



**COUNCIL OF
THE EUROPEAN UNION**

**Brussels, 10 July 2009
(OR. en)**

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AGRILEG 87

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: COUNCIL DECISION concerning the non-inclusion of metam in
Annex I to Directive 91/414/EEC and the withdrawal of authorisations
for plant protection products containing that substance

COUNCIL DECISION

of

**concerning the non-inclusion of metam in Annex I
to Directive 91/414/EEC and the withdrawal of authorisations
for plant protection products containing that substance**

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market¹, and in particular the fourth subparagraph of Article 8(2) thereof,

¹ OJ L 230, 19.8.1991, p. 1.

Whereas:

- (1) Article 8(2) of Directive 91/414/EEC provides that a Member State may, during a period of 12 years following the notification of that Directive, authorise the placing on the market of plant protection products containing active substances not listed in Annex I to that Directive that are already on the market two years after the date of notification, while those substances are gradually being examined within the framework of a programme of work.
- (2) Commission Regulations (EC) No 451/2000¹ and (EC) No 1490/2002² lay down the detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes metam.
- (3) For metam the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulations (EC) No 451/2000 and (EC) No 1490/2002 for a range of uses proposed by the notifier. Moreover, those Regulations designate the rapporteur Member States which have to submit the relevant assessment reports and recommendations to the European Food Safety Authority (EFSA) in accordance with Article 10(1) of Regulation (EC) No 1490/2002. For metam the rapporteur Member State was Belgium and all relevant information was submitted on 10 September 2007.

¹ OJ L 55, 29.2.2000, p. 25.

² OJ L 224, 21.8.2002, p. 23.

- (4) The assessment report has been peer reviewed by the Member States and the EFSA within its Working Group Evaluation and presented to the Commission on 26 November 2008 in the format of the EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance metam. This report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 26 February 2009 in the format of the Commission review report for metam.
- (5) During the evaluation of this active substance, a number of concerns have been identified which did not permit to demonstrate the acceptability of consumer exposure. Those concerns were, in particular, inadequate residues studies and lack of information on a toxicologically relevant impurity, N,N'-dimethylthiourea (DMTU). Furthermore, due to the high rate of application, a large amount of the impurity DMTU is released in the environment and the lack of data with respect to its behaviour in the environment gives rise to concern. Consequently, it was not possible to conclude, on the basis of the information made available within the deadlines, that metam met the criteria for inclusion in Annex I to Directive 91/414/EEC.

- (6) The Commission invited the notifier to submit its comments on the results of the peer review and on its intention or not to further support the substance. The notifier submitted its comments which have been carefully examined. However, despite the arguments put forward by the notifier, the concerns identified could not be eliminated, and assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing metam satisfy in general the requirements laid down in points (a) and (b) of Article 5(1) of Directive 91/414/EEC.
- (7) Metam should therefore not be included in Annex I to Directive 91/414/EEC.
- (8) Measures should be taken to ensure that authorisations granted for plant protection products containing metam are withdrawn within a fixed period of time and are not renewed and that no new authorisations for such products are granted.

- (9) In the light of the information before the Council it appears that, in the absence of efficient alternatives for certain limited uses in certain Member States, there is a need for further use of the active substance so as to enable the development of alternatives. It is therefore justified in the present circumstances to prescribe under strict conditions aimed at minimising risk a longer period for the withdrawal of existing authorisations for the limited uses considered as essential for which no efficient alternatives appear currently to be available for the control of harmful organisms.
- (10) Any period of grace granted by a Member State for the disposal, storage, placing on the market and use of existing stocks of plant protection products containing metam should be limited to 12 months in order to allow existing stocks to be used in one further growing season, which ensures that plant protection products containing metam remain available to farmers for 18 months from the adoption of this Decision.
- (11) This Decision does not prejudice the submission of an application for metam according to the provisions of Article 6(2) of Directive 91/414/EEC, the detailed implementation rules of which have been laid down in Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I¹ in view of the possible inclusion of metam in its Annex I.

¹ OJ L 15, 18.1.2008, p. 5.

- (12) In the absence of a favourable opinion of the Standing Committee on the Food Chain and Animal Health, the Commission has been unable to adopt the provisions it envisaged under the procedure laid down in Article 19 of Council Directive 91/414/EEC,

HAS ADOPTED THIS DECISION:

Article 1

Metam shall not be included as an active substance in Annex I to Directive 91/414/EEC.

Article 2

Member States shall ensure that:

- 1) authorisations for plant protection products containing metam are withdrawn by ...*;
- 2) no authorisations for plant protection products containing metam are granted or renewed from the date of publication of this Decision.

