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Explanatory note on the selection of forage material suitable for the risk assessment of GM feed of plant origin

European Food Safety Authority (EFSA)

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Abstract

The European Food Safety Authority (EFSA) identified the need to provide further clarification on the *Guidance for the risk assessment of food and feed from genetically modified plants* (EFSA GMO Panel, 2011), specifically in the context of the risk assessment of GM feed of plant origin. Regulation (EU) No 503/2013 requires amongst others, data from raw agricultural commodities entering the feed production and processing chain. Different parts of a plant, i.e. whole grain, bean or seed and forage, may enter the feed chain as unprocessed raw material. Whereas the grain, bean and seed are well-defined for each plant, the definition of forage varies on a crop-by-crop basis as the parts likely to enter the feed chain differ among crops. This explanatory note provides a crop-specific definition of forage for maize, soybean, sugarbeet, rapeseed and cotton, mitigating the lack of forage definition in the regulatory context and supporting the appropriate selection of forage material, as required by Regulation (EU) No 503/2013.

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Table of contents

Abstract.....	1
1. Introduction.....	4
1.1. Background and Terms of Reference	4
1.2. Transition period.....	4
2. Data and Methodologies	4
3. Assessment	5
3.1. Background and definitions.....	5
3.2. Maize forage.....	5
3.3. Soybean forage.....	6
3.4. Sugar beet forage	6
3.5. Rapeseed forage.....	6
3.6. Cotton forage	6
3.7. Final considerations.....	7
4. Conclusions	8
References.....	9

1. Introduction

In the European Union (EU) the risk assessment of food and feed derived from GM plants follows the principles and requirements outlined in Regulation (EC) No 1829/2003, Regulation (EU) No 503/2013 and in the recommendations provided by the EFSA Panel on Genetically Modified Organisms (GMO Panel) in its *Guidance for the risk assessment of food and feed from genetically modified plants* (EFSA GMO Panel, 2011).

In the context of GM food and feed risk assessment, Regulation (EU) No 503/2013 and EFSA Guidance (EFSA GMO Panel, 2011) require data obtained from raw agricultural commodities entering the food and feed production chains.

Whereas raw agricultural commodities currently entering the food chain are well known and characterised, those entering the feed chain include forage, the definition of which varies on a crop-by-crop basis, according to what parts of the plant are used for its production.

This note to the guidance provides the definition of forage for maize, soybean, sugarbeet, rapeseed and cotton, which are currently the crops of interest in the context of GM plant applications submitted for authorisation in the EU market.

1.1. Background and Terms of Reference

This explanatory note intends to provide further clarification on the *Guidance for the risk assessment of food and feed from genetically modified plants* (EFSA GMO Panel, 2011), specifically in the context of the risk assessment of GM feed of plant origin. A crop-specific definition of forage for maize, soybean, sugarbeet, rapeseed and cotton is given, supporting the adequate selection of edible plant material as required by Regulation (EU) No 503/2013.

The principles established in this technical report to clarify on an appropriate definition of forage, can be adapted, case by case, to other crops not included in the document, as needed.

EFSA consulted members from its GMO Panel and its Working Group on food and feed safety during the elaboration of this document.

1.2. Transition period

This explanatory note is applicable to all applications submitted for authorisation of GM food and feed in the EU market, submitted 24 months after the publication of this note.

2. Data and Methodologies

In developing this explanatory note to the *Guidance for the risk assessment of food and feed from genetically modified plants* (EFSA GMO Panel, 2011), EFSA took into account principles and requirements defined in GMO EU legislation: Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013. European legislations not directly linked to GMOs, but relevant in the area of food and feed risk assessment, were also considered: Regulation (EC) No 178/2002 laying down general principles and requirements of food law and laying down procedures in matters of food safety; Regulation (EC) No 767/2009 on the placing on the market and use of feed and Regulation (EU) No 2017/1017, amending Regulation No 68/2013 on the Catalogue of feed materials.

Furthermore, EFSA took into account the recommendations given in the appropriate OECD Consensus documents on compositional considerations for new plant varieties (OECD, 2002a, 2002b, 2009, 2011 and 2012) suggesting the key plant constituents to be analysed for several of the crops addressed in this document, in relation to current feed uses.

Scientific literature was considered, when relevant.

