EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Review report for the active substance **fluometuron**

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 fluometuron 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 fluometuron, made in the context of a new application by the data submitter after the non-inclusion of this substance.

Fluometuron is a substance that was covered by the third 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 market[1], with a view to the possible inclusion of this substance in Annex I to the Directive.

Article 11(e) of Commission Regulation (EC) No 1490/2002[2] laying down detailed rules for the implementation of the third stage of the work programme offered the possibility for the notifier to withdraw, under specific conditions, its support for the active substance. All notifiers withdrew their support and fluometuron was not included through Commission Decision 2008/934/EC[3].

In accordance with Article 13 of Regulation (EC) No 33/2008[4], Makhteshim Agan and Nufarm GmbH & Co KG, the sole data submitters presented, on 11 June 2009 a request to Greece, the designated rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

Greece finalised in January 2010 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 27 January 2010 and included a recommendation as to include fluometuron in Annex I for the supported uses.

[1] O.J. No L 230, 19.8.1991
[2] O.J. No L 224, 21.8.2002
[3] OJ No L 333, 11.12.2008, p.11
[4] OJ No L 252, 20.9.2008, p. 37

The EFSA, in accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, organised the consultation on the draft assessment report and on the additional report by all the Member States as well as by Makhteshim Agan and Nufarm GmbH & Co KG, being the sole data submitters, on 15 March 2010 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 of the active substance fluometuron[5]. 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 2011/57/EU**[6] concerning the inclusion of fluometuron in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing fluometuron 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

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5 European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance fluometuron. EFSA Journal 2011;9(1):1958. [54 pp.] doi:10.2903/j.efsa.2011.1958. Available online: www.efsa.europa.eu/efsajournal.htm

6 OJ L 108, 28.4.2011, p. 34–37

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 fluometuron 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 fluometuron 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	0.0005 mg/kg bw/day
ARfD	0.008 mg/kg bw
AOEL	0.008 mg/kg bw/day

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI) is 5.7% of the Acceptable Daily Intake (ADI), (EFSA PRIMo rev.2A model). Additional intake from water is not expected to give rise to intake problems.

Estimates of acute dietary exposure of adults and children revealed that the Acute Reference Dose (ARfD) would not be exceeded (0.7% of ARfD according to EFSA PRIMo rev.2A model).

The review has identified 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 fluometuron is given in Appendix I.

The active substance shall comply with the FAO specification and there seem not to be reasons for deviating from that specification; the FAO specification is given in Appendix I of this report.

The review has established that for the active substance notified by the main data submitters, none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

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 fluometuron

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 protection of the operators and workers. Conditions of use shall include the application of adequate personal protective equipment;

- the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential leaching of fluometuron and soil metabolites desmethyl-fluometuron (CGA 41686) and trifluoromethylaniline (CGA 72903) in vulnerable areas, where appropriate;

- the risk to non-target soil macro-organisms others than earthworms, and non-target plants. Conditions of authorisation shall include risk mitigation measures, where appropriate.

7. List of studies to be generated

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

The Member States concerned shall ensure that the applicants submits to the Commission confirmatory information as regards:

- the toxicological properties of plant metabolite trifluoroacetic acid (TFAA);

- the analytical methods for the monitoring of fluometuron in air;

- the analytical methods for the monitoring of the soil metabolite trifluoromethylaniline (CGA 72903) in soil and water

by 31 March 2013 at the latest.

If fluometuron is classified under Regulation (EC) No 1272/2008 as "suspected of causing cancer", the Member States concerned shall request the submission of further information on the relevance of the soil metabolites desmethyl-fluometuron (CGA 41686) and trifluoromethylaniline (CGA 72903) with respect to groundwater. They shall ensure that the

applicants provide that information to the Commission within six months from the notification of the decision classifying fluometuron..

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

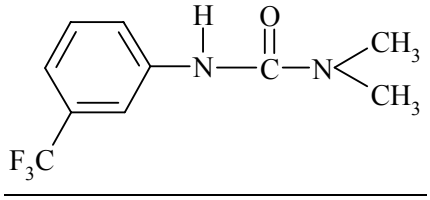
For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. 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 fluometuron in Annex I of the Directive.

APPENDIX I

Identity
FLUOMETURON

Common name (ISO)	Fluometuron
Chemical name (IUPAC)	1,1-dimethyl-3-(α,α,α -trifluoro-*m*-tolyl)urea
Chemical name (CA)	*N*,*N*-dimethyl-*N*'-[3-(trifluoromethyl)phenyl]urea
CIPAC No	159
CAS No	2164-17-2
EEC No	218-500-4
FAO SPECIFICATION	FAO Specification 159/TC/S (AGP:CP/245, 1990) 940 g/kg +/- 20 g/kg
Minimum purity	960 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern)	none
Molecular formula	$C_{10}H_{11}F_3N_2O$
Molecular mass	232.2 g/mol
Structural formula	

APPENDIX II
List of uses supported by available data
FLUOMETURON

Crop and/or situation (a)	F or G (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (k)	Remarks (l)
			Type (d-f)	Conc. of a.s. (i)	Method kind (f-h)	Growth stage (j)	Number	interval between applications (min)	kg a.s./hl	water l/ha	Kg a.s./ha		
Cotton Spain	F	Annual broad leaf weeds and grasses	SC	500 g/l	1st Broadcast application 2nd Band application over rows	1st Pre-sowing Spring 2nd Pre-emergence Spring	2	Dependent on sowing and emergence times 7 days	0.108-0.28	400- 600	1st 1.13 2nd 0.65	>120	
Cotton Spain	F	Annual broad leaf weeds and grasses	SC	500 g/l	1st Band application over rows 2nd Band application between rows	1st Pre-emergence Spring 2nd Post-emergence Spring	2	Once cotton is 15-20 cm high (BBCH 21) 45 days	0.108-0.25	400- 600	1st 0.65 2nd 1.0	>120	
Cotton Spain	F	Annual broad leaf weeds and grasses	SC	500 g/l	Broadcast application	Pre-sowing Spring	1	N/A	0.33-0.5	400- 600	2.0	>120	
Cotton Greece	F	Annual broad leaf weeds and grasses	SC	500 g/l	Broadcast application	Pre-emergence Spring	1	N/A	0.33-0.5	400- 600	2.0	>120	

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval