Note to the file:

This Opinion has been revised by including the sentence "For package sizes ≤ 10kg, loose grains have to be placed on the bait point by using a dosage device (decanting is to be avoided)." in Section 1.1. Mixing & loading - Decanting of grain bait, as agreed by the Ad hoc Working Group on Human Exposure in September 2016.

EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
Chemical assessment and testing

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HEEG opinion on an

Harmonised approach for the assessment of rodenticides (anticoagulants)

This document was prepared by DE in cooperation with HEEG. This document is non confidential and described only the results of a detailed discussion layed out in a former confidential HEEG paper agreed at TM II 2011 (confidential paper on CIRCA available).

AIM

The following paper proposes a harmonised exposure assessment of anticoagulants (grain bait, wax blocks) based on Chambers *et al*. [1]. This paper focuses on professional use of rodenticides only.

INTRODUCTION

Comparing the assessment of rodenticides with anticoagulants as active substance, it is obvious that member states (MS) use the same exposure study in a different way. The interpretation of a study of Chambers *et al* [1] has varied among MSs. The original measurements of inhalation and dermal exposure are not published due to data protection.

This paper is a follow-up discussion of the agreed number of manipulations (TM III/10). The following agreed figures are included in the proposal:

Table 1: Agreed number of manipulation for professional use

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 cartridges	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

1. Assessment of grain baits

Grain baits are loose grain, pellets or granules. These different types of loose grain are assessed with the Chambers study as agreed at TM III 06. In the following section the wording 'grain bait' is used for loose grain bait, pellets and granules.

The following phases of application can be assessed using the Chambers study [1]

1.1 Mixing & loading - Decanting of grain bait

For package sizes ≤ 10kg, loose grains have to be placed on the bait point by using a dosage device (decanting is to be avoided). For package sizes over 10 kg of grain bait a decanting of 3 kg grain bait from a package size over 10 kg into a bucket is assumed. The resulting potential dermal exposure is assessed as follows:

1) For the assessment of 1 to 4 decanting times the value **93.0 mg b.p. / 3 kg decanted grain bait** for potential hand exposure is recommended.
2) For the assessment of more than 4 decanting timesthe value **52.3 mg b.p. / 3 kg decanted grain bait** for potential hand exposure is recommended.

To assess the number of decantings it is necessary to calculate the applied amount of grain bait. To calculate the daily applied amount the number of manipulations and the type of target species (rat or mouse) should be take account. The used amount per bait station is product specific and recommended by the producer depending on the type of rodent and the efficacy of the product (e.g. rat: 100 - 200 g bait, mice: 10 - 30 g bait).

The following calculation is recommended, taking into account both the number of manipulations and the amount used.

Example calculation

63 times of manipulations (see Table 1) of grain bait against rats with 200 g grain bait per bait station is assumed. The resulting used amount per day is 12.6 kg grain bait/day. To assess the potential dermal exposure during decanting phase the total amount of 12.6 kg should be included as follows:

$$\frac{52.3^{*)}\ \text{mg b.p.} \times 12.6\ \text{kg}}{3\ \text{kg}} = 219.7\ \text{mg b.p.}$$

The only relevant inhalation exposure is determined during decanting of loose grain.

The air concentration is assessed as **9.62 mg b.p./m^3**. The internal exposure value is calculated taking into account the duration of decanting. The duration of decanting and waiting period is assumed to be 3 min. per 3 kg grain bait.

Example calculation

Taking into account the agreed number of 63 manipulations and the recommended dose of bait (e.g. 200 g grain bait per bait station), the resulting bait amount is 12.6 kg grain bait. Approximately 5 times decanting of 3 kg bait is necessary with an assumed duration of 15 min. The duration of 15 min. is assumed for the calculation of the internal exposure.

1.2 Application - Loading and placing bait boxes

Grain bait from a 10 L bucket is placed using a plastic scoop. The resulting potential dermal exposure is assessed as follows:

1) For the assessment of up to 4 applications the value **3.57 mg b.p. per manipulation** for potential hand exposure is recommended.
2) For the assessment of more than 4 manipulations (the agreed number is 63 manipulations in professional use) the value **2.04 mg b.p. per manipulation** for potential hand exposure is recommended.

Example calculation

The recommended value for potential dermal exposure is **2.04 mg b.p. per manipulation**. Taking into account the agreed number of 63 manipulations (see Table 1) the resulting **potential** dermal exposure of professionals for the application phase is **128.5 mg b.p**.

Inhalation exposure is assessed as negligible.

1.3 Post-application - Cleaning of bait boxes

The operator emptied a loaded bait station containing with grain bait into a 10 L bucket. The resulting potential dermal exposure is assessed as follows:

1) For the assessment of 1 to 4 cleanings the value **4.52 mg b.p. per manipulation** for potential hand exposure is recommended.
2) For the assessment of more than 4 cleanings (the agreed number is 16 cleanings in professional use) the value **3.79 mg b.p. per manipulation** for potential hand exposure is recommended.

Example calculation

Taking into account the agreed number of 16 (see Table 1) the resulting potential dermal exposure of professionals for the post-application phase is **60.6 mg b.p.** As for the application phase, the amount of disposed bait is not taken into account.

Inhalation exposure is assessed as negligible.

2. Block bait

General issue: The data [1] determined for 'wax blocks' can be used for 'paste bait in sachet' as the handling and characteristics of these products are comparable. This was agreed at TM III 06. In the following section the wording 'block bait' is used for wax block or paste bait in sachet.

2.1 Mixing and loading phase

Not applicable for ready-to-use block baits.

2.2 Application phase – Securing blocks into bait stations

The Chambers study [1] determined the following scenario: securing of 5 compressed wax blocks (each 20 g, in total 100 g bait per box) into a bait station by pushing bait mounting pegs in the stations through holes in wax blocks.

The proposed value of **27.79 mg b.p**. for potential hand exposure is valid for loading of one bait box with block bait.

The resulting potential dermal hand exposure value of **27.79 mg b.p.** is valid for 5 contacts and one manipulation (e.g. one loading of bait box). If a lower number of bait blocks per bait station is needed, the respective number of contacts should be taken into account (see example calculation).

Example calculation

1) 5 bait blocks (each 20 g) per bait station is recommended by the producer. For the resulting potential dermal exposure of application-phase the agreed number of 60 manipulations (see Table 1) should be taken into account. For the application-phase the resulting potential dermal exposure is

27.79 mg b.p. x 60 = **1667.4 mg b.p.**

2) 1 bait block (200 g) per bait station is recommended by the producer. Taking the one contact and the agreed number of 60 manipulations into account the resulting potential dermal exposure is

   (27.79 mg b.p. / 5 contacts) x 60 = **333.5 mg b.p.**

Inhalation exposure is not expected.

1.2.3 Post-application phase – Clean-up and disposal of partly consumed bait blocks

The Chambers study [1] determined the following scenario: emptied a loaded bait station by sliding the wax block off the mounting pegs into a 10 L plastic bucket. The recommended value of **5.7 mg b.p**. for potential hand exposure is valid for the cleaning of one bait box. During the disposal phase the same level of contact occurs when sliding the blocks from the mounting pegs or overturning the bait box to empty it. Therefore the number of disposed blocks per bait box are not considered for this phase.

Example calculation

For the resulting potential dermal exposure of post-application-phase the agreed number of 15 manipulations (see Table 1) should be taken into account. For the post-application phase the resulting potential dermal exposure is **85.5 mg b.p.** The size of one bait block is ignored and the figure is valid for different sized blocks (e.g. 10 g, 100 g) as already proposed for the application phase.

Inhalation exposure is not expected.

Summary Tables

GRAIN BAITS (loose grain, pellets, granules) – summary of proposal

	Inhalation	**Dermal**	**Dermal**
	75th Percentile [mg b.p./m³]	**75th Percentile for 1-4 man. [mg b.p. per manipulation]**	**75th Percentile for >4 man. [mg b.p. per manipulation]**
Decanting 3 kg loose grain bait.	9.62 [1)]	93.01 (per 3 kg decanted grain bait)	52.34 (per 3 kg decanted grain bait)
Loading bait boxes - each manipulation consists of scooping bait material, filling bait point and placing it	-	3.57	2.04
Cleaning up of bait boxes and disposing of unwanted loose grain bait.	-	4.52	3.79

[1)] Measurement result not 8 h TWA

BLOCK BAIT (wax blocks, paste in sachet) – summary of proposal

	Inhalation	**Dermal**
	75th Percentile [mg/m³]	**75th Percentile [mg b.p. per manipulation]**
Loading bait boxes - placing **of 5 blocks** into a bait station	-	27.79
Cleaning up emptying of loaded bait stations, sliding the blocks off into a bucket	-	5.70

REFERENCES

[1] J.G. Chambers, P.J. Snowdon “Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits”. Synergy Laboratories Limited, Thaxted, UK, laboratory report number SYN/1302, 8 March 2004 Sponsor CEFIC/EBPF Rodenticides Data Development Group (unpublished, data protection)