

PRESENTATION OF THE FINAL RESULTS OF DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS

IN ACCORDANCE WITH ARTICLE 10 OF DIRECTIVE 2001/18/EC

The final report format shall be completed by the notifier.

- The notifier shall fill in the report format according to the proposed form.
- The notifier shall illustrate as much as possible the reported data by means of diagrams, figures and tables.
- Statistical data could also be provided where relevant.
- In the case of multi-sites and/or multi-events release(s) the notifier shall provide a general overview of the measures taken and effects observed for the full duration of the consent.
- The space provided after each item is not indicative of the depth of the information required for the purposes of this report.
- The information provided in this report is not considered confidential in accordance with Article 25 of Directive 2001/18/EC.

1. General information

1.1. European notification number: B/NL/06/009

Number can be found on the corresponding SNIF form (i.e. year and number, B/NL/xx/xxx)

1.2. Member State of notification: The Netherlands

1.3. Date of consent: 01-11-2006

Date of issue of permit

1.4. Title of the project: An open-label phase 1 study to evaluate the safety of the HIV-1 vaccine MVA-B in chronic HIV-1 infected patients successfully treated with HAART

1.5. Name of institution or company: Academic Medical Center

i.e. legal entity = notifier

1.6. Duration of release: March 2007 till May, 2008

1.7. Period of release: January 2006 – December 2008

2. Characteristics of the release

2.1 Scientific name of the recipient organism:	Homo sapiens
2.2 Transformation event(s) (acronym(s)) or vectors used: <i>Describe the GMO(s) and/or vector(s) and insert(s) used for the modification</i>	Modified Vaccinia Ankara in which sequences, built from HIV-1 derived recombinant genes, are inserted.
2.3 Unique identifier, if available: <i>i.e. product name or GMO name</i>	MVA-B
2.4 Geographical location(s) (administrative region):	Amsterdam, The Netherlands
2.5 Number of test subjects:	10
2.6 Amount of GMO administered to each test subject:	1 x 10E7,5 fpu MVA-B
2.7 Number of administrations per test subject:	2

3. Risk management measure(s)

Please report the risk-management measures used to avoid or minimize the spread of the GMO(s) outside the site(s) of release, and in particular those measures

- *not originally notified in the application,*
- *applied in addition to the conditions in the consent.*
- *required by the consent only under certain conditions,*
- *that the consent allowed the notifier a choice of measures.*

Answer: No additional measures on top of the application and consent were taken. The environmental risk assessment scored the study as negligible.

4. Post-release monitoring measures

Please describe here any monitoring strategies.

Answer: Next to the monitoring measures described in the application and consent the subjects are send home with instructions concerning the plaster that is applied on the skin of the injection site, indicating proper waste treatment including decontamination of the plaster and the skin with alcohol 70% and subsequent hand washing.

5. Results of the foreseen and unforeseen release(s)

Consider in the following questions 5.1 through 5.4 all results of the foreseen and unforeseen release(s) in respect of any risk for human health or the environment, without prejudice to whether the results indicate that any risk is increased, reduced or remains unchanged.

5.1 Results of the study

Provide a summary of the study results in respect of any risk for human health or the environment. Include also the results of the monitoring measures (if applicable).

Answer: The vaccination went well without additional risk for human health or the environment.

5.2 Unexpected effect(s) and adverse effects

'Unexpected effects' refer to effects on human health or the environment, which were not foreseen or identified in the environmental risk assessment of the notification. This part of the report should contain any information with regard to unexpected effects or observations relevant for the initial environmental risk assessment. In case of any observed unexpected effects or observations, this section should be as detailed as possible to allow a proper interpretation of the data.

Answer: the administration of MVA-B was well tolerated in all subjects. During the study no unexpected or adverse effects occurred.

5.3 Unintended release of the GMO

'Unintended releases' refer to any incidents or spills with regard to the GMO that occurred during the study, where possible effect(s) on human health and/or the environment cannot be excluded. Describe these effects, including actions taken to manage the risks.

Answer: no unintended release of the GMO occurred

5.4 Other information

Notifiers are encouraged to supply information, which is outside the scope of the notification but which might be relevant to the trial(s) in question. This may also include observations of beneficial effects.

Answer: During inspection of VROM-Inspectie Noord-West (dhr. P.J.M. de Wildt) and Bureau GGO Bilthoven (dhr. D.A. Bleijs) July 17, 2007, the study DGM/SAS IM 06-009 was evaluated, and no deviations from the permit were identified.

6. Assessment of risk following completion of release

Please provide a reflection of the risk assessment and risk management strategies carried out prior to the release in relation to the obtained results and findings of for instance monitoring and samples taken from the test subjects. Do the results of the study justify the performed environmental risk assessment and conclusion?

Answer: the results justify the performed environmental risk assessment and conclusion.

7. Conclusion

Here the notifier should elaborate on the efficacy and efficiency of all measures taken, and elaborate on the insights gained during this release. Also, specify how the gain in experience can benefit further (future) releases with respect to risk management.

Answer: the results were in accordance with the expectations. The risk of negative environmental side effects occurring was extremely low. The replication deficient vector was

classified as a pathogenicity risk class-1 organism and the environmental risk assessment considered the environmental risk as negligible.