KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

Ver. 02
2014-05-06

Practical guidance on how to access information from the EU pesticide registration process

Table of content

Akronym	Explanation
ADI	Acceptable Daily Intake
AOEL	Acceptable Operator Exposure Level
ARfD	Acute Reference Dose
a.s.[1]	Active substance
C&L	Classification and labelling
CLP	Regulation on classification and labelling of chemicals and mixtures
COM	The European Commission
DAR	Draft Assessment Report
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GHS	United nations' Globally Harmonised System
MRL	Maximum residue level
MS	EU Member State
Pesticides	*In this document = plant production product*
PPE	Personal protective equipment
PPP	Plant production product[2]
RMS	Rapporteur Member State
RPE	Respiratory protective equipment

Legislation no.	Name
1107/2009/EC	Regulation concerning the placing of plant protection products on the market
1272/2008/EC	Regulation on classification, labelling and packaging of substances and mixtures (CLP)
91/414/EEC	Plant protection products directive
67/548/EEC	Substances directive
1999/45/EC	Preparations directive

[1] Active substance is the chemical that has the pesticidal properties, i.e. it could be a herbicidal active substance that kills weeds, it could be an insecticidal active substance that kills insect pests or a fungicidal active substance that reduces fungal damage.
[2] Plant protection product is the actual product as placed on the market, containing the active substance(s) together with formulation chemicals (such as solvents and emulsifiers).

1 Introduction

1.1 International Code of Conduct on Pesticide Management

The International Code of Conduct on Pesticide Management provides a framework for pesticide management for all public and private entities engaged in, or associated with, production, regulation and management of pesticides.

The latest revision of the Code of Conduct on Pesticide Management was adopted by the Food and Agriculture Organisation of the United Nations (FAO) in June 2013 and endorsed by the World Health Organization (WHO) in January 2014. The Code provides standards of conduct and serves as a point of reference in relation to sound pesticide life cycle management practices, in particular for government authorities and the pesticide industry. The Code of Conduct is supported by technical guidelines that are developed by a FAO/WHO Joint Meeting on Pesticide Management (JMPM).

Regarding the regulatory control of pesticides, the Code of Conduct states:

> 6.1 Governments should:
>
> 6.1.4 establish pesticide registration schemes and infrastructures under which each pesticide product is registered before it can be made available for use;
>
> 6.1.5 conduct risk evaluations and make risk management decisions based on all relevant available data and information, as part of the pesticide registration process;

Furthermore, is noted that authorities should, if possible, make use of already existing information. The Code of Conduct states:

> 9.1 Governments should:
>
> 9.1.1 promote the establishment or strengthening of networks for information exchange on pesticides and IPM/IVM through national institutions, international, regional and sub-regional organizations and public interest groups;
>
> 9.1.2 facilitate the exchange of information between regulatory and implementing authorities to strengthen cooperation.
>
> 9.2 In addition, Governments are encouraged to develop:
>
> 9.2.1 legislation that permits and regulations to permit information exchange to the public about pesticide risks and benefits as well as to facilitate the participation of the public in the management of pesticides in the country.

Risk assessment is a complex process that requires significant human and financial resources. Advanced risk assessment procedures are in place in most developed countries. The European Union established a common registration scheme, which enables extensive and thorough risk

assessment by sharing the burden among all Member States. As a result, the EU has one of the most comprehensive risk assessment procedures for pesticides, which makes it, together with the US, a very valuable source of information for other countries with limited resources.

1.2 Aim

The aim of this guidance document is to provide an overview of the procedures for evaluation and decision making for active substances in pesticides at EU-level. Furthermore, the guidance describes which registration data can be found in different information sources at EU-level and how this data can be accessed. The guidance has been compiled for evaluators and decision makers in pesticide registration processes to enable them to make use of the vast information available from the EU.

It should, however, be emphasized that each country should assess such information against the specific agronomic, social and environmental conditions of their country. This document does not intend to provide guidance on national decision making in pesticide registration processes.

In order to further illustrate what type of information can be found in the EU documentation, examples for selected substances (tribenuron-methyl, oxamyl, atrazin and fipronil) are provided in Annex 1.

1.3 Scope and limitations

This guidance covers EU information for active substances of plant protection products, hereafter referred to as *pesticides*. The process for establishment of EU harmonised maximum residue limits (MRL) is not described. Neither does the document contain details on how to conduct risk assessments for human health (operators, bystanders and consumers) or the environment. Information related to other products and uses (e.g. biocides, household products) and information from other regions than the EU is not included.

2 EU-procedures - Active substances

2.1 History

Since early 1990's, active substances in pesticides are evaluated at EU level according to harmonised data requirements, criteria and guidance documents. The current evaluation process and criteria can be found in Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. This regulation from 2009 replaces the previous Plant Protection Products Directive (91/414/EEC) from 1991.

A decision on approval or non-approval of active substances is taken at EU level, and becomes binding for all Member States. The registration of formulated products is done at Member-State level and can thus vary from country to country, as long as it is in compliance with the decision regarding the active substance taken at EU level. The decision making is a blend of scientific facts, interpretations and criteria for what is agreed as "acceptable risk" at the time of decision.

Following the adoption of the Plant Protection Products Directive (91/414/EEC), there has been a review of all active substances in pesticides on the EU market. This has resulted in a large reduction of the number of approved active substances within EU. Around 70 % of the original 900 active substances have been withdrawn from use, either due to high risks, lack of support by industry or an incomplete dossier.

2.2 Evaluation procedure for active substances

The evaluation procedure is initiated by an application from a company or group of companies (i.e. applicant) who wishes to place an active substance on the EU market. The application involves submission of a dossier with all the required data regarding the active substance, data for a representative formulation and its intended uses (e.g. concentrations, crops, pests, dose levels etc.), which then will be the focus of the risk assessment. The application is submitted to a Rapporteur Member State (RMS).

In the evaluation process, the hazard profile of the active substance is assessed. A risk assessment, based on the intended use of the pesticide, is performed with respect to human health (consumers, operators/farmers and bystanders) and the environment (e.g. groundwater and non-target organisms, such as birds, mammals and bees). A large number of guidance documents on different areas (dermal absorption, risk assessment for birds and mammals, aquatic ecotoxicology etc.) are applied.

Active substances are approved for a maximum of 10 years. After that period, a review will have to be performed and a new decision as to whether to renew the approval of the active substance or not will be made.

2.3 Institutions involved in the risk assessment

Evaluation by Rapporteur Member State, RMS

For each application, a Rapporteur Member State (RMS) is assigned which evaluates the applicant's dossier and prepares a *Draft Assessment Report (DAR)* containing a summary of evaluated studies and a risk assessment for a representative pesticide product containing the active substance with one or more intended uses.

When the evaluation has been finalized, the RMS submits the DAR to the European Commission (COM) and the European Food Safety Authority (EFSA) for review and decision making.

Review by EFSA and MS

EFSA is responsible for peer review of the DAR that has been prepared by the RMS. EFSA organises consultation meetings with experts from Member States (MS) before delivering the outcome in an *EFSA conclusion report*, containing the conclusion of the validated RMS evaluation. The validation process and its conclusions are based on current guidance documents and agreed criteria for risk assessment.

2.4 Classification and labelling

Regulation (EC) No 1272/2008 is the regulation for classification, labelling and packaging of substances and mixtures in the EU and is referred to as the CLP Regulation. The criteria for classification and labelling of active substances are based on the United Nations' Globally Harmonised System (GHS).

