



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
Unit E.3 - Chemicals, contaminants and pesticides

Bromadiolone
SANCO/10203/2011 final
11 March 2011

Review report for the active substance **bromadiolone**
finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
11 March 2011
in view of the inclusion of bromadiolone in Annex I of Directive 91/414/EEC

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of bromadiolone, made in the context of a new application by the data submitter after the non-inclusion of this substance.

bromadiolone is a substance that was covered by the fourth stage of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market¹, with a view to the possible inclusion of this substance in Annex I to the Directive.

Article 24(e) of Commission Regulation (EC) No 2229/2004 laying down detailed rules for the implementation of the fourth stage offered the possibility for the notifier to withdraw, under specific conditions, its support for the active substance. All notifiers withdrew their support and bromadiolone was not included through Commission Decision 2008/941/EC².

In accordance with Article 13 of Regulation (EC) No 33/2008³, Liphatech S.A.S., the sole data submitters presented, on 4 June 2009 a request to Sweden, the designated rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

Sweden finalised in December 2009 its examination, in the form of an additional report to the original Draft Assessment Report. This Report was sent to the Commission and the European Food Safety Authority on 4 December 2009 and included a recommendation to include bromadiolone in Annex I for the supported uses.

The EFSA organised the consultation on the draft assessment report and, in accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, on the additional report by all the Member

¹ O.J. No L 230, 19.8.1991, p. 1.

² OJ No L 335, 13.12.2008, p. 91.

³ OJ No L 252, 20.9.2008, p. 37

States as well as by Liphatech S.A.S., being the sole data submitters, on 7 December 2009 by making it available.

In accordance with the provisions of Article 20 of Regulation (EC) No 33/2008, the Commission asked EFSA to organise a focused consultation of scientific experts from a certain number of Member States, to review the additional report, draft assessment report and the comments received thereon (peer review) and to deliver its conclusion.

In accordance with the provisions of Article 20 of Regulation (EC) No 33/2008 the EFSA sent to the Commission its conclusion on the risk assessment [Conclusions on the peer review of the pesticide risk assessment of the active substance bromadiolone (re-issued on 15 September 2010)⁴]. This conclusion refers to background document A (draft assessment report and additional report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 21 of Regulation (EC) No 33/2008, the Commission referred a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 11 March 2011.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (background document C), these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices hereto, has been developed and finalised in support of Commission **Directive 2011/48/EU**⁵ concerning the inclusion of bromadiolone in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing bromadiolone they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 22 of Regulation (EC) No 33/2008, this review report will be made available for public consultation by any interested parties.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore

⁴ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance bromadiolone. EFSA Journal 2010;8(10):1783. [44 pp.] doi:10.2903/j.efsa.2010.1783. Available online: www.efsa.europa.eu/efsajournal.htm

⁵ OJ L 102, 16.4.2011, p. 28–31

recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing bromadiolone will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each bromadiolone containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

The following reference values have been finalised as part of this re-evaluation:

ADI	not allocated-not required
ARfD	not allocated-not required
AOELsubchrin/chronic	0.0012 µg/kg bw/day
AOEL acute	0.0023 µg/kg bw/day

As the representative use of bromadiolone is a rodenticide in non-crop areas, no significant residues in plant or animal matrices were expected. Data to address the nature and magnitude of residues in food of plant and animal origin were not required for this use.

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC.

4. Identity

The main identity of bromadiolone is given in Appendix I.

At the time of the evaluation no FAO specification was allocated.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of the EFSA, and at section 3 of this report.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing bromadiolone

On the basis of the proposed and supported uses (as listed in Appendix II), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted :

- the risk to professional operators and ensure that conditions of use include the application of adequate personal protective equipment where appropriate;
- the risk to birds and non-target mammals from primary as well as secondary poisoning that may be exposed to the active substance.

Risk mitigation measures shall be applied, where appropriate.

Only uses as rodenticide in the form of pre-prepared baits placed into the rodent tunnels may be authorised.

The nominal concentration of the active substance in the products shall not exceed 50 mg/kg. Authorisations shall be granted for uses by professional users only.

7. List of studies to be generated

Further studies were identified which were at this stage considered necessary in relation to the inclusion of bromadiolone in Annex I under the current inclusion conditions.

The Member States concerned shall request the submission of confirmatory information as regards:

- (a) the specification of the technical material, as commercially manufactured, in the form of appropriate analytical data,
- (b) the relevance of the impurities,
- (c) the determination of bromadiolone in water with a limit of quantification of 0.01 µg/l.
- (d) the effectiveness of proposed mitigation measures to reduce risk to birds and non-target mammals,
- (e) the groundwater exposure assessment for metabolites.

Some other endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. The list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusions.

8. Information on studies with claimed data protection

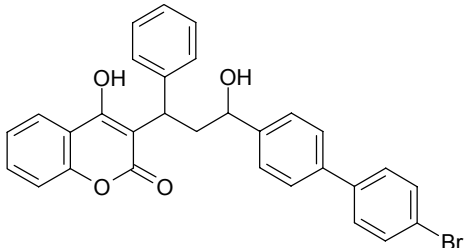
For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC and neither does it commit the Commission.

9. Updating of this review report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for bromadiolone in Annex I of the Directive.

APPENDIX I

Identity
bromadiolone

Common name (ISO)	bromadiolone
Chemical name (IUPAC)	3-[(1 <i>RS</i> ,3 <i>RS</i> ;1 <i>RS</i> ,3 <i>SR</i>)-3-(4'-bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxycoumarin
Chemical name (CA)	3-[3-(4'-bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2 <i>H</i> -1-benzopyran-2-one
CIPAC No	371
CAS No	28772-56-7
EEC No	249-205-9
FAO SPECIFICATION	Not available
Minimum purity	97.0 % w/w 970 g/kg (open)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern)	<i>Open</i>
Molecular formula	C ₃₀ H ₂₃ BrO ₄
Molecular mass	527.40 g/mol
Structural formula	

APPENDIX II
List of uses supported by available data
BROMADIOLONE

Crop	EU Region	Product name	Field (F) or Greenhouse (G)	Diseases controlled	Formulation		Application			Application rate per treatment			PHI (days)
					Type	Conc. of a.s.	Method	Timing ²	Max no.; interval	kg a.s./hL	Water L/ha	Max rate per seed/plant or area	
Non-crop areas	France (North and South EU), Benelux	'Super Caid AS Appat'	F	target pest, underground and meadow voles	AB ¹	50 mg a.s./kg	Placed at bait points in vole tunnels	Depending on the infestation	2	-	-	7.5 kg product/ha (0.375 g a.s./ha)	-

- not applicable

1. AB - Grain bait.

2. This new text is suggested by the applicant to better reflect the actual use of the product. The RMS considers that this is of little importance for the overall assessment and thus can be accepted.