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votre lettre du 26 juillet 2005
vos références DGM/Vet/FF 4245/7/05

nos références RD/RW/IVV/vim.486.22605
date

annexe(s) 01.09.05

Objet : Notification B/BE/04/BV1 de la compagnie Pfizer-Animal Health pour la libération volontaire dans l'environnement d'organismes génétiquement modifiés autres que des plantes supérieures, à des fins de recherche et développement.

Monsieur le Directeur Général,

Par la présente, je vous informe que l'autorisation imposée en vertu de la Section II de l'arrêté royal du 18 décembre 1998 est accordée au notifiant Pfizer Animal Health sur base de l'avis[1] favorable du Conseil de Biosécurité, et ce, aux conditions reprises dans la conclusion de l'avis précité, c-à-d :

« 1. *The treatment is only administered to cats kept in a controlled environment (catteries, veterinary clinics or practices) guaranteeing that i) the treated cats will be kept contained and ii) will not be in contact with other felidae. The cats that have been administered the GMOs must be maintained in this controlled environment for a minimum of 2 weeks following vaccination.*

2. *The monitoring as it is proposed by the notifier, i.e. intra nasal swabs collected every 3 days, from 6 days to 27 days after vaccination for the first 10 cats enrolled in the study should be justified on a rational basis. Moreover, it should address the putative recombination and latency issues. Therefore, the notifier must commit himself to collect additional swabs over a determined period in order to monitor the putative re-excretion of vaccine virus. Swabs positive for the presence of a Herpesvirus should be analysed in order to discriminate putative recombined rFeVH/wildtype isolates from the vaccinal and/or the wildtype parent strains. Since most nasal swabs collected soon after vaccination are expected to be positive for rFeVHenv/gag, not all early swabs must necessarily be tested.*

[1] Référence de l'avis du Conseil de Biosécurité : WIV-ISP/BAC/2005_SC_263

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The Notifier is thus asked to propose a timetable covering an adequately justified period post vaccination, which includes a molecular testing of given positive samples selected on a rational basis. The number of cats to be tested, the number and schedule of swabs per animal and the extent of the testing period should be based on the expected frequency of wildtype FeHV reactivation, in order to have a reasonable probability of isolating any putative re-excreted Herpesvirus . Moreover, any cat presenting unexpected clinical signs that could be related to a FeHV infection must be swabbed. The resulting sample must be carefully analysed for the presence of vaccinal/wildtype/recombined FeHV strains. Should a recombined isolate be detected, the new virus should be analysed for virulence and capacity to spread.

3. *The notifier and the investigators apply the protocol, the biosafety monitoring and, if necessary, emergency measures as described in the dossier and the accepted amendments.*
4. *Any protocol amendment, which could have biosafety implications, has to be reported to the competent authority.*

The Belgian Biosafety Advisory Council *wants also to relay the recommendations of its scientific experts in the prospect of a next trial (point 1 set out below) or a future application for a marketing authorisation (points 2 and 3 set out below):*

1. *If in a next trial the notifier wishes to include cats from individual owners the scientific reason for doing so should be documented.*
2. *It is assumed that the attenuation is the result of the sole TK deletion. However, it is not known whether the genetic manipulation did not introduce other genetic modifications that could account, at least in part, for the attenuated phenotype of the TK-FeHV-1. Studies on revertants, i.e. TK- FeHV-1 having acquired the TK gene by recombination using the same technique as for the production of the TK- FeHV-1, would allow addressing this point.*
3. *Considering that the TK deletion is actually identified as the major cause of attenuation, this does not rule out the virulence activity of other loci, which can undergo recombination. Such an exchange of virulence genes could putatively result in an increased virulence of the recipient virus, even if it is a TK mutant. The notifier is invited to consider this point.* »

Je vous prie d'agréer, Monsieur le Directeur Général, l'expression de mes salutations distinguées.

Rudy Demotte,