The classification is harmonised and made obligatory at EU level to all active substances in pesticides to ensure an adequate risk management throughout the European Community. Active substances used in pesticides are therefore subject both to evaluation under the pesticides regulation and to harmonised classification and labelling under the CLP Regulation.

The classification for the active substance noted in the EFSA conclusion is a proposal under the Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. Thereafter, a "harmonised classification" under the CLP Regulation is agreed, adopted and posted on the ECHA web site.

Before the CLP regulation entered into force in 2009, classification and labelling of substances was already harmonised at EU level (in accordance with EU substance (67/548/EEC) and preparations (1999/45/EC) directives). The system was similar to GHS but used slightly different criteria. Annex VII of the CLP regulation includes a translation table for classification under Directive 67/548/EEC to classification under the CLP regulation.

2.5 Maximum residue level

The amounts of pesticide residues in food must be below established limits deemed safe for consumers and must be as low as possible. EU Regulations harmonise pesticide maximum residue levels (MRL) taking into account the safety of all consumers, including vulnerable groups such as babies, children, women in childbearing age and vegetarians. The residue levels of pesticides in treated products are critical for assessing risk to consumers. The EFSA assesses the safety for consumers based on the risk assessment of the pesticide, the maximum residue levels expected on food and the different diets of Europeans. A maximum residue level (MRL) is the highest level of a pesticide residue that is legally tolerated in or on food or feed. A default MRL of 0.01 mg/kg applies where an assessment is not available.

The MRLs for authorised active substances and relevant crops can be found in the pesticide database on the Commission website.

2.6 Decision making

Based on the EFSA conclusion report, the European Commission drafts a proposal for decision on the active substance. The draft decision will either propose to approve the active substance (with possible restrictions) or not approve the active substance (with possible phase out periods for products already on the EU market).

A Standing Committee, in which all EU Member States are represented, then votes on the proposed decision. Political positions and the need for the active substance in the different Member States may affect the outcome of the voting. The outcome is then formalised by the Commission in a *Directive for approval* of the active substance *or a decision for non-approval*. Active substances are approved for a maximum of 10 years.

Approval

The condition for approval of an active substance is that the risk assessment has shown that a representative pesticide product containing the active substance (with one or several intended uses) has “acceptable risks” to human health and the environment in at least one Member State. The approval may however include extensive risk mitigation measures. Areas that require extensive risk mitigation measures are indicated in the EFSA conclusion report and in the Commission review report.

In certain cases where the data is not complete, it might still be possible to conditionally approve an active substance without a full risk assessment. If it is anticipated that availability of the missing data would not alter the ”acceptable risk status”, the active substance could be approved on the condition that the missing information is being provided within a specified period of time. In these cases, the company applying for approval of the active substance must complete the dossier with “confirmatory data”, i.e. the studies required for a complete risk assessment to be performed, within a certain amount of time. Such requirements are listed

under “Specific provisions” in the Directive for approval and also referred to in the Review report and in the EFSA conclusion report.

Non-approval

Active substances will not be approved if the risk assessment shows that the representative product cannot be used without “unacceptable risks” to human health and/or the environment.

Another ground for non-approval is withdrawal of the substance from the review process by the applicant. This may happen due to knowledge of “unacceptable risks” or large data gaps. For most of the substances that have been withdrawn there are no detailed reports available, only a Commission decision.

Non-approval does not always imply that the substance is permanently prohibited for use in pesticides in EU. There is, in most cases, a possibility to apply for re-approval of an active substance and submit new data etc. However, for substances with high risks this rarely happens.

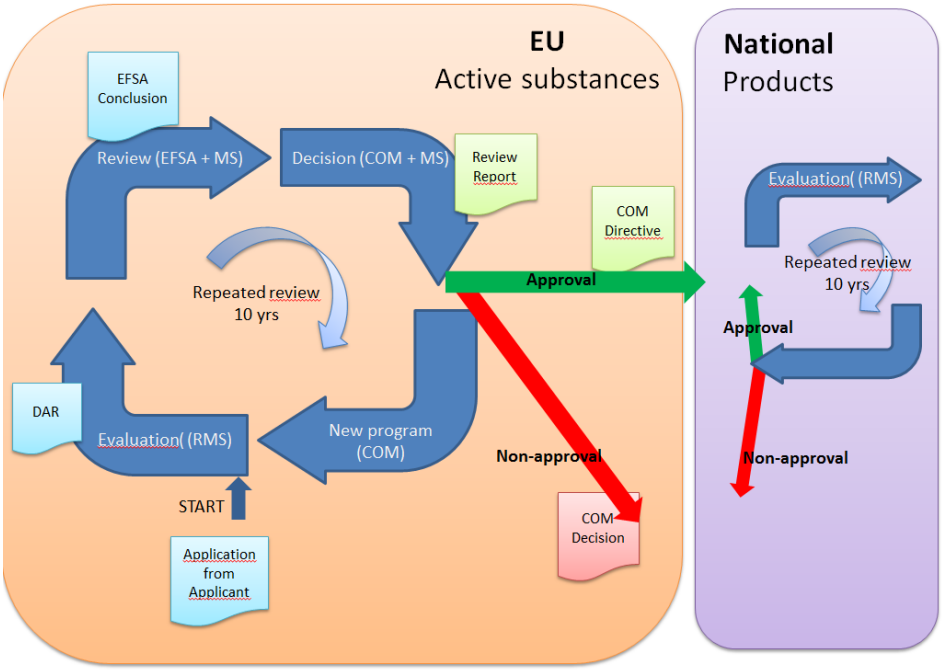


Figure 1. General procedure for review of an active substance in the EU and authorisation for a product at the national level. These procedures are repeated regularly in order to take new scientific information into account. The relevant documents are indicated at each step.

Table 1: Description of the scope, content and owner of the information generated during the EU review process for active substances in pesticides.

Document	Owner	Content/scope
DAR	RMS	An evaluation, not peer-reviewed, presented as 1) A hazard assessment of the active substance, areas evaluated : - Identity and physical/chemical properties - Classification and proposed labelling - Fate and behaviour in the environment - Ecotoxicology - Mammalian toxicology - Residues and analytical methods 2) A risk assessment for one product with one or more intended uses.
EFSA conclusion report	EFSA	Conclusion on the peer review of the active substance, the product and its intended use(s) and the "List of end point" which should be used when carrying out risk assessments for products at Member State level.
Review report	COM	A summary of the evaluation process as background to the Decision/Directive. Contains e.g. • Data submitter • Reference values (human health) • List of studies to be generated • List of supported uses For active substances without an EFSA conclusion[3] the Review report also includes the "List of Endpoints".
Directive /Implementing Regulation	COM	Legal document for approved active substances. Contains e.g. Purity • Specific provisions • Confirmatory data
Decision	COM	Legal document for non-approved active substances. Containing details about withdrawal, and periods of grace, of products from the EU-market.

3 Registration of pesticide products at the national level

The Member States can only authorise pesticide products containing active substances that are approved at EU level. Each Member States should conduct a risk assessment for the proposed uses of the concerned product. These uses can be extended to other uses than those assessed at EU-level, unless a restriction is decided at EU-level.

3.1 Risk assessment and decision making

The risk assessment of pesticide products is also harmonised at EU-level with regard to data requirements, criteria and guidance documents. Decision-making is however done at national level, with the possibility to take certain national conditions into account (such as climatic and agricultural conditions, soil types, etc.).

[3] The review of existing substances was organized as a 4 phase program. No EFSA conclusion reports are available for substances in the first phase started in 1995.

When performing the risk assessment, all Member States should use agreed values for different endpoints and reference values that are stated in the “list of endpoints”.