3. Assessment

3.1. Background and definitions

The main raw agricultural commodities entering the feed chain for maize, soybean, rapeseed and cotton are grain, bean or seed respectively, while for sugarbeet it is the root itself. However, also other parts of the plants enter the feed chain, as in the case of the whole aerial parts for maize and soybean, or tops for sugar beet (OECD, 2015), constituting what is commonly identified as forage. Nonetheless, a definition of forage, detailing on a crop-by-crop basis what parts of the plant are used for its production and enter the feed chain, is missing in the context of European legislation¹ as well as in the respective OECD consensus documents.

In 2011, Allen published "*An international terminology for grazing lands and grazing animals*" with the objective of developing consensus on the terminology to be used for feed in grazing animals (Allen et al, 2011). The author defines forage as the edible parts of plants, other than separated grain, that can provide feed for grazing animals or that can be harvested for feeding, conserved *in situ* or preserved and stored (e.g. hay, silage, haylage). Straw may also be fed to animals as by-product of the removal of ripe grains and beans, mainly from cereal and legume plants, although the high fiber and lignin content and low nutritive value restrict its use mainly to ruminants (McDonald, 2011).

Table 1 defines the types of forage used in this note to the guidance. Furthermore, this document uses the BBCH (**B**iologische **B**undesanstalt, **B**undessortenamt and **C**hemical industry) growth stage scale to indicate specific plant growth stages for optimal collection of feed material for each of the crops considered (Meier, 2001).

Table 1: type of forage, as used in this document

Hay	harvested forage preserved by drying to a moisture content of generally less than 200 g/kg (Allen et al, 2011)
Haylage	harvested forage ensiled at a moisture content of less than 500 g/kg (Allen et al, 2011)
Silage (or ensilage)	harvested forage preserved at high moisture contents (generally >500 g/kg) by organic acids produced during partial anaerobic fermentation (Allen et al, 2011)
Straw	dried by-product obtained after the removal of ripe grains and beans from small cereal and legume plants

3.2. Maize forage

Worldwide, maize is used for collection of grain for human food, animal feed, ethanol production and non-food products. The whole aerial part of the maize plant is fed to animals as forage and usually preserved as silage, mainly for ruminants, less frequently for pigs and horses.

Maize is harvested for the collection of grains around the developmental stage BBCH87 when grains are mature. The whole aerial plant left after grain removal (e.g. straw) is shredded to obtain as by-product forage, consisting of stalks, leaves, cobs and husks.

Maize is also harvested around the developmental stage BBCH85 because of its nutritional properties, collecting the whole aerial plant (including grain), and fed to animals mainly as silage. The whole aerial plant is shredded to obtain forage consisting of stalks, leaves, cobs, husks and grains.

Data for the assessment of forage from GM maize should be provided on material consisting of a mixture of at least stalks, leaves, cobs and husks; the inclusion of grains in the mixture depends upon

¹ e.g. Regulation (EU) No 1829/2003, Regulation (EU) No 503/2013; Regulation (EC) No 767/2009; Regulation (EU) No 68/2013

the stage of development selected (BBCH87 vs BBCH85). The applicant should justify the rationale followed to collect the forage material.

3.3. Soybean forage

Worldwide, soybean is used mainly for collection of oil- and protein-rich beans (full fat beans), processed to obtain vegetable oil used for human food, animal feed and as energy source. By-products of the bean processing (e.g. cake and meal), are used as feed after oil removal. Although the use of soybean as forage is less common, the whole aerial part of the soybean plant is also fed to animals, mainly to ruminants, fresh, ensiled or dried to hay.

Soybean is harvested for the collection of beans around the developmental stage BBCH87, when beans are mature. The whole aerial plant left after removal of beans is shredded to obtain as by-product forage, consisting of stems and leaves.

Soybean is also harvested at other developmental stages, from flowering to maturity, for the collection of the whole aerial plant (including beans) to be fed to animals. The whole aerial plant is shredded to obtain forage consisting of stems, leaves, husks and beans.

Data for the assessment of forage from GM soybean should be provided on material consisting of a mixture of at least stems and leaves; the inclusion of husks and beans in the mixture depends upon the stage of development selected (from flowering to maturity). The applicant should justify the rationale used to collect the forage material.

3.4. Sugar beet forage

Worldwide, sugar beet is harvested at maturity, corresponding to developmental stage BBCH49 and mainly used for sugar production, due to the high concentration of sucrose in the roots.

