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**Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 503/2013. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

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## ANNEX II

### SCIENTIFIC REQUIREMENTS FOR THE RISK ASSESSMENT OF GENETICALLY MODIFIED FOOD AND FEED

#### I. INTRODUCTION

##### 1. DEFINITIONS

For the purpose of this Annex, the following definitions shall apply:

1. 'hazard identification' means the identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food and feed or group of foods and feeds;
2. 'hazard characterisation' means the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food and feed;
3. 'risk characterisation' means the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterisation and exposure assessment.

##### 2. SPECIFIC CONSIDERATIONS

###### 2.1. **Insertion of marker genes and other nucleic acid(s) sequences not essential to achieve the desired trait**

In order to facilitate the risk assessment, the applicant shall endeavour to minimise the presence of inserted nucleic acid(s) sequences not essential to achieve the desired trait.

During the process of genetic modification of plants and other organisms, marker genes are often used to facilitate the selection and identification of genetically modified cells, containing the gene of interest inserted into the genome of the host organism, among the vast majority of untransformed cells. The applicant shall carefully select such marker genes and Article 4(2) of Directive 2001/18/EC shall be respected. Against that background, the applicant shall therefore aim to develop GMOs without the use of antibiotic resistance marker genes.

###### 2.2. **Risk assessment of genetically modified food and feed containing stacked transformation events**

For the risk assessment of genetically modified food and feed containing stacked transformation events obtained by conventional crossing of genetically modified plants containing one or several transformation event(s), the applicant shall provide a risk assessment of each single transformation event or, in accordance with Article 3(6) of this Regulation, refer to already submitted application(s). The risk assessment of genetically modified food and feed containing stacked transformation events shall also include an assessment of the following aspects:

- (a) stability of the transformation events;
- (b) expression of the transformation events;
- (c) potential synergistic or antagonistic effects resulting from the combination of the transformation events shall be subject to an assessment in accordance with Sections 1.4 (Toxicology), 1.5 (Allergenicity) and 1.6 (Nutritional assessment).

For genetically modified food and feed containing, consisting of or produced from genetically modified plants, whose cultivation is associated with the production of genetically modified

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material containing various subcombinations of transformation events (segregating crops), the application shall include all subcombinations independently of their origin which have not yet been authorised. In such a case, the applicant shall provide a scientific rationale justifying that there is no need to provide experimental data for the concerned subcombinations or, in the absence of such scientific rationale, provide the experimental data.

For genetically modified food and feed containing, consisting of or produced from genetically modified plants, the cultivation of which does not lead to the production of genetically modified material containing various combinations of transformation events (non-segregating crops), the application shall only cover the combination which is to be placed on the market.

The rules set out in this Section apply *mutatis mutandis* to transformation events which are combined by other means such as co- and retransformation.

