The Rodenticide Regulatory Situation

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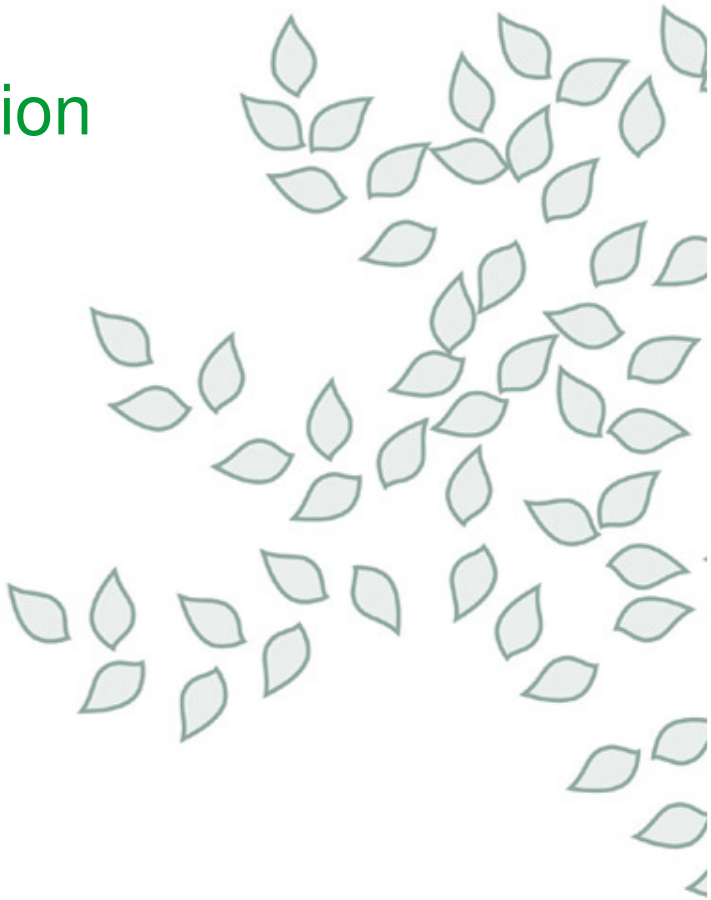

The Commission View of the Anticoagulant Rodenticides

RISK MITIGATION MEASURES FOR ANTICOAGULANTS USED AS RODENTICIDES CA-March07-Doc.6.3 – final

- "All these substances are **highly toxic**. They are also **non-selective**, and can pose a **high risk of primary and secondary poisoning to non-target animals and children**."
- "Most Rapporteur Member States (RMS) for these anticoagulants suggested **specific mitigation measures** to address these risks"
- BUT Commission and Member States do not believe that these mitigation measures can properly protect human health and the environment from these compounds

Rodenticides BPD Review is Completed!

Active Substance (AS)	Date of Inclusion Directive	Date of Annex I inclusion	Date of Expiry
difethialone	29 Nov 2007	1 Nov 2009	31 Oct 2014
carbon dioxide	24 Jul 2008	1 Nov 2009	31 Oct 2019
difenacoum	29 Jul 2008	1 Apr 2010	31 Mar 2015
bromadiolone	31 Jul 2009	1 Jul 2011	30 Jun 2016
alphachloralose	31 Jul 2009	1 Jul 2011	31 Jun 2021
aluminium phosphide	31 Jul 2009	1 Sep 2011	31 Aug 2021
coumatetralyl	29 Jul 2009	1 Jul 2011	30 Jun 2016
chlorophacinone	4 Aug 2009	1 Jul 2011	30 Jun 2016
flocoumafen	27 Nov 2009	1 Oct 2011	30 Sep 2016
warfarin sodium	9 Feb 2010	1 Feb 2012	31 Jan 2017
warfarin	9 Feb 2010	1 Feb 2012	31 Jan 2017
brodifacoum	9 Feb 2010	1 Feb 2012	31 Jan 2017
powdered corn cob	to be done	to be done	-

Rodenticides Complete BPD Review!

Active Substance (AS)	Date of Inclusion Directive	Date of Annex I inclusion	Date of Expiry
difethialone	29 Nov 2007	1 Nov 2009	31 Oct 2014
carbon dioxide	24 Jul 2008	1 Nov 200	31 Oct 2019
difenacoum	29 Jul 2008		Mar 2015
bromadiolone	31 Jul 2009		30 Jun 2016
alphachloralose	31 Jul 2009		Jun 2021
aluminium phosphide	31 Jul 2009		2021
coumatetralyl	29 Jul 2009		30 Jun 2016
chlorophacinone	4 Aug 2009	1 Jul 201	30 Jun 2016
flocoumafen	27 Nov 2009	1 Oct 2011	30 Sep 2016
warfarin sodium	9 Feb 2010	1 Feb 2012	31 Jan 2017
warfarin	9 Feb 2010	1 Feb 2012	31 Jan 2017
brodifacoum	9 Feb 2010	1 Feb 2012	31 Jan 2017
powdered corn cob	to be done	to be done	-

Date Commission's review of an AS is completed

Rodenticides Complete BPD Review!

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difethialone	29 Nov 2007	1 Nov 2009	31 Oct 2014
carbon dioxide	24 Jul 2008	1 Nov 2009	31 Oct 2019
difenacoum	29 Jul 2008	1 Apr 2010	31 Mar 2015
bromadiolone	[illegible]	1 Jul 2011	30 Jun 2016
alphachloralose		1 Jul 2011	31 Jun 2021
aluminium phosphi		1 Sep 2011	31 Aug 2021
coumatetralyl		1 Jul 2011	30 Jun 2016
chlorophacinone		1 Jul 2011	30 Jun 2016
flocoumafen		1 Oct 2011	30 Sep 2016
warfarin sodium	9 Feb 2010	1 Feb 2012	31 Jan 2017
warfarin	9 Feb 2010	1 Feb 2012	31 Jan 2017
brodifacoum	9 Feb 2010	1 Feb 2012	31 Jan 2017
powdered corn cob	to be done	to be done	-

Date of formal addition to BPD Annex I

Rodenticides Complete BPD Review!

Active Substance (AS)	Date of Inclusion Directive	Date of Annex I inclusion	Date of Expiry
difethialone	29 Nov 2007	1 Nov 2009	31 Oct 2014
carbon dioxide	24 Jul 2008	1 Nov 2009	31 Oct 2019
difenacoum	29 Jul 2008	1 Apr 2010	31 Mar 2015
bromadiolone	[illegible]	1 Jul 2011	30 Jun 2016
alphachloralose		1 Jul 2011	[illegible]
aluminium phosphi		1 Sep 2011	
coumatetralyl		1 Jul 2011	
chlorophacinone		1 Jul 2011	
flocoumafen		1 Oct 2011	
warfarin sodium	9 Feb 2010	1 Feb 2012	[illegible]
warfarin	9 Feb 2010	1 Feb 2012	31 Jan 2017
brodifacoum	9 Feb 2010	1 Feb 2012	31 Jan 2017
powdered corn cob	to be done	to be done	-

Date of formal addition to BPD Annex I

Date all applications for product authorisations must be submitted

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Rodenticides Complete BPD Review!

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difethialone	29 Nov 2007	1 Nov 2009	31 Oct 2014
carbon dioxide	24 Jul 2008	1 Nov 2009	31 Oct 2019
difenacoum	29 Jul 2008	1 Apr 2010	31 Mar 2015
bromadiolone	31 Jul 2009	Jul 2[illegible]	30 Jun 2016
alphachloralose	31 Jul 2009		31 Jun 2021
aluminium phosphide	31 Jul 2009		31 Aug 2021
coumatetralyl	29 Jul 2009		30 Jun 2016
chlorophacinone	4 Aug 2009		30 Jun 2016
flocoumafen	27 Nov 2009	1 [illegible] 20[illegible]	30 Sep 2016
warfarin sodium	9 Feb 2010	1 Feb 2012	31 Jan 2017
warfarin	9 Feb 2010	1 Feb 2012	31 Jan 2017
brodifacoum	9 Feb 2010	1 Feb 2012	31 Jan 2017
powdered corn cob	to be done	to be done	-

Date by which the next review must be completed

Rodenticides Complete BPD Review!

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difethialone	29 Nov 2007	1 Nov 2009	31 Oct 2014
carbon dioxide	24 Jul 2008	1 Nov 200	31 Oct 2019
difenacoum	29 Jul 2008	1 A	Mar 2015
bromadiolone	31 Jul 2009		30 Jun 2016
alphachloralose	31 Jul 2009		Jun 2021
aluminium phosphide	31 Jul 2009		2021
coumatetralyl	29 Jul 2009		30 Jun 2016
chlorophacinone	4 Aug 2009	Jul 201	30 Jun 2016
flocoumafen	27 Nov 2009	1 Oct 2011	30 Sep 2016
warfarin sodium	9 Feb 2010	1 Feb 2012	31 Jan 2017
warfarin	9 Feb 2010	1 Feb 2012	31 Jan 2017
brodifacoum	9 Feb 2010	1 Feb 2012	31 Jan 2017
powdered corn cob	to be done	to be done	-

Last anticoagulant completes BPD review!

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Rodenticides Complete BPD Review!

Active Substance (AS)	Date of Inclusion Directive	Date of Annex I inclusion	Date of Expiry
difethialone	29 Nov 2007	1 Nov 2009	31 Oct 2014
carbon dioxide	24 Jul 2008	1 Nov 2009	31 Oct 2019
difenacoum	29 Jul 2008	[illegible]	31 Mar 2015
bromadiolone	31 Jul [illegible]	[illegible]011	30 Jun 2016
alphachloralose	31 Jul [illegible]	[illegible]	31 Jun 2021
aluminium phosphide	31 Jul [illegible]	[illegible]	31 Aug 2021
coumatetralyl	29 Jul [illegible]	[illegible] 2011	30 Jun 2016
chlorophacinone	4 Aug [illegible]	1 [illegible] 2011	30 Jun 2016
flocoumafen	27 N[illegible] 2009	1 Oct 2011	30 Sep 2016
warfarin sodium	[illegible]Feb 2010	1 Feb 2012	31 Jan 2017
warfarin	9 Feb 2010	1 Feb 2012	31 Jan 2017
brodifacoum	9 Feb 2010	1 Feb 2012	31 Jan 2017
powdered corn cob	to be done	to be done	-

Only active substance still under review

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Rodenticides Complete BPD Review!

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difenacoum	29 Jul 2008	Apr 2010	31 Mar 2015
bromadiolone	31 Jul 2009	[illegible]	30 Jun 2016
alphachloralose	31 Jul 2009		31 Jun 2021
aluminium phosphide	31 Jul 2009		31 Aug 2021
coumatetralyl	29 Jul 2009		30 Jun 2016
chlorophacinone	4 Aug 2009		30 Jun 2016
flocoumafen	27 Nov 2009	1 Oct 201[illegible]	30 Sep 2016
warfarin sodium	9 Feb 2010	1 Feb 2012	31 Jan 2017
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powdered corn cob	to be done	to be done	-

First anticoagulant needs renewal – only 5 years

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The review under BPD is completed…….but

- Before any products are on sale under the “old” BPD, the Commission is considering new rules – the proposed Biocides Regulation (http://ec.europa.eu/environment/biocides/revision.htm)
- Key element of the new Regulation is the internationally accepted scheme for chemicals regulation based on **risk assessment** is replaced (in some cases) by **hazard**-based criteria

Hazard versus Risk

- **Hazard** exists where a substance (or object or situation) has a built-in ability to cause harm
- **Exposure** is the extent to which the likely recipient of the harm is exposed to the hazard
- **Risk** is the chance that such effects will occur

hazard + exposure = risk

http://www.dehp-facts.com/upload/documents/webpage/document52.pdf

Why are anticoagulants toxic to reproduction?