Among the several by-products produced from sugar beet, tops, consisting of leaves and crowns may be fed (fresh, preserved as silage or dried) to animals, mainly cattle. Sugar beet roots as such are seldom used in livestock feeding, even though fresh roots are occasionally fed to dairy cattle and to pigs (OECD, 2002a).

Data for the assessment of forage from GM sugar beet should be provided on material consisting of tops (mixture of leaves and crowns), harvested approximately at developmental stage BBCH49. The applicant should justify the rationale used to collect the forage material.

3.5. Rapeseed forage

Worldwide, rapeseed is almost exclusively harvested for the collection of oil-rich seeds (full fat seeds), processed to obtain vegetable oil used for human food, animal feed and as energy source. By-products of the seeds processing (e.g. cake, meal and protein concentrate), are also used as animal feed after oil removal.

The use of rapeseed as forage in animals is currently not a common practice, even as by-product of the seed collection. Occasionally, it can be used as emergency feed, as it may happen in case of adverse weather condition limiting seed collection. In line with current feeding practices, the OECD consensus document (OECD, 2011), does not include a list of key constituents for rapeseed forage.

For these reasons, data from rapeseed forage are not considered necessary to assess the safety of the commonly used rapeseed feed materials.

3.6. Cotton forage

Worldwide, cotton is cultivated for the collection of oil-rich seeds (full fat seeds), processed to obtain vegetable oil used for human food and animal feed and for the collection of fibers for uses other than

food and feed (e.g. textile fiber). By-products of the seeds processing (e.g. cake and meal), are also used as animal feed after oil removal.

The use of cotton as forage is currently not a common practice, even as by-product of the seed and fibre collection, because the quality is variable and the nutritive value is low. In line with current feeding practices, the OECD consensus document (OECD, 2009), does not include a list of key constituents for cotton forage.

For these reasons, data from cotton forage are not considered necessary to assess the safety of the commonly used cotton feed materials.

3.7. Final considerations

Table 2 summarises the recommendations for collecting forage material from maize, soybean, sugarbeet, rapeseed and cotton plants suitable for the risk assessment of GM feed of plant origin, as required by Regulation (EU) No 503/2013 and EFSA guidance (EFSA, GMO Panel 2011).

The applicant should include the following information relevant for the collection of forage material:

- a complete list of the parts of the plant included in the forage samples analysed;
- an indication of the growth stage at which the crop selected for the analyses was harvested;
- a report on how samples have been collected;
- a description of all the steps from harvest to analyses (e.g. date of harvesting, storage conditions, date of analyses).

Table 2: Summary of the criteria for selecting forage material of GM plant origin

Crop	Forage material
Maize	Mixture of stalks, leaves, cobs and husks, excluding grains (e.g. stage BBCH87) and/or Mixture of stalks, leaves, cobs and husks, including grains (e.g. stage BBCH85) An explanation of the rational followed to sample forage material should be provided.
Soybean	Mixture of stems and leaves, excluding husks and beans (e.g. stage BBCH87) and/or Mixture of stems and leaves, including husks and beans (any stage from flowering to maturity could be selected). An explanation of the rational followed to sample forage material should be provided.
Sugarbeet	Tops (mixture of leaves and crowns) (stage BBCH49)
Rapeseed	The use of rapeseed forage is currently not a common practice, and the OECD consensus document does not include a list of key constituents for forage. Data from rapeseed forage are not considered necessary to assess the safety of the commonly used rapeseed feed materials.
Cotton	The use of cotton forage is currently not a common practice, and the OECD consensus document does not include a list of key constituents for forage. Data from cotton forage are not considered necessary to assess the safety of the commonly used cotton feed materials

EFSA notes that feed products and their uses are expected to evolve according to the developments of feed production practices (see for example the recent update of the EU catalogue of feed materials with *Regulation (EU) No 2017/1017*, which included rapeseed straw into the list of forages). Therefore EFSA will update this Technical Report, as needed.

4. Conclusions

This explanatory note to the *Guidance for the risk assessment of food and feed from genetically modified plants* (EFSA GMO Panel, 2011), provides further clarifications for the risk assessment of GM feed. A crop-specific definition of forage for maize, soybean, sugarbeet, rapeseed and cotton is given, taking into account the specific parts of the plant likely to enter the feed chain and their stage of development at harvesting. These clarifications mitigate the lack of forage definition in the regulatory context, as discussed in the document, and support the appropriate selection of forage material, suitable for the risk assessment of GM feed, as required by Regulation (EU) No 503/2013.

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