



CONNECT.EFSA – problems in context of targeted consultations of the CAs of the member states



The Federal Office of Consumer Protection and Food Safety (BVL) is the national competent authority (CA) concerning applications for marketing authorisation of GMOs either for cultivation or for the use as food and/or feed according to Regulation (EC) No 1829/2003.

After EFSA validated a new GMO application it has to consult the national CAs according to article 6 (4) and article 18 (4) of Regulation (EC) No 1829/2003 in line with Directive 2001/18/EC, which then have a 3-month time period to comment on the application.

The BVL delivers its opinion on these applications to EFSA as part of the EU Community approval procedure as prescribed by law.

Although the BVL highly appreciates the improvements made concerning the submission of its comments for targeted consultations on CONNECT.EFSA, we still have to face several difficulties.



The competent authorities of the member states submit their comments to the different chapters

 Respond to consultation

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Submit Comments

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Please note the the max number of characters allowed per section is 10000.

- 1. Hazard identification and characterisation
- 2. Exposure assessment - anticipated intake or extent of use
- 3. Risk characterisation
- 4. Post-market monitoring on the genetically modified food or feed
- 5. Environmental Risk Assessment
- 6. Environmental Monitoring Plan
- 7. Additional information related to the safety of the genetically modified food or feed



...which are further divided into subchapters

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1. Hazard identification and characterisation

Comments for 1. Hazard identification and characterisation

10000 characters remaining

Attach file to Comments for 1. Hazard identification and characterisation

1.1 Information relating to the recipient or (where appropriate) parental plants

Comments for 1.1 Information relating to the recipient or (where appropriate) parental plants

10000 characters remaining

Attach file to Comments for 1.1 Information relating to the recipient or (where appropriate) parental plants



However, there are inconsistencies between the entry masks of different targeted consultations. For some full applications the structure is correct, for others not:

Document title ▼

File Type ▼

File Respond to consultation Save Draft Submit Comments

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> 1. Hazard identification and characterisation

> Other information (e.g. additional information on single events or sub-combinations in the frame of stacks applications)

> 3. Risk characterisation

> 4. Post-market monitoring on the genetically modified food or feed

> 5. Environmental Risk Assessment

> 6. Environmental Monitoring Plan

> 7. Additional information related to the safety of the genetically modified food or feed 7.1 Studies published in the Scientific Literature

Are you having trouble with this consultation? For support click [here](#).

Here, e. g. the main chapter 2 is missing and its subchapters are...



However, there are inconsistencies between the entry masks of different targeted consultations. For some full applications the structure is correct, for others not:

Document title File Type

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> 1. Hazard identification and characterisation

> Other information (e.g. additional information on s

> 3. Risk characterisation

> 4. Post-market monitoring on the genetically modifi

> 5. Environmental Risk Assessment

> 6. Environmental Monitoring Plan

> 7. Additional information related to the safety of th

> 1.6 Nutritional assessment

> 1.6.1 Nutritional assessment of the genetically modified food

> 1.6.2 Nutritional assessment of the genetically modified feed

> 1.6.3 Conclusion of the nutritional assessment

> 2.1 Dietary role in food and feed

> 2.2 Import and production of commodity in the EU

> 2.3 Animal dietary intake of newly expressed proteins

> 2.4 Human dietary intake of the newly expressed protein

> 3. Risk characterisation

> 4. Post-market monitoring on the genetically modified food or feed

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... listed under the main chapter 1



For renewal applications, there is no numbering of the commenting fields, which are consequently listed in a randomized order:

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- › Post-Market Monitoring and Post-Market Environmental Monitoring Reports
- › New information - Updated Bioinformatics
- › New information - Systematic search and evaluation of literature
- › New information - Additional documents or studies performed by or on behalf of the applicant
- › Environmental Risk Assessment
- › Molecular Characterisation
- › Comparative Analysis
- › Food/Feed Risk Assessment
- › New Information - Overall assessment
- › Monitoring Plan and proposal for improving the conditions of the original author

