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KENMERK CGM/110124-01
ONDERWERP Reactie op de herziene versie van de EFSA 'Guidance on the risk asessment of genetically modified microoganisms and their food and feed products'

Geachte heer Atsma,

De EFSA heeft haar richtsnoer 'Guidance on the risk assessment of genetically modified microorganisms and their food and feed products' herzien. Het conceptdocument is opengesteld voor commentaar. De COGEM heeft er voor gekozen om haar commentaar gelijktijdig zowel aan u als direct aan de EFSA te doen toekomen.

Samenvatting
De EFSA beoogt met het richtsnoer de wetenschappelijke risicoanalyse van genetisch gemodificeerde micro-organismen en hiervan afgeleide voedselproducten te beschrijven ten einde vergunningaanvragers een leidraad te bieden. Daartoe zijn door de EFSA genetisch gemodificeerde micro-organismen en de daarvan afgeleide voedselproducten in 4 categorieën verdeeld, variërend van chemisch gedefinieerde gezuiverde producten met behulp van genetisch gemodificeerde micro-organismen geproduceerd tot producten bestaande uit levende genetisch gemodificeerde micro-organismen.
De COGEM merkt op dat waar de beoordeling van de veiligheid van voedselproducten door een andere instantie in Nederland wordt uitgevoerd, zij zich van dit onderdeel onthoudt. Zij heeft zich daarom beperkt tot het becommentariëren van de in het conceptrichtsnoer beschreven milieurisicoanalyse van genetisch gemodificeerde micro-organismen en de hiervan afgeleide voedselproducten.
De COGEM onderschrijft in grote lijnen de in het richtsnoer beschreven milieurisicoanalyse, een aantal punten verdient echter meer verduidelijking. Daarnaast is de COGEM van mening dat het milieumonitoringsplan te algemeen is en meer uitwerking behoeft.

De door de COGEM gehanteerde overwegingen en het hieruit voortvloeiende advies treft u hierbij aan als bijlage.

Hoogachtend,

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Comments on the European Food Safety Authority revised 'Guidance on the risk assessment of genetically modified microorganisms and their food and feed products'

COGEM advice CGM/110124-01

Introduction

EFSA published her first 'Guidance for the risk assessment of genetically modified microorganisms (GMMs) and their derived products intended for food and feed use' in October 2006. This guidance is currently under revision. The draft version of the revised guidance is now open for public consultation.

EFSA defines the scope of the guidance as 'providing guidance for the scientific risk assessment of GMMs, and food and/or feed containing, consisting of, produced from and produced with GMMs'. EFSA distinguishes four categories of GMMs, ranging from chemically defined purified compounds produced with GMMs to pure cultures of viable GMMs. The four categories are briefly described below:

Category 1: Chemically defined purified compounds and their mixtures produced with GMMs in which both GMMs and newly introduced genes have been removed (*e.g.* amino acids, vitamins),

Category 2: Complex products produced with GMMs in which both GMMs and newly introduced genes have been removed (*e.g.* most enzyme preparations); or from GMMs in which both GMMs and newly introduced genes are no longer present (*e.g.* cell extracts),

Category 3: Products produced from GMMs in which GMMs capable of replication or of transferring newly introduced genes are not present; but in which newly introduced genes are still present (*e.g.* heat-inactivated starter cultures),

Category 4: Products consisting of or containing GMMs capable of replication or of transferring newly introduced genes (*e.g.* live starter cultures).

COGEM welcomes the initiative of the EFSA to revise her guidance for the risk assessment of GMMs and their derived products intended for food and feed use. In general COGEM supports the guidance document. However, she has some comments for improvement. The comments are listed according to the order in the text in the guidance document. Numbered paragraph headings refer to the exact paragraph as found in the document.

In the Netherlands a food/feed risk assessment is usually carried out by other organizations and, therefore, the COGEM confines her comments to the parts of the guidance document that discuss the environmental risk assessment (ERA) of GMMs and their derived products.

Comments

1. Introduction

The GMMs covered in the guidance document include the domains of the *Archaea*, *Bacteria* and *Eukarya* (line 163). In the document *Eukarya* includes 'filamentous fungi, yeasts, protozoa, and microalgae' (line 163-164). From a biological and taxonomical point of view, the description of the organisms used is not precise. The term 'protozoa' is outdated and microalgae are not a well-defined group of organisms. Algae are present in varies eukaryotic lineages[1]. COGEM is of the opinion that EFSA should adhere to the latest taxonomic classification and should use terms that are taxonomically correct.

