



Secretariat

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Title: Advice of the Belgian Biosafety Advisory Council on the procedures followed by the European Food Safety Authority (EFSA) for the scientific evaluation and the risk assessment of genetically modified organisms (GMO) for food and feed use and on the European decision rules pertaining to the marketing authorisations given to these GMOs

Context

The Belgian Federal Minister for the Environment, B. Tobback, addressed on 15 February 2006 a request to the Biosafety Advisory Council (BAC) to give its advice/comments on the following aspects:

- What kind of problems did the Council encounter for the risk assessment of GMOs intended for food or feed use under Regulation (EC) No. 1829/2003?
- How could the existing EFSA procedures be improved?
- How could the European decision rules pertaining to the marketing authorisations given to the GMOs become more transparent?

Introductory remarks

From 2004 till now, the BAC has fully evaluated 3 applications introduced under Regulation (EC) No. 1829/2003 ("EFSA dossiers") while 2 other EFSA dossiers were evaluated by the Division of Biosafety and Biotechnology (SBB) of the Scientific Institute of Public Health on mandate of the Council. The list of those dossiers and, when available, the reference of the advice of the Biosafety Council¹ are given in appendix I.

The current advice is mainly based on the experience acquired with those dossiers.

¹ The advices of the Biosafety Advisory Council are published on internet and are available at the following address: http://www.bio-council.be/bac_advices.html



It also fits in the ongoing discussion at EU level (Belgium has already expressed an official political opinion on this matter at the Council of EU Ministers of Environment of 9 March 2006) and it should be noted that the European Commission has recently issued several proposals to practically improve the way the EU GMO legislative framework is implemented².

Not everybody is familiar with the procedures and timelines for the scientific evaluation and the authorisation of a GMO application submitted at EFSA under Regulation (EC) No. 1829/2003. These procedures are summarised in the diagram given in appendix 2. Each procedural step has been numbered and the current advice makes direct reference to those numbers.

Answers to the questions of the Minister

1. What kind of problems did the Council encounter for the risk assessment of GMOs intended for food or feed use and how could the existing EFSA procedures be improved?

1.1 Problems during step 1 of the procedure: The dossier and its validation

In order to have better documented dossiers, EFSA should complete the current guidance notes^{3,4,5} with guidance summarising for the applicants some generally recognised valid research protocols and based on the experience acquired with previous dossiers. The revised guidance notes should, however, remain general. Flexibility and rapid adaptation to new scientific knowledge should be kept. The BAC supports the Commission's proposal in this matter and also supports the Commission when it proposed to ask to the applicant and EFSA "to address more explicitly potential long-term effects and bio-diversity issues in their risk assessments"⁶. The members of the BAC insist to consider not only obvious direct potential effects but also to anticipate the most possible indirect long-term effects on all levels of the biotic and abiotic environment conferred to the GMO by the new trait, as required by annex II of directive 2001/18/EC.

² Press release IP/06/498, 12 April 2006

³ EFSA, 2004. Guidance document of the scientific panel on genetically modified organisms for the risk assessment of genetically modified plants and derived food and feed. EFSA Journal (99), 1-94.
http://www.efsa.eu.int/science/gmo/gmo_guidance/660/guidance_docfinal1.pdf

⁴ EFSA, 2005. New chapter 11.4. General surveillance of the impact of the GM Plant. EFSA Guidance document for the risk assessment of genetically modified plants and derived food and feed.
http://www.efsa.eu.int/science/gmo/gmo_guidance/catindex_en.html

⁵ Commission decision 2002/623/EC of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

⁶ Press release IP/06/498, 12 April 2006



The monitoring plan proposed by the applicant should be more specific and detailed for example in terms of precision in the action plan, in the schedule of monitoring activities and in the people involved.

1.2 Problems during step 2 of the procedure: Consultation of the National Competent Authorities under 2001/18/EC"

The 3 months of the consultation of the National Competent Authorities (NCA) under Directive 2001/18/EC starts as soon as an application is declared valid by EFSA. All the EFSA dossiers are announced well in advance but it is impossible to know when a dossier will actually be declared valid.

The practical organisation of the Member States consultation could be improved if EFSA could send an alert as soon as a dossier is almost ready to be declared valid and, if possible, about one month before the opening of the consultation period.