* OJ: Please insert date 6 months from the date of adoption of this decision.

Article 3

1. By way of derogation from Article 2, a Member State listed in column A of Annex I may maintain authorisations for plant protection products containing metam for the uses listed in column B of that Annex until 31 December 2014, provided that it complies with the following conditions:
 - (a) it ensures that no harmful effects to human and animal health and no unacceptable influence on the environment are caused;
 - (b) it ensures that such plant protection products remaining on the market are relabelled in order to match the restricted use conditions;
 - (c) it imposes all appropriate risk mitigation measures to reduce any possible risks in order to ensure the protection of human and animal health and the environment;
 - (d) it ensures that alternative products or methods for such uses are being seriously sought, in particular, by means of action plans.

2. The Member State making use of the derogation provided for in paragraph 1 shall inform the Commission about the measures taken under paragraph 1, and, in particular, under points (a) to (d) by 31 December of each year and provide on a yearly basis estimates of the amounts of metam used for essential uses pursuant to this Article.

Article 4

Any period of grace granted by Member States in accordance with the provisions of Article 4(6) of Directive 91/414/EEC, shall be as short as possible.

For authorisations which are withdrawn in accordance with Article 2, that period shall expire by ...*
at the latest.

For authorisations which are withdrawn in accordance with Article 3, it shall expire by
31 December 2014 at the latest.

* OJ: Insert date 18 months from adoption of this decision.

Article 5

This Decision is addressed to the Member States.

Done at Brussels,

For the Council

The President

ANNEX

List of authorisations referred to in Article 3(2)

Column A	Column B
Member State	Use Soil disinfection and weed control before planting/sowing, limited to professional users with appropriate protective equipment under specific authorised conditions as laid down in Article 3 and subject to the following restrictions per Member State:
Belgium	Potting Soil (all crops). Potatoes (seed, ware and starch potatoes), sugar and fodder beets, onions, vegetables, fruit crops, herbs, orchards (replanting), ornamentals.
Bulgaria	Glasshouse use: tomatoes, cucumbers, lettuce, carrots, peppers, aubergines and tobacco.
Cyprus	Nurseries, vegetables, potatoes, ornamentals, deciduous fruits, citrus fruits, and grapes.

Column A	Column B
France	Vegetable and fruit crops and mainly lamb's lettuce, carrots, tomatoes, strawberries, asparagus, ornamental plants, trees and shrubs.
Greece	Potting soil and soil compost (for all crops), indoor and outdoor use for soil treatment (for vegetable and ornamental crops), tobacco nurseries.
Hungary	<p>Field use: potatoes, carrots, celeriac, parsley root, ornamentals, berries, apples, pears, tobacco, wine grapes, stone fruits, fruit and grapevine nurseries.</p> <p>Glasshouse use: green peppers, tomatoes, cucumbers, carrots, celeriac, parsley root, tobacco, berries, ornamentals.</p>
Italy	Rice, lettuce and similar, tomatoes, peppers and aubergines, cucurbits, carrots, bulb vegetables, stem vegetables, potatoes, tobacco, replanting vineyards and orchards, flowers.

Column A	Column B
Ireland	<p>Glasshouse use: tomatoes, carnations, cucumbers, ornamentals, chrysanthemum and lettuce.</p> <p>Field use: potatoes, bulbs, hardy nursery stock, cane fruit, turf, strawberries and forestry plantations.</p>
Malta	tomatoes, aubergines, peppers, melons, watermelons, squash, cucumbers and strawberries.
The Netherlands	Potatoes (seed, ware and starch potatoes), sugar and fodder beets, onions, vegetables, strawberries, orchards (replanting), ornamentals (including growing of bulbs), yellow nutsedge in all crops.
Poland	<p>Field use: strawberries, cabbages, carrots, lettuce, onions, garlic.</p> <p>Glasshouse use: tomatoes, cucumbers, peppers, aubergines.</p>

Column A	Column B
Portugal	Potatoes, onions, carrots, melons, strawberries, cucumbers, peppers, tomatoes, citrus crops, ornamentals, glasshouse soil fumigation, nursery soil fumigation.
Romania	Vegetables and ornamental plants.
Spain	Nurseries, seedbeds, vegetables, tobacco, flowers, strawberries, seed potatoes, vineyards.
United Kingdom	Glasshouse soils, nursery soils, outdoor soils and potting soils prior to planting of fruit crops, vegetable crops, potatoes, herbs, flowers, bulbs, ornamental plants, perennial plants.
