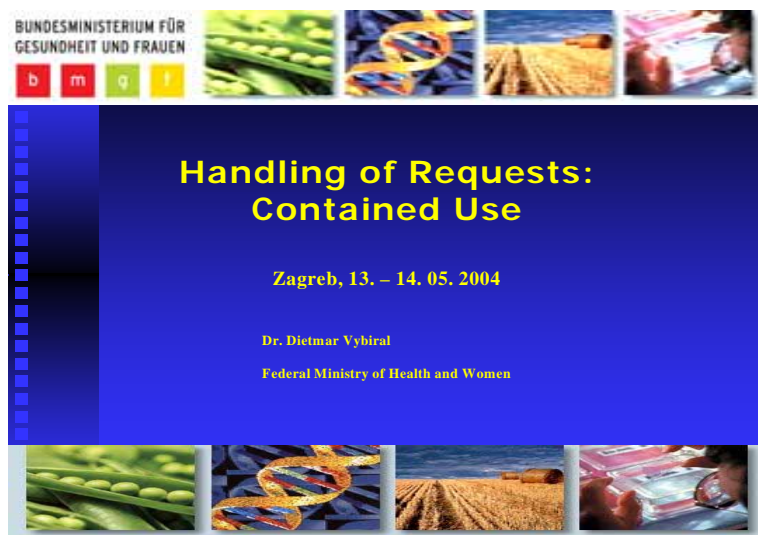


Handling of Requests:

Contained Use



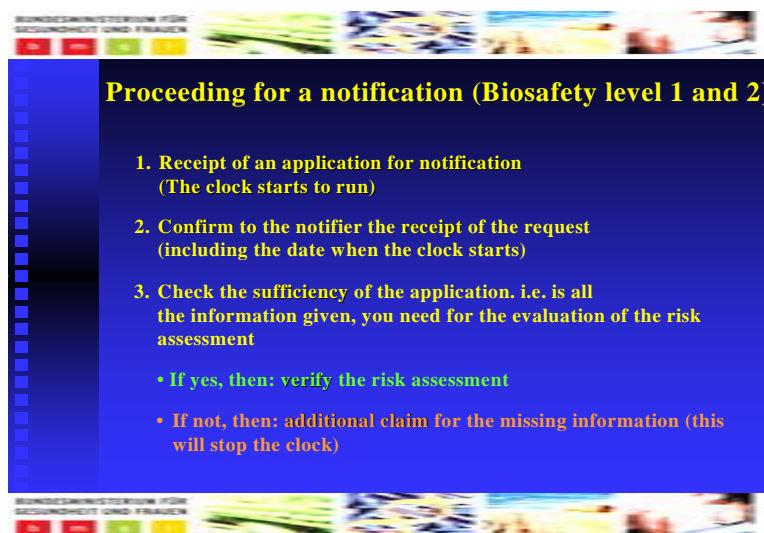
In this talk, the Austrian proceeding for a notification as well as for a permit for work with GMO in the contained use, will be explained. Based on the Austrian Gene Technology Act, there is a difference between a notification and a permit. If the intended work with GMO in the contained use is classified into biosafety level 1 or 2, the applicant needs to make an application for a notification. If the intended work is classified into biosafety level 3 or 4 then the applicant needs an application for a permit.

A notification has to be done for the following types of work:

- 1.) first time work with GMM in a premises in biosafety level 1
- 2.) first time work with GMM in a premises in biosafety level 2
- 3.) further work with GMM in a premises in biosafety level 2
- 4.) first time work with transgenic plants or animals in a premises
- 5.) further work with transgenic plants or animals in a premises if the work can not be classified into biosafety level 1
- 6.) further work with transgenic vertebrates in a premises in biosafety level 1

This means, for example, that if a company intends to make further work with GMM in biosafety level 1, which is comparable to the first time work, they have notified to the competent authority (hereafter named CA), they do not need a new notification.