The BAC is also of the view that the EFSAnet (the electronic facility developed by EFSA to store dossiers and NCA comments) should be practically improved in order to facilitate the download, the use and the upload of information by the Member States. In particular:

- The download of the dossiers under consultation for further evaluation by Belgian experts has been problematic in many cases due to the large size of the files. Despite intensive contacts between the secretariat of the Council and EFSA, no satisfactory technical solution has been implemented by EFSA up to now. This problem should be solved very urgently.
- During the consultation period, any comment that the BAC would like to relay to the GMO panel of EFSA has to be electronically posted on the EFSAnet. However for each category of comments the available space is limited (maximum 4000 characters)⁷. For dossiers UK/2004/06 and BE/2004/07 the BAC had to extensively summarise some comments made by the Belgian experts. Even if the BAC agrees that concision should be a general rule for comments posted by the Member States, it also considers that the EFSAnet should provide for sufficient flexibility in order to allow comments from national experts to be fully relayed to EFSA.
- The way the electronic dossier is structured on the EFSAnet should be improved in order to facilitate the retrieval and use of specific information by national experts. The BAC suggests adding a comprehensive table of contents including a clear heading of the annexes.

1.3 Problems with step 3: Scientific evaluation and report of EFSA GMO panel

Concerning the scientific evaluation, the BAC is of the opinion that when the EFSA GMO panel concludes in the absence of risk for human health and/or the environment, detailed scientific justification should be given in all cases. The BAC has noticed in some cases (for

⁷ in: "How to use GMO EFSAnet", June 2004 (document available only on GMO EFSAnet)



example in the paragraph 5.2.2 of dossier UK/2004/06) that the justification is rather theoretical and not supported by references to scientific data.

The applicant (in the dossier) and EFSA (in its opinion) should quantify their statements whenever possible or indicate the absence of scientific data.

A special attention should be paid to the statistical parts of the dossier: justification of the sample size, methods, trial circumstances and periods, should be carefully documented, analysed and referenced. Conclusions should be scientifically supported and take into account possible variations between populations and environments.

The scientific opinions of the GMO panel should be written according to scientific standards. When relevant, these opinions should also better address the issue of scientific uncertainties and the possible management measures to be implemented as appropriate. Apparent irrelevancies should be further investigated. Lack of scientific data should not be considered as lack of risks.

Concerning the reporting, EFSA states that in compliance with Article 6.6 and Art. 18.6 of Regulation (EC) No. 1829/2003, the GMO panel will consider all scientific comments posted on the EFSAnet by the NCA for Directive 2001/18/EC even if possibly grouped together. In the practice, this statement does not seem to be fully applied. Indeed, although most of the comments posted up to now by the BAC have been considered by EFSA, some of them requiring answer or further investigation did not seem to be taken into account nor forwarded to the applicant⁸. All scientific comments posted up on the EFSAnet should be considered appropriately and fully processed (i.e. transmitted to the notifier, found non relevant for the EFSA GMO panel and why...).

In this respect, the BAC supports the Commission's proposals⁹ to improve the relationship and interaction between EFSA and national scientific bodies. This could be achieved for example by (i) inviting EFSA to provide more detailed justification for not accepting scientific opinions raised by national experts; (ii) organising on a case by case basis bilateral meetings between EFSA and national scientific bodies; (iii) inviting national experts to attend meetings of the GMO panel as observers.

In relation to the recent Commission's proposal to address more explicitly biodiversity issues, the composition of the EFSA GMO panel could be reconsidered relatively to the respective necessary expertises.

⁸ This applies in particular to the evaluation of the dossiers UK-2004-06 and BE-2004-07, for which the BAC stated that the feeding trials, which are the same for both dossiers, should have included more animals per treatment to increase the power of the statistical analysis or sensitivity of the trials. This scientific comment was not taken into account by EFSA.

⁹ Press release IP/06/498, 12 April 2006



2. How could the European decision rules pertaining to the marketing authorisations given to the GMOs become more transparent?

2.1. Step 5 of the procedure: Public consultation

Public consultation takes place during one month after the publication of the overall opinion of EFSA. The documents available for the public are a summary of the application, and the final opinion of EFSA including among others, the GMO panel opinion, the monitoring plan and information related to the detection method.