III.B. Hazard identification and characterization

According to EFSA, several analyses have to be performed in order to obtain information relating to the GMM or the products derived with or from the GMM. For categorization of a product in group 1 and 2, the absence of the GMM has to be determined. Guidance for the selection of the detection methods to be used for the demonstration of the absence of a GMM consists of descriptions like 'appropriate methods' (line 527), 'a proper sampling method' (line 800), or 'a recognized method' (line 824). The limit for detection of a GMM in a product is determined by the analytical sensitivity of the applied method, however, the document does not provide guidance which detection limit is acceptable for a chosen method. COGEM is of the opinion that more guidance is needed on the methods to be used and the quality requirements that should be met by those methods.

III.B.2. Information relating to the product

EFSA states that applicants should indicate in which of the four categories the GMM or the products derived with or from the GMM belongs. For products belonging to category 2 and 3 it must be demonstrated that the GMM has been inactivated. According to the document, for both product categories it has to be confirmed that viable but non-culturable cells (VBNCs) are absent (line 724-725). Bacteria and fungi may also produce spores that permit survival. Therefore, in COGEM's view the absence of both viable spores and VBNCs has to be confirmed in products belonging to category 2 and 3.

III.B.2.2.1. Information on the removal of the GMM cells from the product

According to the guidance, removal of the GMM is required in products belonging to categories 1 and 2 (lines 790-792). For verification of the removal, the performance of a resuscitation step is recommended. Resuscitation should be done with a longer incubation time compared to the normal culturing of viable organisms (line 796-798). 'A longer incubation time' is too vague and should be specified more precisely, *e.g.* the incubation time will be at least 1000 times the generation time of the GMM.

III.B.2.4.4. Testing of the whole GM product

Line 967-968 states that, if no corresponding conventional product exists, or if there are *any* indications from the risk assessment for further testing of the GM product, toxicological testing should be considered. 'Any indication' is vague. The guidance document should indicate in which cases toxicological testing is needed.

III.B.3.3. ERA of products consisting of or containing GMMs capable of replication or of transferring genetic material (Category 4)

The ERA of category 4 products includes the assessment of potential ecological effects (lines 1210-1223). This part of the guidance document also applies to microbial plant protection products, which are developed for agricultural use. Therefore, in COGEM's view, the potential effect of the GMM on the agro-ecosystem should receive particular attention in the ERA of genetically modified microbial plant protection products.

In addition, in the guidance document it is mentioned that potential effects of toxic compounds produced by the GMM on other microorganisms should be assessed (line 1215-1216). The term 'ecotoxicity' should be used in this context.

The guidance document states that if the GMM causes an adverse effect and disrupts vital ecological processes the consequences of the effect should be assessed (line 1220-1223). The document does not state which ecological processes are considered 'vital'. More guidance is needed in this respect.

III.F.3. General Surveillance of the impact of GM and III.F.4. Monitoring systems

General surveillance is a legal requirement which purpose is to detect unforeseen or unanticipated adverse effects of a GMO. The detection of unforeseen, unanticipated effects is difficult because no hypotheses can be formulated with regard to the type of effect or the place where an effect might occur. In case of a GMM the detection of unforeseen, unanticipated adverse effects is even more difficult. The variety of possible applications is broad and potential effects will take place in environments which are notoriously difficult to characterize, like soil. In COGEM's view the provided guidance is too general. More guidance should be given with regard to the methods that should be used to detect unexpected effects caused by GMMs.

In addition, in the guidance document it is stated that for GMM products under category 3 post-market environmental monitoring should be considered for identified environmental risks (line 1429-1430). In this category newly introduced genes are still present, but GMMs capable of replication or of transferring newly introduced genes are absent. The guidance states that the risk assessment for category 3 products should focus on the potential risks of recombinant DNA such as horizontal gene transfer to other micro-organisms (line 1140-1141). Due to the broad variety of the many possible applications of GMMs and due to the inevitably rather vague description of recombinant DNA the specific cases for which environmental monitoring is needed, should be specified.

Conclusion

In general COGEM endorses the revised guidance for the risk assessment of GMMs and their food and feed products. COGEM identified some points of improvement. Especially, the guidance for post-market environmental monitoring of GMMs is an aspect which should be further developed in order to give more detailed guidance to applicants.

Reference

1. Sadava D. *et al*. 2007. In 'Life: The Science of Biology. 8th edition. Ed. Sinauer Associates Inc.