RF3; MS11; RF3) will be analysed
  - both MS11 & MS11 x RF3 will be covered
- Approach has been followed before (e.g. MS8 x RF3)

ADVANTAGES:

1° it would allow to conduct a full food/feed risk assessment of MS11 (part of seed mixture that is imported) in line with the requirements of the CIR (application of herbicide)

2° it would allow a risk assessment of single event MS11 (CIR requirement) which information can be taken into account in evaluation of MS11 x RF3

3° it would allow a risk assessment of the intended use of MS11 (RA principle)

4° it would avoid an inconclusive opinion on a hypothetical product (and issues of inconclusive opinions of stacks including this single event);

5° it would avoid unnecessary workload for the GMO risk assessment bodies (and in the end also for risk managers).