The BAC and the SBB have already mentioned since several years that the summary of the notification (SNIF) as foreseen by Directive 2001/18 was not fully adapted as a mean to provide readable and easily understandable information to the general public. It is indeed important to use a comprehensible language, which is accessible to everyone. Scientific terminology and concepts should be explained; advertising messages should be avoided; advantages and inconvenients of the GMO in comparison with the present situation could be exposed, with as much as possible precise scientific arguments.

For experimental releases with GM plants, Belgium has issued guidelines to compile the information sheet for the public¹⁰, which could be used as a basis for further discussion on this matter at EU level.

Meanwhile EFSA should always make the public aware that on request access can be given to documents (for example results from the toxicology, allergenicity or environmental studies) available in the dossiers.

Finally, one-month consultation for the public is short. If the timelines can't be extended an alert on the website of EFSA could make the public aware at the time a dossier is open for consultation.

2.2. Step 6 of the procedure: Commission draft decision

The draft decision of the Commission should be based on an EFSA report where scientific uncertainties and lack of sufficient data are clarified. Potential risks are good reasons to be cautious, to refuse the authorisation or to impose specific monitoring plans.

¹⁰ available on the Belgian Biosafety server on the following address:
http://www.biosafety.be/gmcropff/EN/TP/partB/public_info_dos.htm



Conclusion

In conclusion, the BAC would like to underline the following suggestions as a way to improve the risk assessment procedure for GMOs intended for food or feed uses:

- The applicant and EFSA should address more explicitly potential long-term effects and biodiversity issues in their risk assessments, underpinned by the necessary expertise in the EFSA GMO Panel;
- The current guidance notes developed by EFSA should be completed with guidance summarising for the applicants some generally recognised valid research protocols whereas allowing at the same time flexibility and rapid adaptation to new scientific knowledge; The statistical protocol for data analyses should be provided;
- The EFSAnet should be practically improved in order to facilitate the download, the use and the upload of information by the national scientific bodies;
- Interaction between the EFSA GMO panel and national experts should be improved in a realistic way with a view to resolving possible diverging scientific opinions between EFSA and Member States, in a collective, interactive and iterative learning process with continuous feed backs;
- The scientific opinions of the EFSA GMO panel should be written according to scientific standards, providing detailed scientific justification and addressing, when relevant, scientific uncertainties;
- The public should be better informed through comprehensible and easy accessible information;
- Each decision proposal should be based on scientific arguments.



Prof. D. Reheul
President of the Biosafety Advisory Council.

Annex I: List of EFSA dossiers which from 2004 till now were fully evaluated by the Biosafety Council or by the Division of Biosafety and Biotechnology on mandate of the Biosafety Council

Annex II: Procedures and timelines for the scientific evaluation and the authorisation of a GMO application submitted at EFSA)



Annex I
List of EFSA dossiers that from 2004 till now were fully evaluated by the Biosafety Advisory Council (BAC) or by the Division of Biosafety and Biotechnology (SBB) on mandate of the Biosafety Advisory Council

EFSA GMO nr.	GMO	Notifier	Activity	Reference and date of EFSA GMO panel opinion	Reference and date of advice of the BAC
UK-2004-01	Maize (NK603 x MON810)	Monsanto	Food/feed		WIV/1520/GMCROFFF/06-0421 (08-05-2006)
DE-2004-03	Maize (MON863 x MON810)	Monsanto	Food/feed		WIV/1520/GMCROFFF/06-0420 (08-05-2006)
UK-2004-04	LLRICE62	Bayer CropScience	Food/Feed Import and processing		Comments posted by the BAC on the EFSAAnet – waiting GMO panel opinion to finalise for the Belgian authority
UK-2004-06	Maize (MON863 x NK603)	Monsanto	Food/Feed Import and processing	6 July 2005 (The EFSA Journal, 2005, 255, 1-21) ¹¹	BAC_2006_SC_308 (01-02-2006)
BE-2004-07	Maize (MON863 x MON810 x NK603)	Monsanto	Food/Feed Import and processing	6 July 2005 (The EFSA Journal, 2005, 256, 1-25) ¹²	BAC_2006_SC_309 (01-02-2006)