E.g.:

- AOEL
- ADI
- Dermal absorption
- Rate of degradation in soil, water etc.
- Toxicity to aquatic organisms

The authorisations of pesticide products is limited to a maximum 10 or 15 (low risk products) years and may include possible restrictions on the usage of the product.

3.2 Data protection

The EU regulation provides a possibility for Member States to grant a so called ‘data protection’ to the applicant. This means that the proprietary right of data is recognized to prevent that specific data submitted by the applicant concerned can also be used for the benefit of other applicants. Data protection is usually granted for a period of 10 years.

4 How to search and find information

Table 2. A summary guide to where specific information can be found. The table in the EU pesticide database is in general the most straightforward source, see below. Explanations and comments are included for some data. A tick means that the information can be found in the document/source/table.

Information	Comment	EU pesticide data base				EFSA	ECHA
		Table	Decision	Directive	Review Report	Conclusion report	C&L data bas
Approval	Date	√	√				
Approval, expiration	Date	√	√				
Category	Herbicide, insecticide etc.	√	√	√	√	√	
Classification	Classification of a substance can be of different status. 1. Proposal by RMS 2. EU agreed classification	√				√	√
Data gaps and confirmatory data	Data needed to perform a complete risk assessment.			√	√	√	
Data submitter	The company/group of company that submitted the data in the dossier (applicant)				√		
Intended uses	Uses evaluated by RMS and peer reviewed by EFSA. *Comment: Might cover uses that present "unacceptable" risk in the risk assessment.*					√	
List of Endpoints	List of agreed values for different endpoints. Contains e.g. reference values for the risk assessment.					√	
MRLs	Maximum Residue Levels on agricultural products allowed in the EU	√					
Purity	Minimum purity of active substance in the studies of the dossier. *Comment: Active substances with a lower purity and/or another impurity profile might have other properties.*			√	√	√	
RMS	The MS that performed the evaluation of the substance	√	√	√	√	√	
Restrictions	Certain issues that have to be taken into account when authorising products containing the active substance. Listed under "specific provisions"			√			
Status in EU	Approved or not approved	√	√	√	√		
Supported uses	Uses for which the risk is considered "acceptable". *Comment: Other uses might also present "acceptable" risk.*				√		

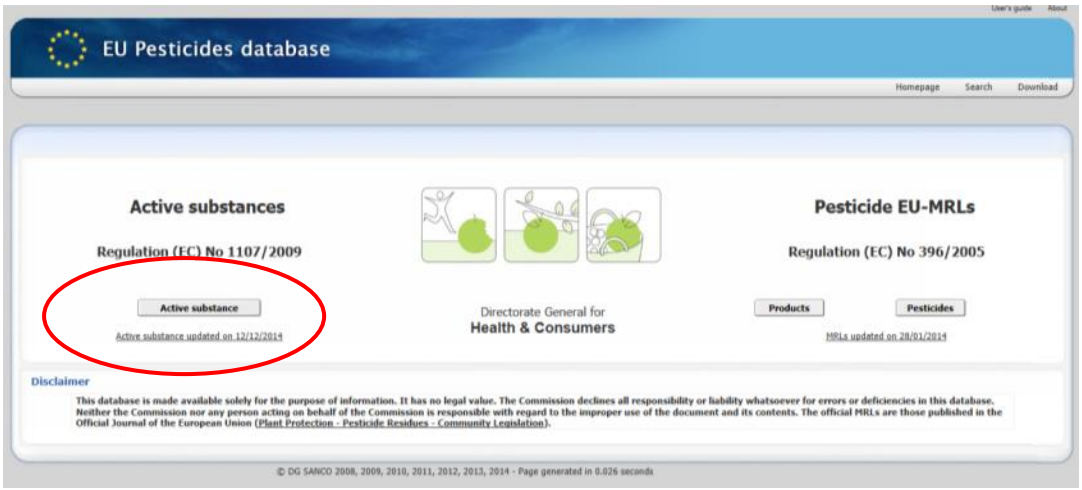
4.1 EU Pesticides database

The EU Pesticides database provides a structured overview of information on all active substances that have been reviewed (the information can also be downloaded as a table in Excel format), as well as the formal documents for individual active substances, i.e. the review report and the Commission decision. In addition, there are links to the classification at the ECHA website, and to the EFSA conclusion report at the EFSA website. The overview table provides a useful quick overview of which substances have been approved and which not.

Start by entering the following website: http://ec.europa.eu/sanco_pesticides

Data on active substances

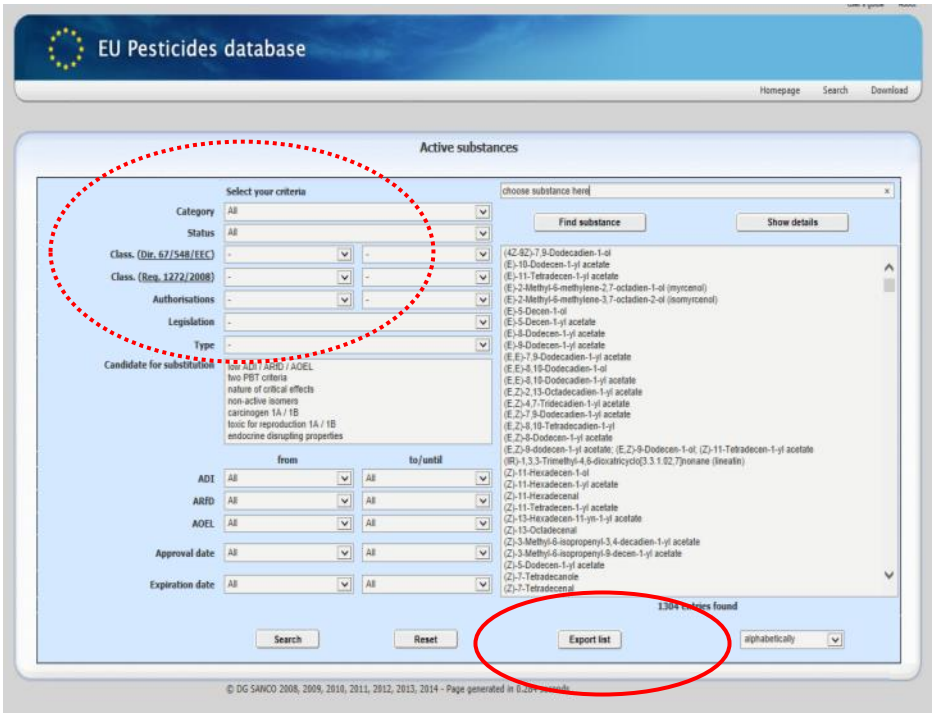
- Choose 'Active substances'