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### Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by [S.I. 2019/705 reg. 53](#)
- Annex 1 Pt. 7 para. 1.1(a) omitted by [S.I. 2019/705 reg. 54\(e\)\(iii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(e) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(b))
- Annex 1 Pt. 7 para. 1 substituted by S.I. 2019/705, reg. 54(e)(iv) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(b\)](#)
- Annex 1 Pt. 1 para. 2 words substituted by [S.I. 2019/705 reg. 54\(a\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(a)(b) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(a))
- Annex 1 Pt. 1 para. 4(c) words substituted by [S.I. 2019/705 reg. 54\(a\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(a)(b) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(a))
- Annex 1 Pt. 1 para. 8 words substituted by [S.I. 2019/705 reg. 54\(a\)\(iii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(a)(b) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(a))
- Annex 1 Pt. 2 para. 1.1(b) words substituted by [S.I. 2019/705 reg. 54\(b\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(a)(b) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(a))
- Annex 1 Pt. 2 para. 1.1(e)(v) words substituted by [S.I. 2019/705 reg. 54\(b\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(a)(b) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(a))
- Annex 1 Pt. 2 para. 1.1(e)(vi) words substituted by [S.I. 2019/705 reg. 54\(b\)\(iii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(a)(b) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(a))
- Annex 1 Pt. 2 para. 7 words substituted by [S.I. 2019/705 reg. 54\(b\)\(iv\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(a)(b) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(a))
- Annex 1 Pt. 7 para. 1.8(h) words substituted by [S.I. 2019/705 reg. 54\(e\)\(iv\)](#) (This amendment not applied to legislation.gov.uk. Reg. 54(e) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 17(10)(b))
- Annex 1 Pt. 1 para. 2 words substituted by S.I. 2019/705, reg. 54(a)(i) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(a\)](#)
- Annex 1 Pt. 1 para. 4 words substituted by S.I. 2019/705, reg. 54(a)(ii) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(a\)](#)
- Annex 1 Pt. 1 para. 8 words substituted by S.I. 2019/705, reg. 54(a)(iii) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(a\)](#)
- Annex 1 Pt. 2 para. 1 words substituted by S.I. 2019/705, reg. 54(b)(i) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(a\)](#)
- Annex 1 Pt. 2 para. 1 words substituted by S.I. 2019/705, reg. 54(b)(ii) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(a\)](#)
- Annex 1 Pt. 2 para. 1 words substituted by S.I. 2019/705, reg. 54(b)(iii) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(a\)](#)
- Annex 1 Pt. 2 para. 7 words substituted by S.I. 2019/705, reg. 54(b)(iii) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(a\)](#)
- Annex 1 Pt. 7 para. 1 words substituted by S.I. 2019/705, reg. 54(e)(iii) (as substituted) by [S.I. 2020/1504 reg. 17\(10\)\(b\)](#)
- Annex 3 para. 1 words omitted by [S.I. 2019/705 reg. 56\(a\)\(ii\)](#)
- Annex 3 point C para. 3.1(4) words omitted by [S.I. 2019/705 reg. 56\(c\)](#)
- Annex 3 para. 1(3) words substituted by [S.I. 2019/705 reg. 56\(a\)\(i\)](#)

- Annex 2 s. 2para. 1.3.1 words omitted by [S.I. 2019/705 reg. 55\(a\)\(ii\)](#)
- Annex 2 s. 2para. 2 words omitted by [S.I. 2019/705 reg. 55\(a\)\(ix\)\(aa\)](#)
- Annex 2 s. 2para. 1.1.2(b) words substituted by [S.I. 2019/705 reg. 55\(a\)\(i\)](#)
- Annex 2 s. 2para. 1.3.2.1 words substituted by [S.I. 2019/705 reg. 55\(a\)\(iii\)](#)
- Annex 2 s. 2para. 1.3.2.2 words substituted by [S.I. 2019/705 reg. 55\(a\)\(iv\)](#)
- Annex 2 s. 2para. 2 words substituted by [S.I. 2019/705 reg. 55\(a\)\(ix\)\(bb\)](#)
- Annex 2 s. 2para. 1.4.2 words substituted by [S.I. 2019/705 reg. 55\(a\)\(v\)](#)
- Annex 2 s. 2para. 1.4.4.1 words substituted by [S.I. 2019/705 reg. 55\(a\)\(vi\)](#)
- Annex 2 s. 2para. 1.5 words substituted by [S.I. 2019/705 reg. 55\(a\)\(vii\)](#)
- Annex 2 s. 2para. 1.6.4 words substituted by [S.I. 2019/705 reg. 55\(a\)\(viii\)](#)
- Art. 4(1)(b) words substituted by [S.I. 2019/705 reg. 49](#) (This amendment not applied to legislation.gov.uk. Reg. 49 substituted immediately before IP completion day by [S.I. 2020/1504, regs. 1\(2\), 17\(9\)](#))
- Art. 4(1)(b) words substituted by [S.I. 2019/705, reg. 49](#) (as substituted) by [S.I. 2020/1504 reg. 17\(9\)](#)