Comments on the European Food Safety Authority draft guidance on the agronomic and phenotypic characterisation of genetically modified plants

COGEM advice CGM/141106-01

Introduction

Recently, the EFSA GMO Panel published a draft guidance document on the agronomic and phenotypic characterisation of genetically modified plants. This draft guidance document is open for public consultation by EU member states and stakeholders.

The document provides guidance on the agronomic and phenotypic characterisation of genetically modified (GM) plants submitted within the framework of Regulation (EC) No. 1829/2003 on GM food and feed or under Directive 2001/18/EC on the deliberate release into the environment of GMOs. It aims to provide a comprehensive and harmonised approach for the agronomic and phenotypic characterisation of GM plants. It contains chapters on the selection of sites and test materials; the quality of starting materials used as test materials; the design of field trials; agronomic and phenotypic endpoints; data analysis; and relevance of agronomic and phenotypic data for environmental risk assessment (ERA).

General comments

COGEM welcomes the initiative of EFSA to come to a comprehensive and harmonised approach for the agronomic and phenotypic characterisation of GM plants. The objective of this guidance is to obtain data to inform the risk assessment of GM crops. Remarkably, the majority of the data which is required according to this guidance is of no or limited relevance to the risk assessment.

Much of the data seems to deal with agronomic performance rather than ERA. By requiring applicants to submit data on agronomic performance, the faulty suggestion may arise that EFSA also includes the agronomical performance of a GM crop in its assessment. A clear example of the focus on agronomic performance is that economic injury levels are mentioned as a criterion to consider when selecting pest species which should be monitored during the field trial.

The guidance describes much data necessary for the characterisation of GM plants. COGEM points out that the extent of the data required may create the undesirable suggestion that the objective to develop a harmonised and comprehensive approach equals a request for as much data as possible. This is especially the case since the rationale for many of the imposed data requirements is lacking. For instance, the guidance requires a great amount of detailed information on the selected field trial sites. COGEM questions whether all these data are necessary in order to study the phenotypic and agronomic characteristics of the GM plant. For instance, COGEM questions the extensive amount of detailed agrometereological data, which is deemed necessary by the guidance.

In Appendix A, a decision tree is presented that can be used to determine whether additional data is required to assess invasiveness and persistence of the GM plant. In this appendix, a clear connection is present between the assessment of potential environmental risks and the data which is deemed necessary. COGEM is of the opinion that the guidance would be greatly improved if the same approach is adopted in the main text of the guidance.

COGEM notices that the majority of the data are required for all types of authorisations. A greater distinction between the data requirements for the ERA of import and cultivation applications would be of great help to applicants and risk assessors.

In addition, COGEM points out that some of the mandatory endpoints listed (including yield, absence of lodging and disease resistance) are favorable traits pursued by any plant breeder. Several of these endpoints appear to have no link with the ERA. Moreover, beneficial traits pursued by plant breeders appear to be considered negative aspects for GM plants.

Specific comments

The guidance document could also be improved on minor points. Some examples of these minor points are listed below.

Lines 256 to 260 describe several factors that influence the suitability of a site to grow a particular variety of crop. One of these factors is earliness of flowering. However, this is a characteristic of a variety and not a characteristic of a site. Similarly, earliness of flowering is listed as relevant information for a site (lines 328-331) and as a factor to assess site representativeness (footnote 6).

In section 4.1 it is stated that protein expression and compositional data from the same field trials in which the agronomic and phenotypic characterization is carried out, may deliver useful information on the quality of the field trials. COGEM questions whether this type of data can be used for this purpose.

Lines 676 to 692 list options for GM plants with tolerance to multiple herbicidal active substances. The option ‘GMHT plant treated with the full conventional herbicide regime’ is missing from this list.

Conclusion

COGEM welcomes the initiative of the EFSA to come to a comprehensive and harmonised approach for the agronomic and phenotypic characterisation of GM plants. However, after assessing the guidance document, COGEM is of the opinion that much of the required data has no clear relevance to the ERA. A considerable part of the data requirements deal with agronomic performance, which is not part of the ERA of GM plants. In addition, COGEM has reservations with regard to the detailed data requirements for the selected field trial sites. COGEM is of the

opinion that only the data that is crucial to assess the environmental risks of GM plants should be required.