EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Evaluation of veterinary medicinal products containing or consisting of Genetically Modified Organisms		
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1. Purpose

This SOP describes the steps taken by the Committee for Medicinal Products for Veterinary Use (CVMP) and the European Medicines Agency to satisfy the legislative requirements of the evaluation of veterinary medicinal products containing or consisting of genetically modified organisms (GMOs).

Background

The requirements for GMOs are generally considered as being of two distinct phases as described below.

Research and Development Phase

Where necessary (i.e. where a product contains or consists of organisms within the meaning of Article 2 of Directive 2001/18/EC), the Agency will draw the company's attention to Directive 2001/18/EC and to Article 31 of Regulation (EC) No. 726/2004. This should be done every time a potential applicant first makes contact with the Agency at the beginning of or during its development programme.

The potential applicant should then keep the Agency informed of any discussions that it might have with the competent authorities set up by Directive 2001/18/EC (GMO CAs).

(a) If, during such discussions, it is established that the product contains or consists of GMOs within the meaning of Article 2 of Directive 2001/18/EC, no further action is required with regard to the marketing authorisation application until the letter of intent to submit an application for the granting of Community marketing authorisation is sent to the Agency. The Agency will however remind potential applicants of their obligations in this context.

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(b) If it is established that the product contains or consists of organisms within the meaning of Article 2(1) of Directive 2001/18/EC, but that they are not GMOs within the meaning of Article 2(2) of Directive 2001/18/EC, the Agency, through its Scientific Committees, may confirm this position. If confirmation cannot be given, the Agency will contact the bodies set up by the Community and member states in accordance with Directive 2001/18/EC.

Evaluation Phase

In the case of a veterinary medicinal product containing or consisting of GMOs within the meaning of Article 2 of Directive 2001/18/EC, the application must be, in accordance with Article 31 of Regulation (EC) No. 726/2004, accompanied by:

- a copy of any written consent or consents of the competent authorities to the deliberate release into the environment of the GMO for research and development purposes, or for any other purpose than placing on the market where provided for in Part B of Directive 2001/18/EC or in Part B of Directive 90/220/EEC;
- the complete technical file supplying the information required under Annexes III and IV to Directive 2001/18/EC;
- the results of any investigations performed for the purposes of research or development.
- the environmental risk assessment and its conclusion performed as requested in Annex II section D of Directive 2001/18/EC and following the guidance presented in the Notice to Applicants (NtA);

The responsibility to assess whether the release into the environment, for the purposes of research or development, poses a hazard or not, rests with the competent authority set up by Directive 2001/18/EC in the Member State where these investigations take place.

However, it is the responsibility of the Agency, through its Committee for Medicinal Products for Veterinary Use, to assess whether the placing on the market of a veterinary medicinal product containing or consisting of GMOs within the meaning of Article 2 of Directive 2001/18/EC poses a hazard to human health and/or to the environment. Such an assessment is made in conjunction with the other particulars submitted for the granting of a community marketing authorisation.

Once a pre-submission meeting has taken place and the CVMP has appointed a rapporteur and co-rapporteur, the GMO CAs will be advised that an application for a product falling under Article 31 of Regulation (EC) No. 726/2004 is expected, with an indication of the intended date of submission. Updates are provided to the GMO CAs indicating the status of each product containing or consisting of a GMO, whether authorised, under evaluation or anticipated.

To expedite the progress of the consultation with the GMO CAs, the Scientific Administrator appointed to the procedure (PM) should consider appointing one of the GMO CAs to act as “lead consulted competent authority” to act as contact point in the consultation and who would liaise as necessary with fellow GMO CAs on the review of Part III.E, as provided by the applicant.

The PM will make clear that the data provided by the applicant and any other documentation are strictly confidential.

2. Scope

This SOP applies to the Veterinary Medicines department.

It applies to veterinary medicinal products evaluated in accordance with Article 31 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council.

