

EUROPEAN COMMISSION

JOINT RESEARCH CENTRE Institute for Health and Consumer Protection Chemicals Assessment and Testing

HEEG Opinion 10

Agreed at TM III 2010

Ispra, 13/08/2010

HEEG opinion on Harmonising the number of manipulations in the assessment of rodenticides (anticoagulants)

This document was prepared by DE in cooperation with HEEG.

Comparing the assessment of rodenticides with anticoagulants as active substance, it is obvious that member states (MS) use the same data basis in a different way. The following paper proposes a harmonisation of the interpretation of the outcome of a questionnaire evaluated by CEFIC [1], interpretation that is different within MS in relation to the number of manipulations for application of bait and for cleaning of bait stations (for details please see Appendix). The number of manipulations has a direct impact on exposure and is a relevant parameter, therefore harmonisation is needed.

Agreements of TM III 06

The TM III 06 agreed to use the following figures to assess the number of manipulations of baits (source: CEFIC questionnaire by Vetter and Sendor [1], 90th percentile of the determined figures):

Table 1: Agreed Number of manipulations

Type of bait	Number of manipulation per day and person	
Loose grain ¹⁾	79	
Wax block/Paste bait in sachets	75	
Paste bait in prefilled cartridge ²⁾	14	

¹⁾ Also valid for pellets/granules

The handling of bait is differentiated between a loading phase (application phase) of bait into bait stations and a cleaning phase (post-application phase) of bait stations after a waiting period. "It was agreed that 20 % of the exposure frequencies of daily use will be used to include the clean-up phase" (minutes of TM III 06).

For the handling of paste bait the following was agreed: The paste bait described in the report by Vetter and Sendor [1] was paste bait deployed using prefilled cartridges. Dermal exposure was considered possible only at removal and re-attachment of the nozzle's protection cap and was assumed to occur only before the first and after the last bait placing on a given site. Hence, the number of sites visited per day (multiplied with 2) was considered to be the relevant exposure determinant.

²⁾ Number of sites visited per day (multiplied with 2) to assess the dermal contact

For paste baits in sachets with a different exposure pattern than the one referred in the report, the figure used for wax blocks (for which the exposure determinant was the number of bait stations handled per day) was agreed on TMIII06. This was agreed for the active substance diffethialone.

Number of manipulations for application and for cleaning:

Discussion:

MS used the following three different options to assess the loading phase and cleaning phase:

- The number of manipulation includes a loading phase which is 80% of the number of manipulation and a cleaning phase with 20% of the number of manipulation (see e.g. Appendix evaluation of ES, FI).
- The number of manipulation is used for the loading phase and <u>additionally</u> 20% of this figure is used to assess the cleaning phase (see e.g. Appendix evaluation of NO, SE)
- The same number for manipulation is used to assess the loading and cleaning phase (see Appendix evaluation of NL)
- Furthermore a majority of MS did not assess a cleaning phase for the use of rodenticides in sewage system

In the report of Vetter and Sandor there is no hint that the number of manipulations take into account a cleaning phase (which means the disposal of the bait). The majority of MS use the number of manipulation for loading phase and additionally 20 % of the number of manipulations for the cleaning phase to assess the professional exposure to rodenticides.

In a position paper by the CEFIC Rodenticides Working Group (RWG) (13. July 2010) the CEFIC group is against using an additional number of 20% for the cleaning phase since the selection of the 90^{th} percentile appears to be very conservative. Thus the use of an additional number of 20% will combine two conservative exposure determinants. The proposal of CEFIC is to include the clean-up phase in the bait loading figure as 80/20 %.

Proposal:

HEEG follows the position of industry (further based on additional data determined by AT) and propose the following harmonised figures for the number of manipulations:

Table 2a: Harmonised number of manipulations for professional user

Type of bait	Number of loadings of e.g. bait stations per day and person (application phase)	Number of cleaning e.g. bait stations ^{1), 2)} per day and person (post-application phase)
Loose grain, pellets, granules	63	16
Wax block / Paste bait in sachets	60	15
Paste bait in prefilled cartridge	11	3

^{1) 20 %} of the number of manipulations per day and person

²⁾ For the application of rodenticides in sewage system no cleaning phase have to be assumed

Table 2b: Harmonised number of manipulations for <u>non-professional user</u>

The majority of the MS use the following numbers for non-professional exposure estimation

Type of bait	Number of loading bait stations per day and person (application phase)	Number of cleaning bait stations*) per day and person (post- application phase)
Loose grain, pellets, granules	5	5
Wax block	5	5
Paste bait in sachets	5	5

[1] T. Vetter, T. Sendor "Estimation of the frequency of dermal exposure during the occupational use of rodenticides", CEFIC Rodenticides Working Group, report and addendum (2006)



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Appendix: Overview about the different assessment of rodenticides by \overline{MS}

Grain bait

Active substance - Member State	Date of CAR	Frequency
Name of product		
Bromadiolan – Sweden	03-2008	Treating – 79
Super caid as appat		Cleaning – 16
Difenacoum –Finland	03-2008	Treating – 63
Neosorexa Pellets		Cleaning – 16
Difethialone – Norway	12-2006	Treating – 79
RODILLON pellets		Cleaning – 16
Chlorophacinone – Spain	07-2007	Treating and
Product p2		Cleaning – 80
Brodifacoum – Italy	2008	Treating – 37
Klerat pellets		

Wax Block

Active substance - Member State	Date of CAR	Frequency
Name of product Bromadiolan – Sweden Protect B wax block	03-2008	Treating – 75 Cleaning – 15
Difethialone – Norway FRAP BLOC	12–2006	Treating – 75 Cleaning – 15
Difenacoum – Finland Rabon Wax Block	06-2009	Treating – 60 Cleaning – 15
Brodifacoum - Italy Vertox wax block	07-2008	Treating – 33 Cleaning – 33
Flocoumafen – Netherlands Storm BB wax block	01-2009	Treating - 74.9 Cleaning – 74.9