Contrary to this is the application for a permit for work with GMM in the contained use in biosafety level 3 or 4. In this cases, even when the company has an permit for first time work with GMM, they have to applicate for a permit for each other work, too.



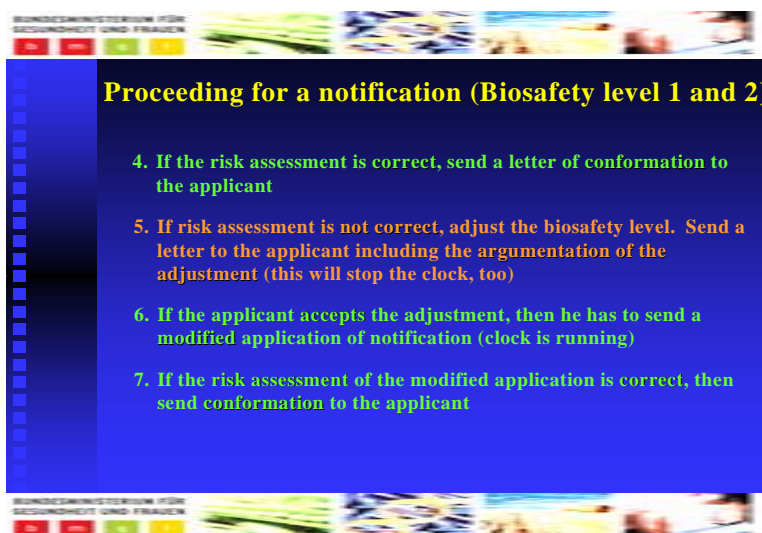
The first example deals with an application for a notification in biosafety level 1 or 2.

If an application for notification is received by the CA the first important point is to confirm the applicant the receipt of the request, including the date of reception. This is important, because this is the moment, when the clock starts to run. Based on the Austrian law, the CA has a given timeframe for the proceeding. Work mentioned above under point 1 and 2 are allowed to be started 45 days after the notification was received by the CA, if there is no reason for an interdiction recognized by the CA. If the minutes of the biological safety committee (BSC) is attached, this timeframe is reduced to 30

days. If the applicant has an notification or a permit by the CA for work which is classified in higher biosafety level in the same premises, the work, mentioned above under point 1 and 2, is allowed to be started immediately after the notification as it is the case for work mentioned above under point 3.

For notifications mentioned under points 4 to 6 the timeframe is 30 days. If the minutes of the BSC are attached for work mentioned under point 5 and 6 the work is allowed to be started immediately, presumed that no permit according to the law on animal experiments is need.

After the timeframe for the proceeding is set, the next important step is to check the application for its sufficiency. This means all information must be given for the evaluation of the risk assessment. If the information in the application is sufficient, than the risk assessment done by the applicant has to be verified by the CA, if there is some information missing, than the CA will claim for additional information, which will stop the clock until the information is received.

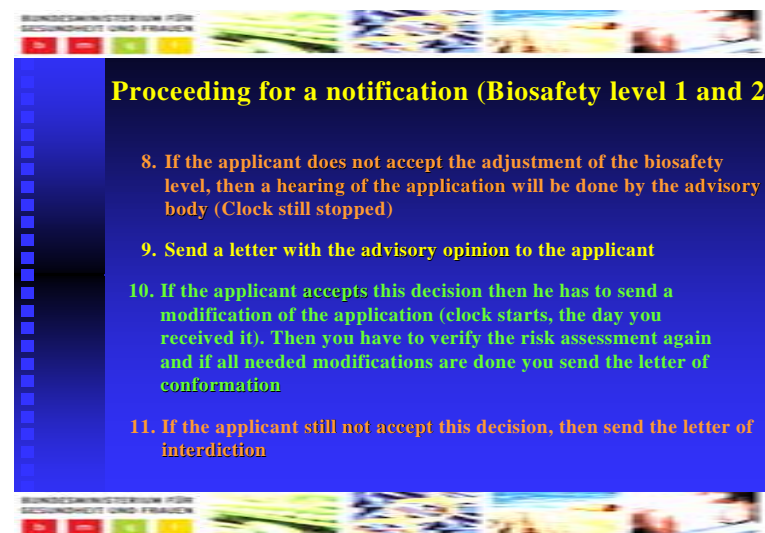


If the verification of the risk assessment turns leads to the opinion, that the intended work is classified correctly, the safety precautions are sufficient and therefore there is no risk for human beings and the environment then the applicant will receive a letter of conformation by the CA and the proceeding ends.