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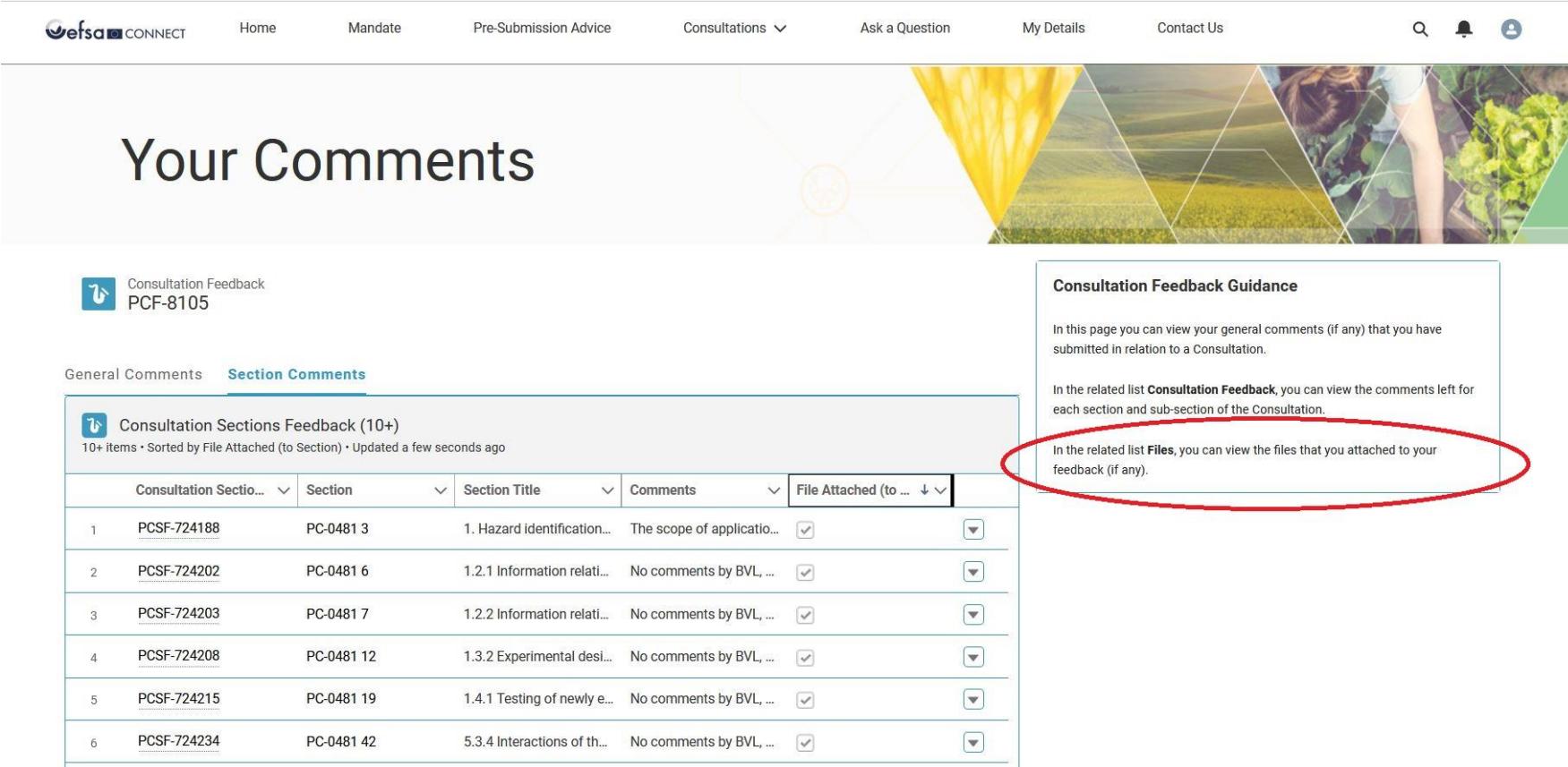
Please note the the max number of characters allowed per section is 5000.

- › Molecular Characterisation
- › Environmental Risk Assessment
- › Comparative Analysis
- › Food/Feed Risk Assessment
- › New information - Systematic search and evaluation of literature
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- › New Information - Overall assessment
- › Monitoring Plan and proposal for improving the conditions of the original author

Are you having trouble with this consultation? For support [click here](#).



Fortunately, there is now an upload function for every chapter and subchapter of the entry form, however, we can only see after submission that we attached a file marked by a checkmark, but not the file name and we cannot open the attached files:



Consultation Feedback
PCF-8105

[General Comments](#) [Section Comments](#)

Consultation Sections Feedback (10+)
10+ items • Sorted by File Attached (to Section) • Updated a few seconds ago

Consultation Sectio...	Section	Section Title	Comments	File Attached (to ...
1 PCSF-724188	PC-0481 3	1. Hazard identification...	The scope of applicatio...	<input checked="" type="checkbox"/>
2 PCSF-724202	PC-0481 6	1.2.1 Information relati...	No comments by BVL, ...	<input checked="" type="checkbox"/>
3 PCSF-724203	PC-0481 7	1.2.2 Information relati...	No comments by BVL, ...	<input checked="" type="checkbox"/>
4 PCSF-724208	PC-0481 12	1.3.2 Experimental desi...	No comments by BVL, ...	<input checked="" type="checkbox"/>
5 PCSF-724215	PC-0481 19	1.4.1 Testing of newly e...	No comments by BVL, ...	<input checked="" type="checkbox"/>
6 PCSF-724234	PC-0481 42	5.3.4 Interactions of th...	No comments by BVL, ...	<input checked="" type="checkbox"/>

Consultation Feedback Guidance

In this page you can view your general comments (if any) that you have submitted in relation to a Consultation.

In the related list **Consultation Feedback**, you can view the comments left for each section and sub-section of the Consultation.

In the related list **Files**, you can view the files that you attached to your feedback (if any).



The BVL highly appreciates the improvements made concerning the submission of its comments for targeted consultations on CONNECT.EFSA and thanks EFSA for the efforts.

It would also be highly appreciated, if the entry forms would be consistent between all full as well as between all renewal applications in the future.

It would be most important for us to be able to check the content of the uploaded files in order to control if the comments are/were submitted correctly and completely.



Thank you for your attention!

Contact:

Internet: www.bvl.bund.de