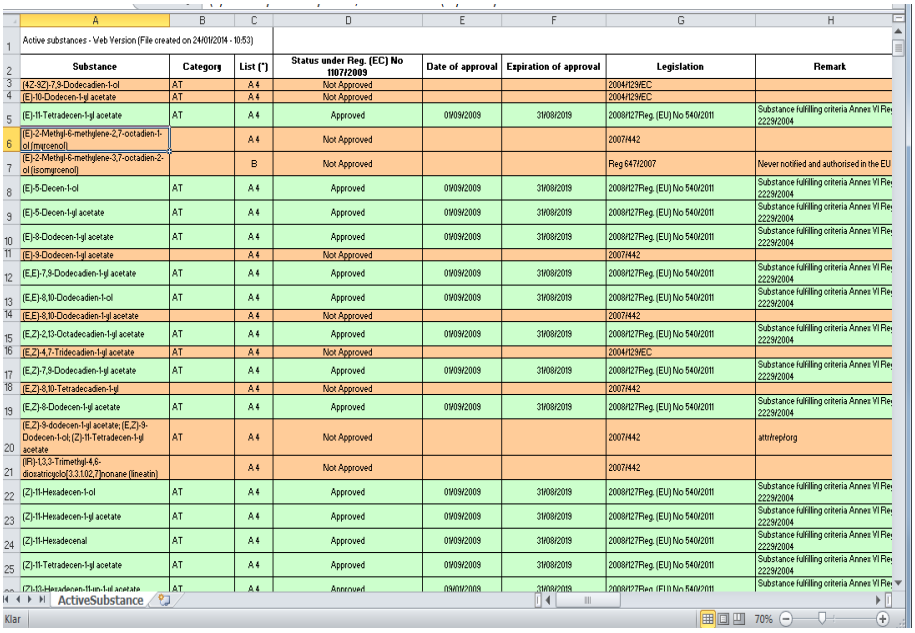
Overview table

Provides summary information for all substances that have been reviewed

- Select your criteria; 'All' or depending on need/preferences, specify 'status, category etc.'
- Click on 'Export list', see below



Result – an XML-file:



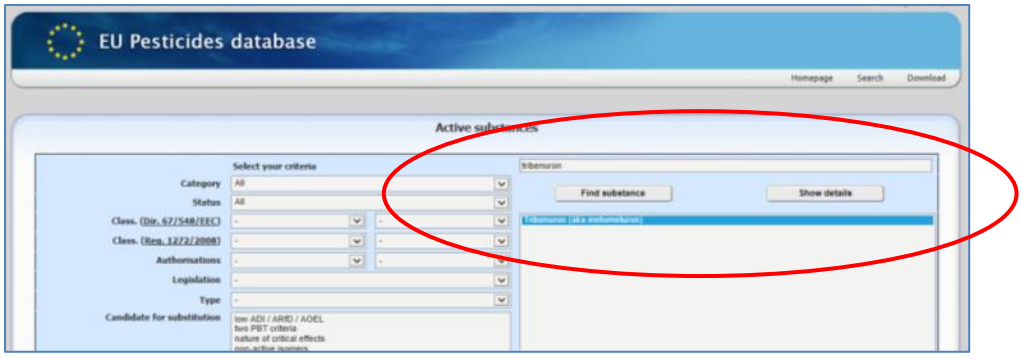
	Substance	Category	List (*)	Status under Reg. (EC) No 1107/2009	Date of approval	Expiration of approval	Legislation	Remark
3	(4Z-8Z)-7,9-Dodecadien-1-ol	AT	A 4	Not Approved			2004/129/EC	
4	(E)-10-Dodecen-1-yl acetate	AT	A 4	Not Approved			2004/129/EC	
5	(E)-11-Tetradecen-1-yl acetate	AT	A 4	Approved	01/09/2009	31/08/2019	2008/127/Reg. (EU) No 540/2011	Substance fulfilling criteria Annex VI Reg 2229/2004
6	(E)-2-Methyl-6-methylene-2,7-octadien-1-ol (myrcenol)		A 4	Not Approved			2007/442	
7	(E)-2-Methyl-6-methylene-3,7-octadien-2-ol (isomyrcenol)		B	Not Approved			Reg 647/2007	Never notified and authorised in the EU
8	(E)-5-Decen-1-ol	AT	A 4	Approved	01/09/2009	31/08/2019	2008/127/Reg. (EU) No 540/2011	Substance fulfilling criteria Annex VI Reg 2229/2004
9	(E)-5-Decen-1-yl acetate	AT	A 4	Approved	01/09/2009	31/08/2019	2008/127/Reg. (EU) No 540/2011	Substance fulfilling criteria Annex VI Reg 2229/2004
10	(E)-8-Dodecen-1-yl acetate	AT	A 4	Approved	01/09/2009	31/08/2019	2008/127/Reg. (EU) No 540/2011	Substance fulfilling criteria Annex VI Reg 2229/2004
11	(E)-9-Dodecen-1-yl acetate		A 4	Not Approved			2007/442	
12	(E,E)-7,9-Dodecadien-1-yl acetate	AT	A 4	Approved	01/09/2009	31/08/2019	2008/127/Reg. (EU) No 540/2011	Substance fulfilling criteria Annex VI Reg 2229/2004
13	(E,E)-8,10-Dodecadien-1-ol	AT	A 4	Approved	01/09/2009	31/08/2019	2008/127/Reg. (EU) No 540/2011	Substance fulfilling criteria Annex VI Reg 2229/2004
14	(E,E)-8,10-Dodecadien-1-yl acetate		A 4	Not Approved			2007/442	
15	(E,Z)-2,13-Octadecadien-1-yl acetate	AT	A 4	Approved	01/09/2009	31/08/2019	2008/127/Reg. (EU) No 540/2011	Substance fulfilling criteria Annex VI Reg 2229/2004
16	(E,Z)-4,7-Tridecadien-1-yl acetate	AT	A 4	Not Approved			2004/129/EC	
17	(E,Z)-7,9-Dodecadien-1-yl acetate	AT	A 4	Approved	01/09/2009	31/08/2019	2008/127/Reg. (EU) No 540/2011	Substance fulfilling criteria Annex VI Reg 2229/2004
18	(E,Z)-8,10-Tetradecadien-1-yl		A 4	Not Approved			2007/442	
19	(E,Z)-8-Dodecen-1-yl acetate	AT	A 4	Approved	01/09/2009	31/08/2019	2008/127/Reg. (EU) No 540/2011	Substance fulfilling criteria Annex VI Reg 2229/2004
20	(E,Z)-9-dodecen-1-yl acetate; (E,Z)-9-Dodecen-1-ol; (Z)-11-Tetradecen-1-yl acetate	AT	A 4	Not Approved			2007/442	attr/repr/org
21	(IR)-1,3,3-Trimethyl-4,6-dioxatricyclo[3.3.1.02,7]nonane (lineatin)		A 4	Not Approved			2007/442	
22	(Z)-11-Hexadecen-1-ol	AT	A 4	Approved	01/09/2009	31/08/2019	2008/127/Reg. (EU) No 540/2011	Substance fulfilling criteria Annex VI Reg 2229/2004
23	(Z)-11-Hexadecen-1-yl acetate	AT	A 4	Approved	01/09/2009	31/08/2019	2008/127/Reg. (EU) No 540/2011	Substance fulfilling criteria Annex VI Reg 2229/2004
24	(Z)-11-Hexadecenal	AT	A 4	Approved	01/09/2009	31/08/2019	2008/127/Reg. (EU) No 540/2011	Substance fulfilling criteria Annex VI Reg 2229/2004
25	(Z)-11-Tetradecen-1-yl acetate	AT	A 4	Approved	01/09/2009	31/08/2019	2008/127/Reg. (EU) No 540/2011	Substance fulfilling criteria Annex VI Reg 2229/2004

If there is a need to sort and filter the information (on dates, stages, status etc.), the file has to be converted to XLS-format:

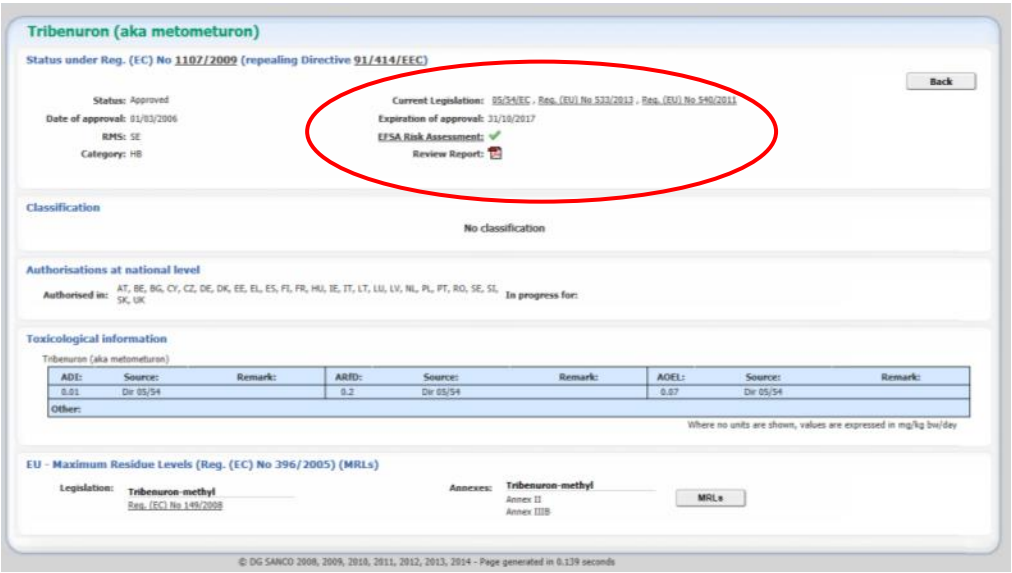
- Start with 'Save as:' an Excel-file (.XLS)
- Go to 'Examine' and remove the ´Protection of file´
- Mark row no. 2
- Go to ´Start' and add the filter-function under 'Sort & Filter'
- Save

Information for one specific active substance

- Type the name of the active substance in the field on the top to the right
- Click on 'Find substance'
- Mark on the name of the active substance
- 'Show details'



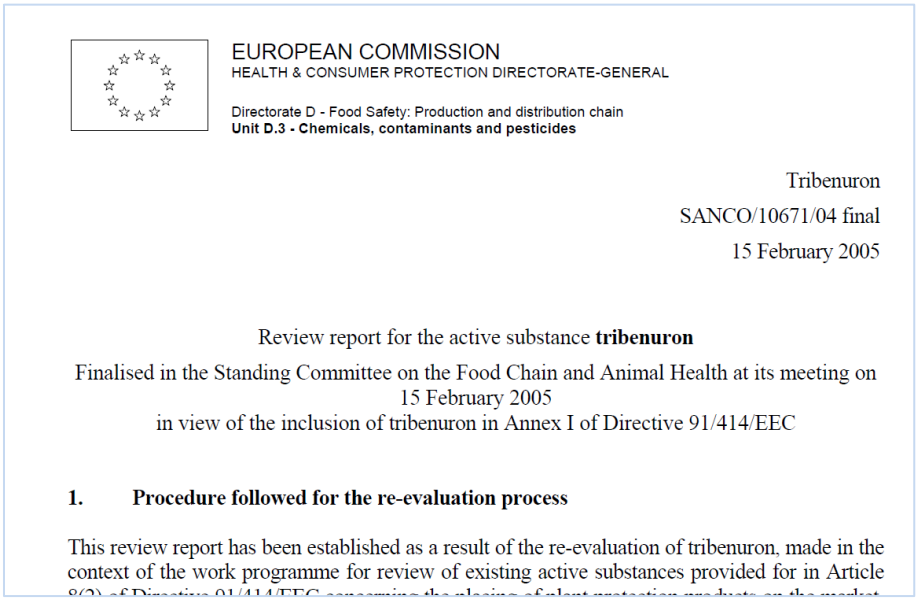
The following page is shown:



On this page one can see the approval status at EU level and the list of countries that have provided authorisations for products containing this active substance. It also contains key toxicological data and links to EFSA Review Report (with all the review details) and the current legislation (with the formal registration decision).

a) To see the Review Report click on the PDF symbol.

One then gets the Review Report, which looks like this:



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: Production and distribution chain
Unit D.3 - Chemicals, contaminants and pesticides

Tribenuron
SANCO/10671/04 final
15 February 2005

Review report for the active substance **tribenuron**

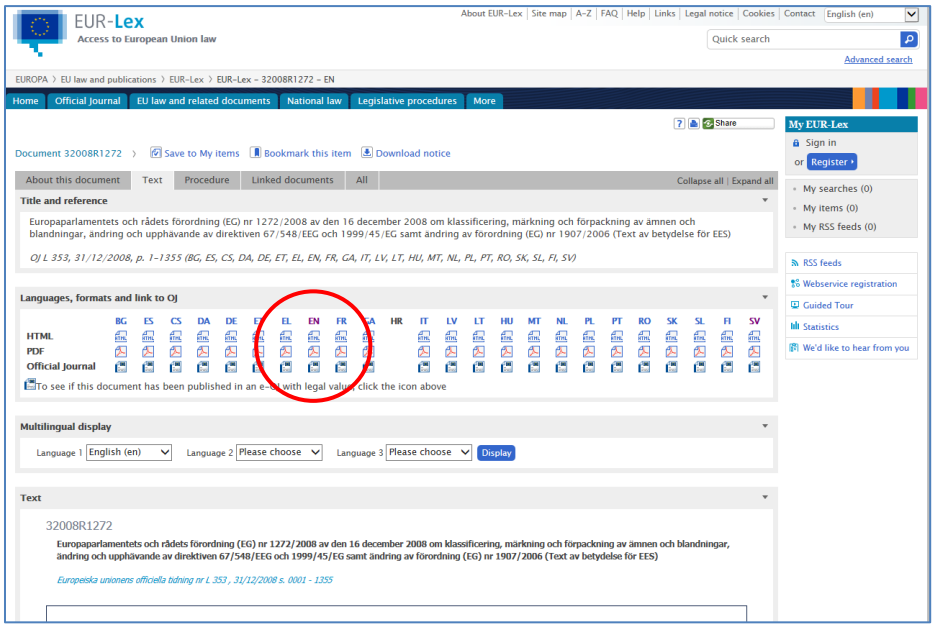
Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 February 2005
in view of the inclusion of tribenuron in Annex I of Directive 91/414/EEC

1. Procedure followed for the re-evaluation process

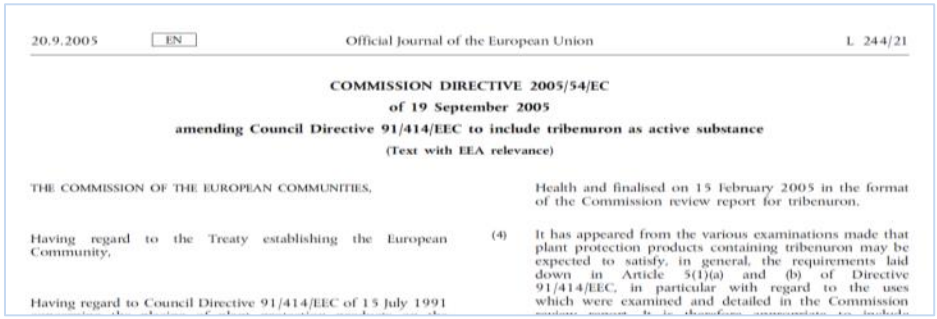
This review report has been established as a result of the re-evaluation of tribenuron, made in the context of the work programme for review of existing active substances provided for in Article

This report follows a standard format and has many fixed clauses. The specific details are presented in the Annexes at the end. Here one can find the supported uses for which the substance has been evaluated and for which the risk was found “acceptable”, but also other specific information such as pre-harvest interval (PHI value) etc.

b) To see the current Legislation, with the formal registration decision, click on the links after "current legislation". Then choose your language and click on preferred format.