According to conventional toxicology criteria they are NOT!

- Cefic RWG has been fighting to maintain this position since 2004
- Warfarin is known to cause birth defects when taken for blood-thinning during pregnancy
- Standard toxicological test for this is the **teratogenicity study**
- All anticoagulants have teratogenicity studies that show no adverse effects (for 7 active substances in 2 mammalian species)
- BUT, the European Commission says the standard test is ineffective and declared all anticoagulants toxic to reproduction by **read-across** to warfarin
- Industry has conducted a study with warfarin which shows the test CAN detect reproductive toxicity
- Study is under consideration by Member States and a position will be taken by the European Chemicals Agency (ECHA)
- If the conclusions of the study are accepted, and the Industry position prevails, anticoagulants will not be CMR substances

Biocides Regulation – Article 5 Hazard-based "Exclusion Criteria"

Article 5
Exclusion criteria

1. Notwithstanding Article 4(1), active substances referred to in paragraph 2 shall be included in Annex I only if at least one of the following conditions is met:

   (a) the exposure of humans to that active substance in a biocidal product, under normal conditions of use, is negligible, in particular where the product is used in closed systems or strictly controlled conditions;

   (b) it is shown that the active substance is necessary to control a serious danger to public health;

   (c) it is shown that not including the active substance in Annex I would cause disproportionate negative impacts when compared with the risk to human health or the environment arising from the use of the substance and that there are no suitable alternative substances or technologies.

   Point (c) shall not apply to active substances for product types 4 and 14 to 19.

2. The following active substances shall be included in Annex I where at least one of the conditions set out in paragraph 1 is met:

   (a) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meets the criteria to be classified as, carcinogen category 1A or 1B;

   (b) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B;

   (c) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B;

   (d) active substances identified under Article 57(f) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties.

- Any substance with the following hazards may not be included in Annex I of the Regulation:
  - (a) **carcinogen** category 1A or 1B;
  - (b) **mutagen** category 1A or 1B;
  - (c) **toxic for reproduction** category 1A or 1B;

    The so-called CMR criteria
  - (d) having **endocrine disrupting** properties

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Commission's views on the derogations: 5.1 (a)

- (a) the exposure of humans to that active substance in a biocidal product, under normal conditions of use, is negligible, in particular where the product is used in closed systems or strictly controlled conditions;

- This cannot be used for rodenticides

Commission's views on the derogations: 5.1 (b)

- (b) it is shown that the active substance is necessary to control a **serious danger to public health**
- It had not been the intention of the Commission to ban anticoagulants!
- Commission thought this derogation **was enough**!
- But it would disqualify many essential uses including:
  - Uses in farming and animal husbandry
  - Routine use to prevent development of infestations
  - Prevention of rodent damage to foodstuffs
  - Prevention of rodent damage to buildings
  - Rodent control for conservation and protection of endangered species

Commission's views on the derogations: 5.1 (c)

- (c) it is shown that not including the active substance in Annex I would cause **disproportionate negative impacts when compared with the risk to human health or the environment arising from the use of the substance** and that there are **no suitable alternative substances** or technologies.
  - Point (c) shall not apply to active substances for product types 4 and 14-19
- Reason this derogation was NOT allowed to rodenticides (and other product types) was to prevent cross-over sales from biocidal into crop protection uses – extremely short-sighted and unsustainable position
- **We MUST have this derogation as well – exemption must be removed**

Actions Required by the Industry

- Industry must:
  - insist that derogations in Regulation Article 5.1 (b) and (c) are BOTH applied to rodenticides (PT14) i.e. exemption to derogation (c) must be removed
  - BUT then we will be at the mercy of qualitative decisions by Commission and Member States on what is:
    - "serious danger to public health"
    - "disproportionate negative impacts when compared to risk….."
    - "no alternatives……"
- So, Industry must also:
  - pursue the fundamental argument that all anticoagulants are NOT toxic to reproduction
  - argue that chemicals regulation should be based on RISK ASSESSMENT and not just HAZARD criteria