The SOP addresses two points specifically:

- How the Agency complies with the specific requirements regarding applications for veterinary medicinal products containing or consisting of genetically modified organisms within the meaning of Directive 2001/18/EC on the release of genetically modified organisms into the environment; and
- How the CVMP ensures that all appropriate measures are taken to avoid adverse effects on human health and the environment that might arise from the release of genetically modified organisms into the environment.

The SOP also describes the procedure by which the rapporteur holds the necessary consultations with the GMO CAs during the evaluation under the centralised procedure for products containing or consisting of GMOs.

3. Responsibilities

It is the responsibility of the Head of the Veterinary Medicines department to ensure that this procedure is adhered to. The responsibility for the execution of a particular part of this procedure is identified in the right hand column of section 9.

4. Changes since last revision

Update of contact details in Annex and revision of organisational denominators following restructuring of the European Medicines Agency.

5. Documents needed for this SOP

- List of official contact points in competent authorities in accordance with Directive 2001/18/EC (see Annex)

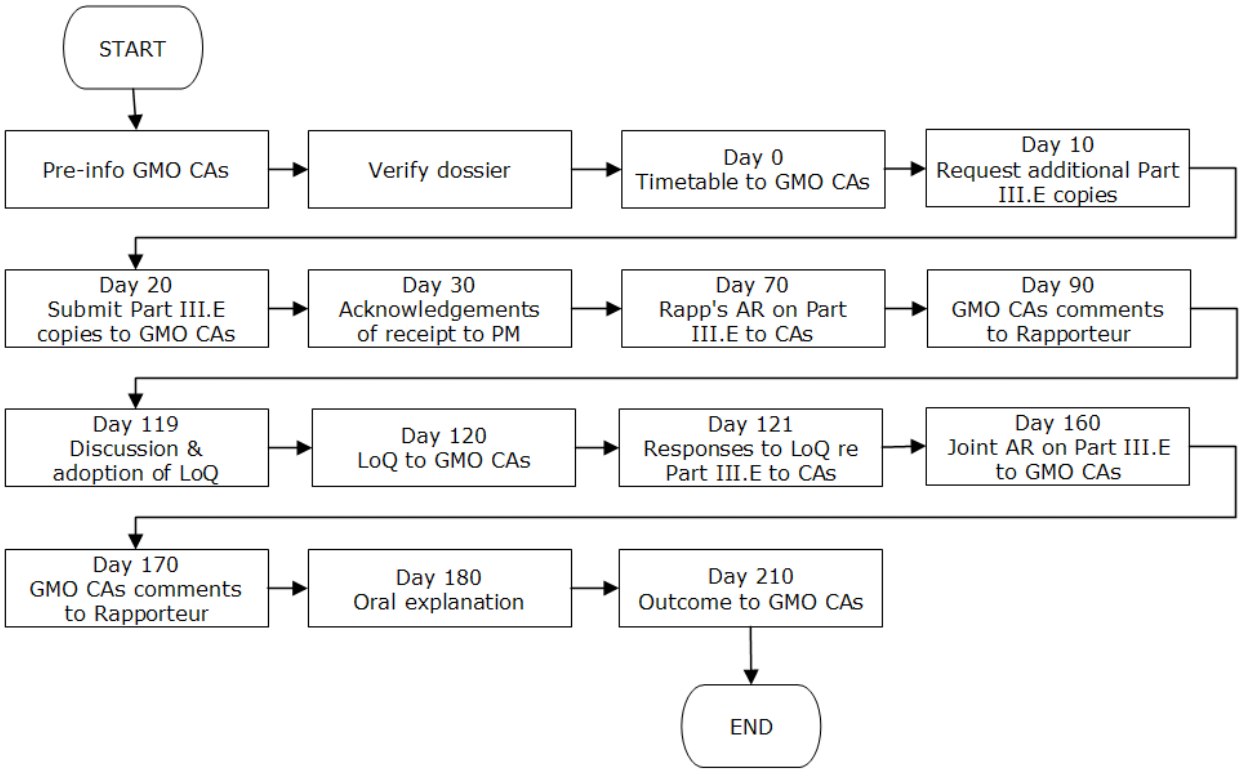
6. Related documents

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms
- Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms
- Volume 6C of the Rules Governing Medicinal Products in the European Union ("Notice to Applicants"; NtA)