¹¹ see: http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/703_en.html

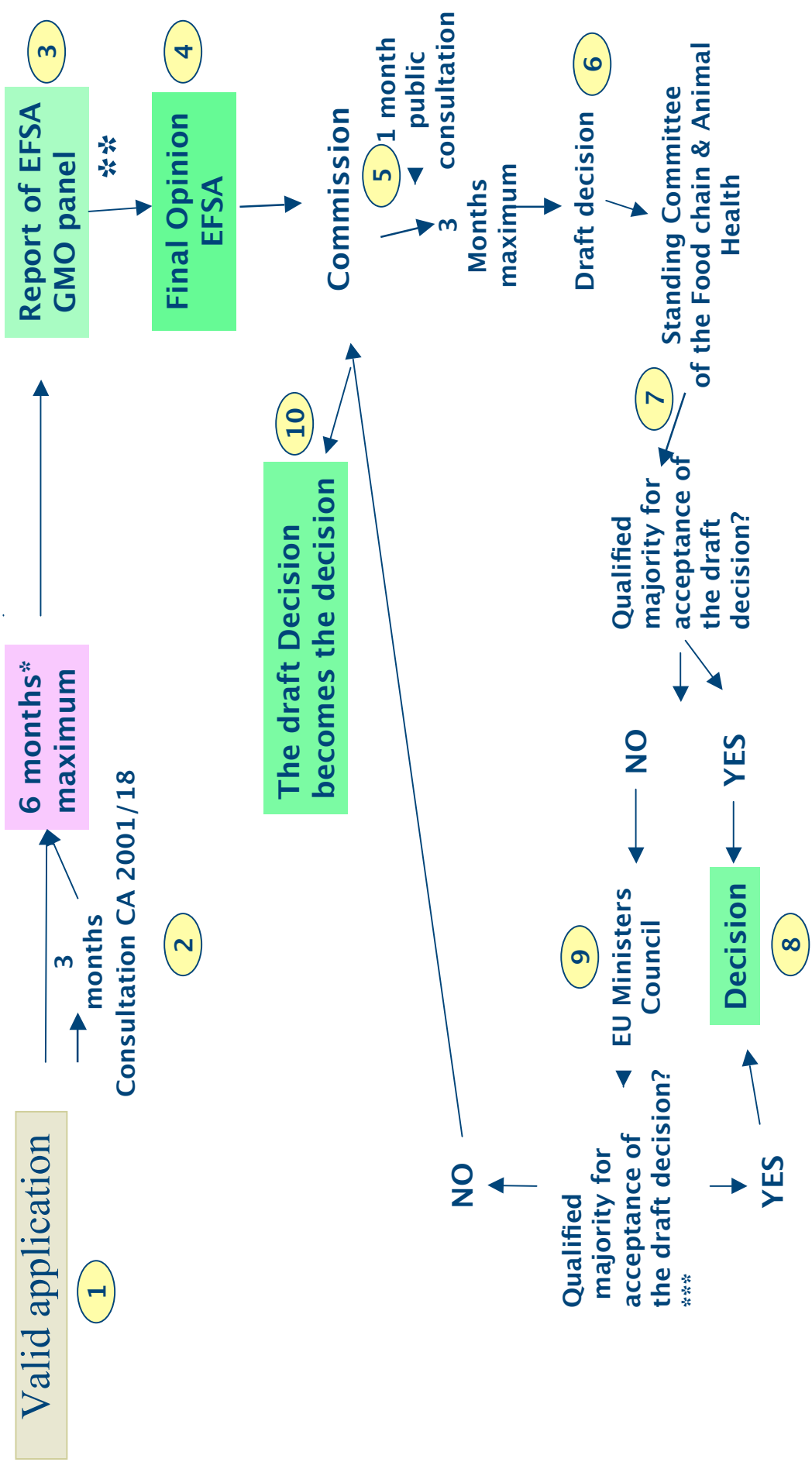
¹² see: http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/720_en.html



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Timelines dossier 1829/2003 (EFSA)



* Clock stop when request for additional info

** Clock stop if JRC or other bodies wait for additional info

*** If qualified majority for rejection of the decision, the Commission is asked to draft a new decision