Commission Directive



20.9.2005 EN Official Journal of the European Union L 244/21

COMMISSION DIRECTIVE 2005/54/EC
of 19 September 2005
amending Council Directive 91/414/EEC to include tribenuron as active substance
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991

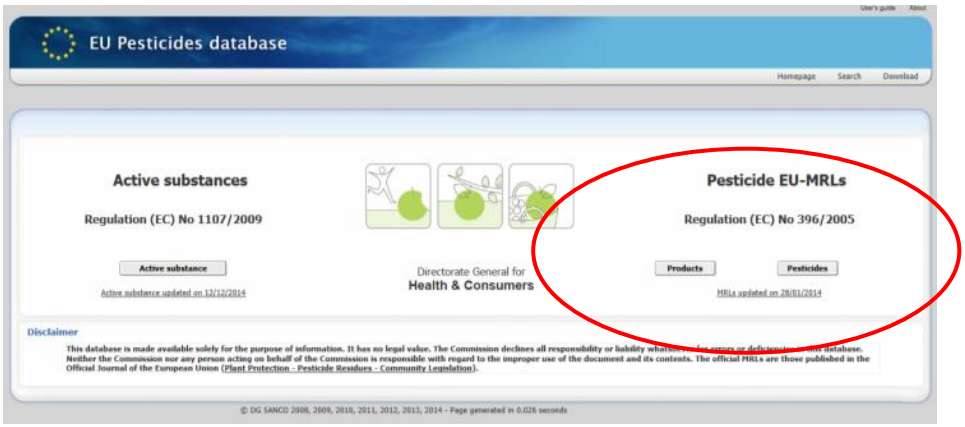
Health and finalised on 15 February 2005 in the format of the Commission review report for tribenuron.

(4) It has appeared from the various examinations made that plant protection products containing tribenuron may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission

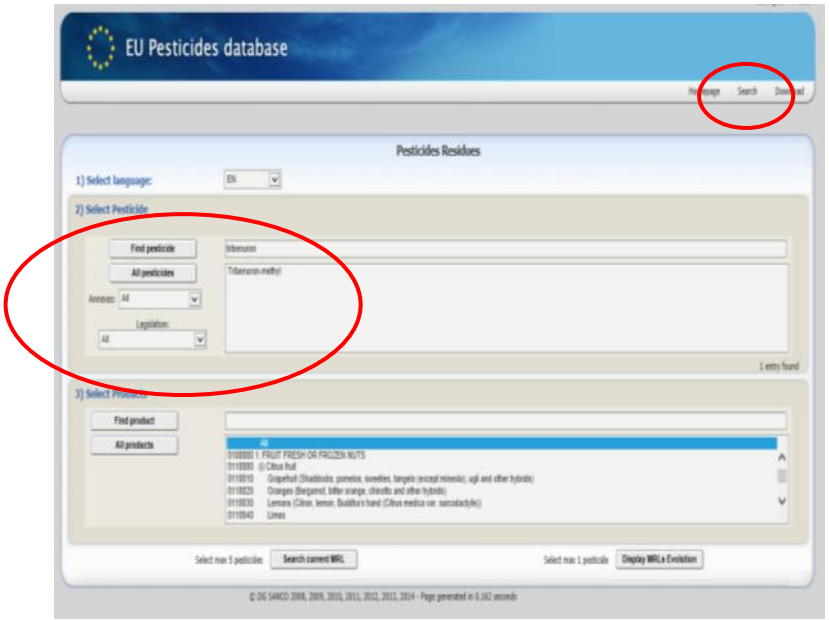
Maximum residue level, MRL

To find the MRLs that have been established for a specific active substance go to the start screen.

- Chose ‘Pesticides’

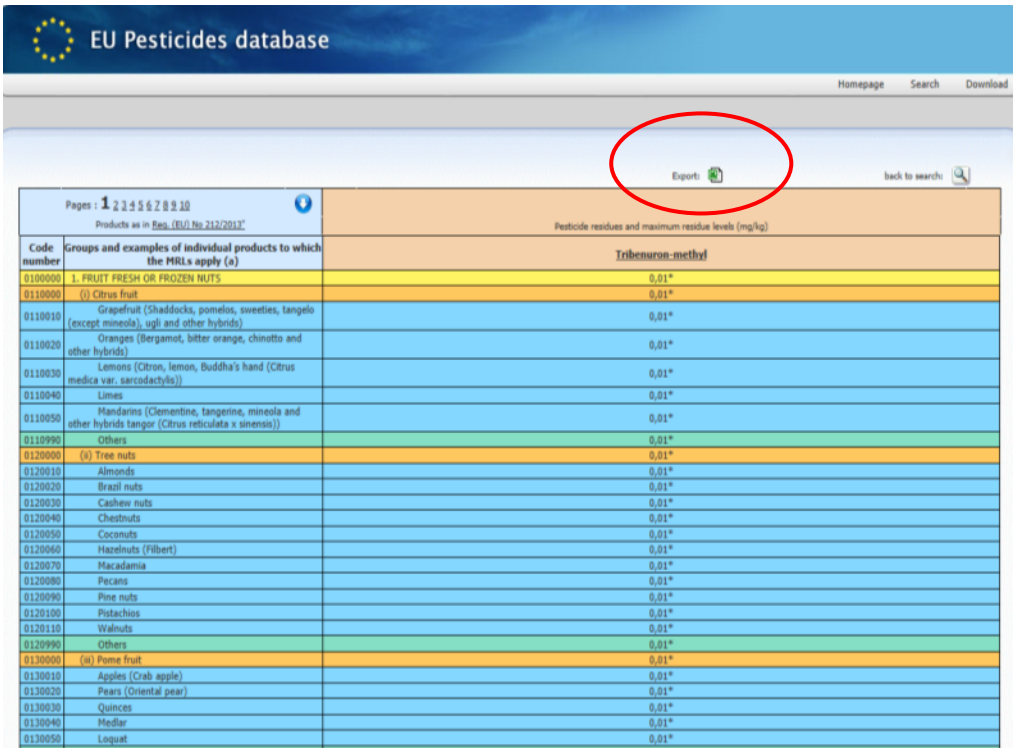


- Type the name of the active substance
- Click enter or on ‘Find substance’
- Double click on the active substance you are searching for



You will then get a table of maximum residue levels (MRL) in different crops. The table can be downloaded and exported as an Excel file.

Further detailed guidance is found when clicking on “search” at the right top of the page.