7. Definitions

Centralised Procedure	evaluation procedure for veterinary medicinal products as specified in Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
CVMP	Committee for Medicinal Products for Veterinary Use: the Committee established by Title IV of Regulation (EC) No. 726/2004 replacing and repealing Council Regulation (EEC) No. 2309/93 and Article 31 of Directive 2001/82/EC (replacing and repealing Directive 81/851/EEC as amended)
GMO	Genetically modified organism: an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination and produced by techniques detailed in Annex IA of Directive 2001/18/EC
GMO CA	Competent authorities under Directive 2001/18/EC
Lead CA	Lead competent authority: A competent authority under 2001/18/EC volunteering to co-ordinate the comments of the GMO CAs and to act as the rapporteur's contact point in the consultation
LoQ	CVMP List of Questions
NtA	Notice to Applicants: the guidance published by the European Commission to assist applicants in their marketing authorisation application submissions
PM	Project manager: responsible for procedural support to the rapporteur and co-rapporteur and to act as a liaison point between the applicant for marketing authorisation and the agency
Rapporteur	Member of the CVMP appointed to lead the evaluation for the product concerned (assisted by the co-rapporteur, a second Member of the CVMP)

8. Process map(s)/ flow chart(s)



9. Procedure

Please note that this procedure details **only** the additional steps to be taken for the evaluation of products containing or consisting of GMOs and that **it is imperative to follow** SOP/V/4013 on the submission of an application for the granting of a community marketing authorisation.

Step	Action		Responsibility
1	Inform GMO CAs of intended application, including intended submission date, and request volunteers for the role of Lead CA.		PM
2	Verify that the documentation requested in Article 31 of Regulation (EC) 726/2004 has been submitted with the dossier.		PM
3	Day 0	Once the application has been validated, send a copy of the timetable to the GMO CAs and request feedback by day 10 whether a copy of Part III.E is required (from here on "involved GMO CAs"); informing also that the rapporteurs AR will be circulated by day 70 and that comments will be required by day 90.	PM
4	Day 10	Send requests for submission of additional copies of Part III.E to the applicant; having ensured that contact details are included in the requests.	PM
5	*Day 20*	*Applicant sends copies of Part III.E to involved GMO CAs.*	
6	Day 30	Ensure acknowledgements of receipt for involved GMO CAs have been submitted by applicant, together with the regular acknowledgements for receipt relating to the centralised procedure.	PM
7	Day 70	Send rapporteur's assessment report on Part III.E to the involved GMO CAs for comments to be sent to the Lead CA by day 90. Should no Lead CA have been appointed the comments should be sent directly to the PM.	PM
8	Day 90	Ensure that the Lead CA (or PM, as applicable) forwards all comments to the rapporteur, with a copy to the PM, if applicable.	PM/Lead CA
9	Day 119	The rapporteur will decide on the inclusion, or not, of any questions from the GMO CAs in the draft LoQ. All questions will be circulated to CVMP members and discussed at the rapporteur's meeting (if required) prior to adoption of the LoQ at CVMP. The exclusion of any questions should be justified by the rapporteur and agreed by the CVMP.	Rapporteur/CVMP

