

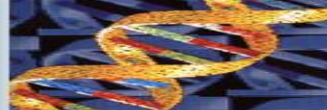
DEALING WITH GMO'S IN EUROPE

Handling of Requests: Contained Use

Zagreb, 22. 10. 2004

Dr. Dietmar Vybiral
Federal Ministry of Health and Women, Vienna, Austria
Division IV, Department B/12
Biotechnology and Genetic Engineering





Proceeding for a notification (Biosafety level 1 and 2)

1. Receipt of an application for notification
(The clock starts to run)
2. Confirm to the applicant the receipt of the request
(including the date when the clock starts)
3. Check the sufficiency of the application. i.e. is all
the information given, you need for the evaluation of the risk
assessment

- If yes, then: verify the risk assessment

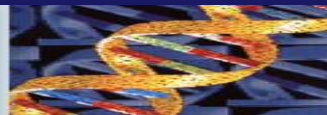
- If not, then: additional claim for the missing information (this
will stop the clock)





Proceeding for a notification (Biosafety level 1 and 2)

4. If the risk assessment is correct, send a letter of conformation to the applicant
5. If risk assessment is not correct, adjust the biosafety level. Send a letter to the applicant including the argumentation of the adjustment (this will stop the clock, too)
6. If the applicant accepts the adjustment, then he has to send a modified application of notification (clock is running)
7. If the risk assessment of the modified application is correct, then send conformation to the applicant





Proceeding for a notification (Biosafety level 1 and 2)

8. If the applicant does not accept the adjustment of the biosafety level, then a hearing of the application will be done by the advisory body (Clock still stopped)
9. Send a letter with the advisory opinion to the applicant
10. If the applicant accepts this decision then he has to send a modification of the application (clock starts, the day you received it). Then you have to verify the risk assessment again and if all needed modifications are done you send the letter of conformation
11. If the applicant still not accept this decision, then send the letter of interdiction





Proceeding for a permit (Biosafety level 3 and 4)

- basically the same as for the notification
- exception: A hearing of the application by the advisory body is an obligation
- the further proceeding is the same as for a notification; i.e. verification of the risk assessment, letter of permission or interdiction





Mandatory Information in the Application ("need to know")

- **scale of the work**
- **biosafety level**
- **classification of the GMO**
- **informations about the carrier, the BSO the BSC, the project manager and the premises**
- **summary of the intended work (title, description of the projected experiments, description of the recipient- and donor-organisms, the used vectors and the genetic manipulation**





Mandatory Information in the Application ("need to know")

- **statement of the risk assessment and the resulting biosafety classification**
- **inactivation of GMO and waste disposal**
- **signature of the carrier**
- **above biosafety level 1: additional information about the measures for preventing accidents**
- **above biosafety level 2: additional information about the emergency plan**





Obligatory Attachments to the Application: "need to know"

- curriculum vitae of the BSO, the deputy of the BSO, the members of the BSC and the project manager
- constructional drawings of the premises

Additional Attachments (not obligatory): "nice to know"

- relevant literature
- minutes of the BSC
- maps of the used vectors





Verification of the Risk Assessment

- based on the law, and the accompanying regulations of your country
- based on international guidelines and biosafety lists
- based on the experience of the responsible scientific officer at the competent authority





Some Hints for the Verification

- try to understand the aim of the project
- find and read relevant literature, separate from the literature, the applicant attached
- make your own risk assessment and compare it with the risk assessment of the applicant





Expertise

- based on the results of the verification of the risk assessment, write a detailed expertise
- including the argumentation of the risk assessment as well as citations of the relevant literature, laws, accompanying regulations, international guidelines and biosafety lists

Based on this expertise, the decision if the notification will be confirmed or the permit will be given, is taken