4.2 EFSA

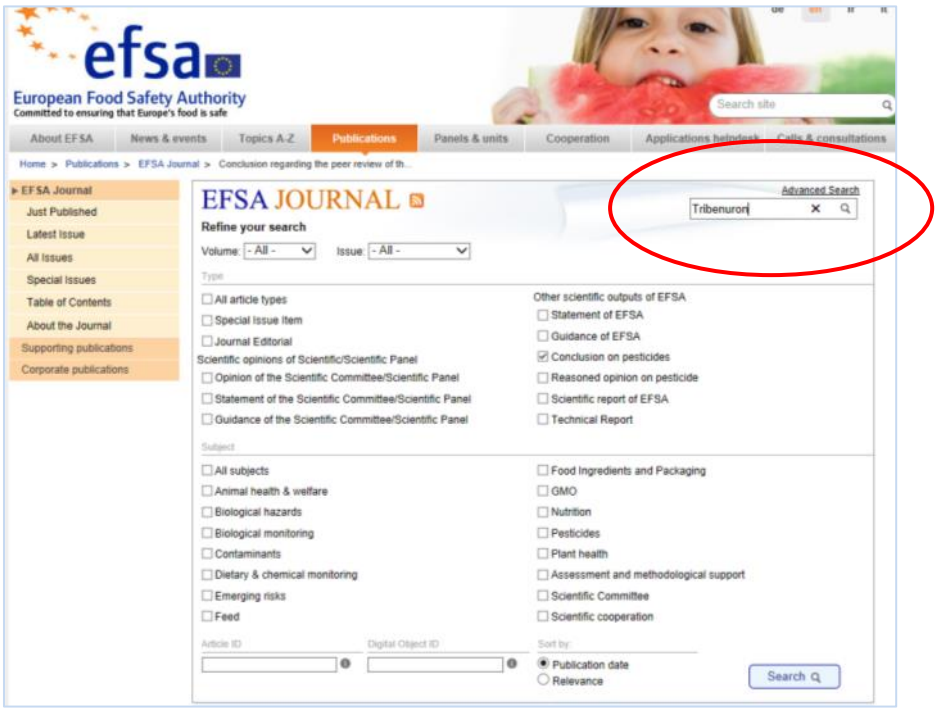
At the EFSA website one can find the EFSA conclusions.
These include comprehensive information on substance properties, calculations of exposure and the risk assessment.

Start by entering the following website: http://www.efsa.europa.eu/

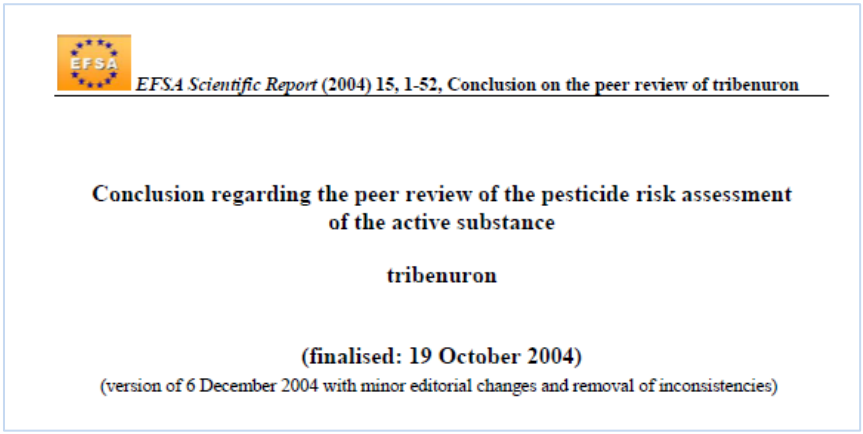
- Go to: 'Publications'

Then go to:

- "Advanced search" (above the search box)
- Tick the box 'Conclusion on pesticides'
- Type the name of the pesticide in the search box, and press enter



You then get one or more links to documents under results.
Click on the latest one that says "Conclusion regarding the peer review of the pesticide risk assessment of the active substance".


EFSA Scientific Report (2004) 15, 1-52, Conclusion on the peer review of tribenuron

Conclusion regarding the peer review of the pesticide risk assessment of the active substance

tribenuron

(finalised: 19 October 2004)

(version of 6 December 2004 with minor editorial changes and removal of inconsistencies)

In the EFSA conclusion document one can find information about the properties of the substance, exposure assessment and risk assessment.