Step	Action		Responsibility
10	Day 120	Questions raised on Part III.E to be extracted from LoQ and sent to involved GMO CAs together with the justification for the exclusion of any questions, as applicable.	PM
		Inform applicant with the letter on the LoQ that the responses to questions on Part III.E will need to be sent to all involved GMO CAs.	PM
11	Day 121	*Applicant sends copies of responses to questions on Part III.E to all involved GMO CAs.*	
		Send timetable to all GMO CAs with information on the circulation of the joint rapporteur's and co-rapporteur's assessment by day 160 and the need for comments by day 170.	PM
12	Day 160	Send joint assessment report on Part III.E to the involved GMO CAs for comments to the Lead CA by day 170. Should no Lead CA have been appointed, the comments should be sent directly to the PM.	PM
13	Day 170	Ensure that the Lead CA (or PM, as applicable) forwards all comments to the rapporteur, with a copy to the PM, if applicable.	PM
14	Day 180	*In case of clock stop*: inform involved GMO CAs on relevant Part III.E questions in the list of outstanding issues. GMO CAs may be invited to attend the oral explanation.	PM
		PM to inform involved GMO CAs of the outcome of the oral explanation, if applicable.	PM
15	Day 210	Communicate the outcome of the assessment to all GMO CAs.	PM

10. Records

When completed and approved, original signed hard copies are filed in the Master File. Electronic copies are saved in the appropriately labelled product folder in DREAM, in accordance with the Core Master File procedure.

Annex I: Member state competent authorities / official contact points under Directive 2001/18/EC

MS	Contact person	Organisation	Address, tel.	e-mail
BE	Diederik Standaert Kelly Lardinois Lucette Flandroy	Federal Public Services (FPS) Health, Food Chain Safety and Environment	Place Victor Horta 40 bte 10 1060 Brussels BELGIUM Tel. +32 2 5247354 +32 2 5247399 Tel. +32 2 5247357 +32 2 5249622	diederik.standaert@gezondheid.belgie.be Kelly.lardinois@sante.belgique.be lucette.flandroy@health.fgov.be
BE	Adinda De Schrijver	Scientific Institute of Public Health (IPH) Division of Biosafety and Biotechnology (SBB)	Rue Juliette Wytsmanstraat 14 1050 Brussels BELGIUM Tel. +32 2 6425293	adinda.deschrijver@wiv-isp.be
BG	Tatiana Sultanova Nikolay Tzvetkov	Ministry of Environment and Water	22 Maria Luiza Blvd 1000 Sofia BULGARIA Tel: +359 2 9406123	tsultanova@moew.government.bg ntsvetkov@moew.government.bg
BG	Ms Desislava Vaseva	Ministry of Environment and Water	67 William Gladstone St 1000 Sofia BULGARIA Tel: +359 2 9406388	dvaseva@moew.government.bg
CZ	Zuzana Doubková	Ministry of Environment	Vrsovicka 65 10010 Prague 10 CZECH REPUBLIC	zuzana.doubkova@mzp.cz

MS	Contact person	Organisation	Address, tel.	e-mail
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DE	Detlef Bartsch	Federal Office of Consumer Protection and Food Safety	Mauerstrasse 39-42 10117 Berlin GERMANY Tel. +49 30 18445 6400	detlef.bartsch@bvl.bund.de
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IE	John O'Neill	Department of Environment, Heritage and Local Government	Custom House Dublin 1 IRELAND Tel. +353 1 8882554	john.oneill@environ.ie
IE	Lorraine O'Donoghue Alex Hurley	Department of Environment, Heritage and Local Government Environment Policy and Awareness Section	Newtown Road Wexford IRELAND Tel. +353 53 9117337 Tel. +353 53 9117341	lorraine.o'donoghue@environ.ie alex.hurley@environ.ie

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EL	Argyrios Boulis	Ministry of Rural Development and Food Directorate of Animal Production Inputs	Veranzerou 46 10438 Athens GREECE Tel. +30 210 5271627	me22u066@minagric.gr
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HU	Dóra Kovács	National Institute of Quality and Organizational Development in Healthcare and Medicines	Zrínyi u. 3 1051 Budapest HUNGARY Tel: +36-1-8869300/178	kovacs.dora@gyemszi.hu
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NO	Nina Vik Janne Bohnhorst Ingrild Skorve	Norwegian Directorate for Nature Management	Tungasletta 2 P.O. Box 5672 Sluppen 7485 Trondheim NORWAY Tel. +47 73 580636	nina.vik@dirnat.no Janne-ovrebo.bohnhorst@dirnat.no Ingrild.skorve@dirnat.no
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