If the risk assessment done by the applicant is not correct, then the biosafety level has to be adjusted. Therefore the CA will inform the applicant that the intended work is not allowed to conduct under the mentioned safety precautions. Attached to this information should be a statement made by the CA, why the intended safety precautions are not sufficient, that the applicant has to improve them and send the

adjustments again to the CA and that the clock is stopped until the CA has received the adjustments.

If the improvements are sufficient, then the CA will send the letter of conformation and the proceeding ends.



In cases where the applicant does not accept the adjustment recommended by the CA, the Austrian law provides the opportunity of a hearing held by the scientific committee for contained use (Wissenschaftlicher Ausschuß für Geschlossene Systeme; WAGS). In this case, the application will be judged by the members of the WAGS and based on their opinion a statement will be send to the applicant by

the CA. During the time, the opinion of the WAGS is prepared, the clock is stopped again.

If the applicant accepts this decision he can send a modified application to the CA. Based on the modified information, the risk assessment is verified again, and if all is correct the letter of conformation will be send to the applicant.

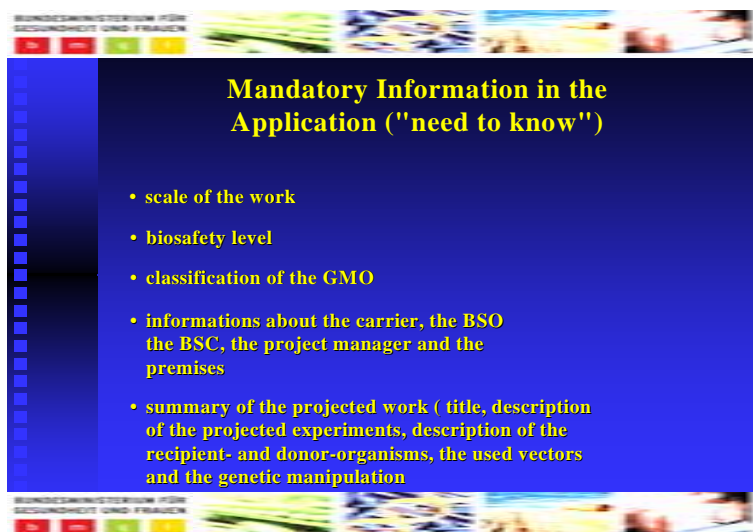
If the applicant will still not accept this decision, then a letter of interdiction will be send by the CA and the intended work will be not allowed.

As mentioned above, if the intended work is classified into biosafety level 3 or 4 an application for an permit for work with GMM in the contained use is a must. These works are not allowed to be started before the permit is given to the applicant by the CA. The timeframe in this cases is 45 days for an permit for first time work in biosafety level 3 when the applicant has an permit for first time work in biosafety level 4 in the same premises as well as for permits for further work in biosafety level 3. In cases of first time work in biosafety level 3 in an premises which has no permit to work in biosafety level 4 or for all application in biosafety level 4 the timeframe is 90 days. This can be shortened down to 60 days, when the minutes of the BSC are attached.

The proceeding is basically the same as the proceeding for an notification. The only exception is, that a hearing of the application by the WAGS is an obligation.

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 rest of the proceeding is the same as for a notification; i.e. verification of the risk assessment, letter of permission or interdiction

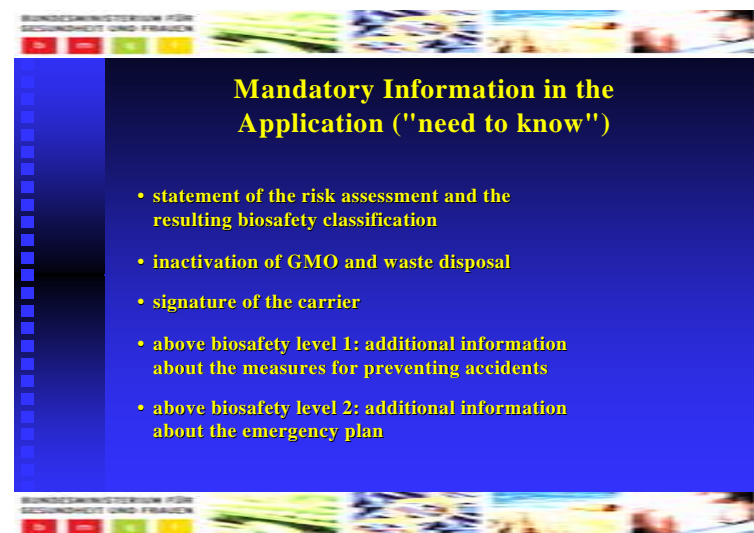


As it was mentioned before the major task of the CA is to verify the risk assessment made by the applicant concerning to the precautionary principle, which means that the containment has to be sufficient so that no risk for human beings and the environment is given.

Therefore some mandatory Information has to be in the application.

This „need to know“ includes information about the scale of the work, the biosafety level, the classification of the GMO, the carrier, the qualification of the biological safety officer (BSO) and his deputy, the members of the BSC and if applicable (for work above biosafety level 1) the project manager as well as detailed information about the premises and the equipment. Furthermore there has to be a summary

of the projected work including a title, a detailed description of the intended experiments as well as a description of the recipient- and donor organisms, the used vectors and the intended genetic manipulation.



More mandatory information concerns the statement of the risk assessment and the resulting biosafety classification and information of the intended inactivation of GMM and the waste disposal.

Applications above biosafety level 1 need additional information about the measures for preventing accidents and applications above

Biosafety Regulation in Croatia – Workshop in Zagreb, 13. – 14. 05. 2004; Handling of requests; Dr. Dietmar Vybiral, Federal Ministry of Health an Women, Div. IV/B/12, Austria

biosafety level 2 need additional information about the emergency plan. The application has to be signed by the carrier to be valid. It is recommended that the CA provides a form, where the applicant can fill in all the mandatory information and which will be send signed to the CA.

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

Additional to the filled form, some obligatory attachments has to be send to the CA by the applicant. These are the curriculum vitae of the BSO, the deputy of the BSO, the members of the BSC and the project manager. Based on this information the CA can get an idea if the proposed persons fulfill the requirements based on the Austrian law.

The BSO and his deputy need at least 2 years practical experience with work with GMO comparable to the GMO in the intended work, and has to have knowledge about safety precaution measurements. The project leader has to prove sufficient experience in work with GMO and safety precaution measurements and the members of the BSC have to have a proved knowledge about work with GMO.

Some additional attachments, which are not obligatory, can be send by the applicant attached to the application. This „nice to know“ things can be relevant literature, maps of the used vectors, the minutes of the BSC etc.

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 official 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

The verification of the risk assessment provided by the applicant is based on the law as well as on the accompanying regulations of your country. Also international guidelines and biosafety lists has to be used. However, the most important fact for a correct verification of a risk assessment is the experience of the responsible official at the CA. It is very important to understand the aim of the intended project otherwise it is difficult to assess the potential risks and adverse effects. Therefore it is recommended to find, read and understand relevant literature, separate from literature the applicant has eventually send with. Based on the given information, the experience and the literature it is important to make an own risk assessment and to compare it with the risk assessment the applicant has made.



When the risk assessment is verified the CA has to write a detailed expertise including the argumentation of the risk assessment together with the citations of all used literature, laws, accompanying regulations, international guidelines and biosafety lists. It important to remember, that based on this expertise the decision if the notification will be permitted or the permit will be given or not.