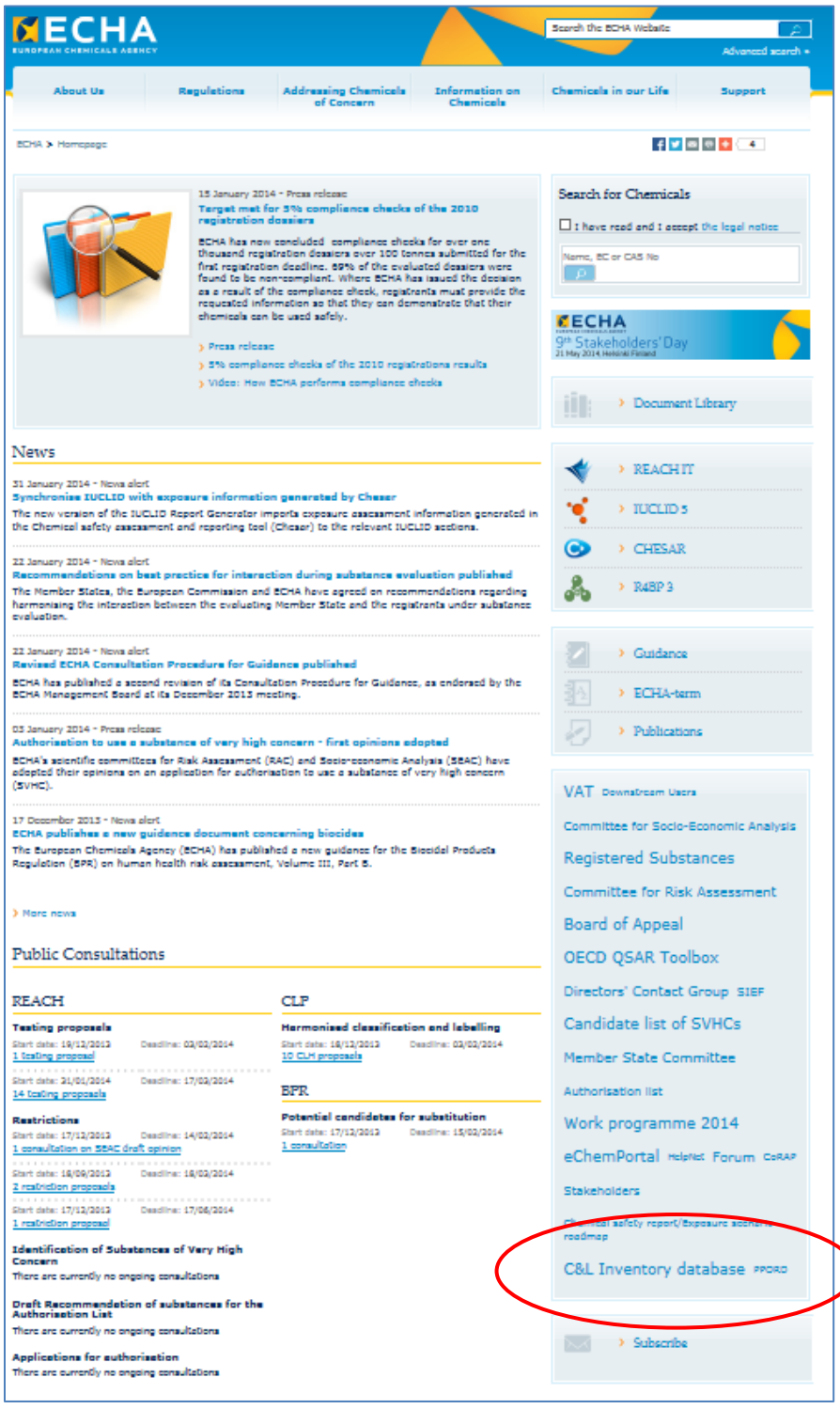
4.3 ECHA

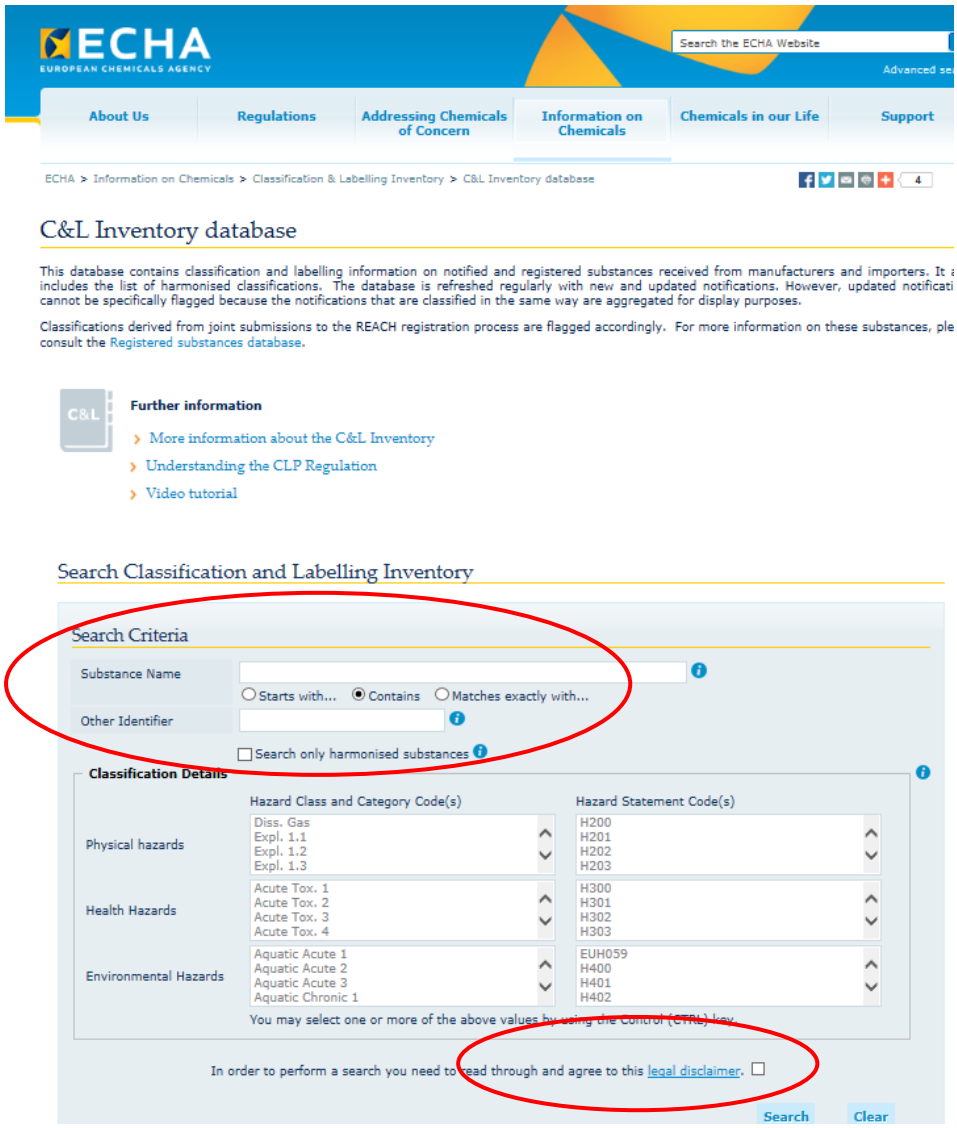
The European Chemicals Agency (ECHA) is maintaining a Classification & Labelling Inventory. This is a database with information on classification and labelling for substances notified under the CLP Regulation. It also contains the list of legally binding harmonised classifications, Annex VI to the CLP Regulation. The C&L Inventory is the best place to find the GHS classification of active substances in pesticides.

The C&L Inventory provides multiple search options based on both substance identity and classification. A user can search using the full or partial EC name, the CLP Annex VI Index name and IUPAC name.

Webb: http://echa.europa.eu/en

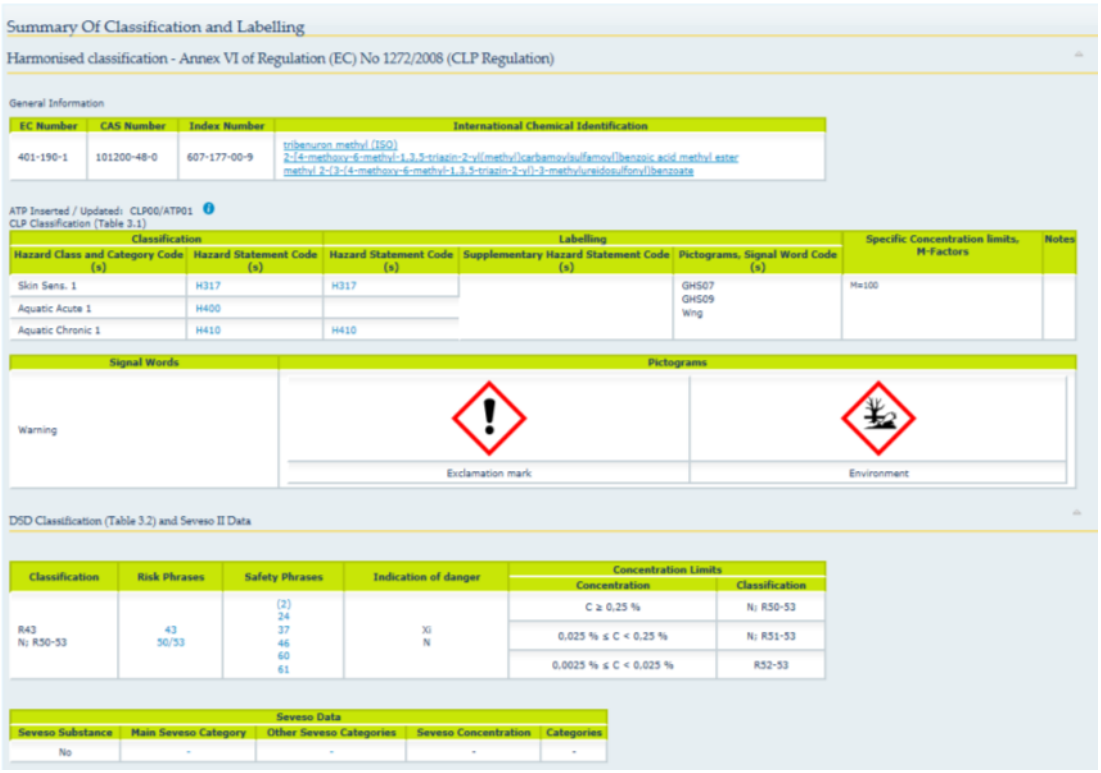
Go to ”C&L Inventory database”


ECHA
Search the ECHA Website
Advanced search »
About Us
Regulations
Addressing Chemicals of Concern
Information on Chemicals
Chemicals in our Life
Support
ECHA > Homepage
15 January 2014 - Press release
Target met for 5% compliance checks of the 2010 registration dossiers
ECHA has now concluded compliance checks for over one thousand registration dossiers over 100 tonnes submitted for the first registration deadline. 69% of the evaluated dossiers were found to be non-compliant. Where ECHA has issued the decision as a result of the compliance check, registrants must provide the requested information so that they can demonstrate that their chemicals can be used safely.
› Press release
› 5% compliance checks of the 2010 registrations results
› Video: How ECHA performs compliance checks
Search for Chemicals
I have read and I accept the legal notice
Name, EC or CAS No
ECHA
9th Stakeholders' Day
21 May 2014, Helsinki Finland
› Document Library
› REACH IT
› IUCLID 5
› CHESAR
› R4BP 3
› Guidance
› ECHA-term
› Publications
News
31 January 2014 - News alert
Synchronise IUCLID with exposure information generated by Chesar
The new version of the IUCLID Report Generator imports exposure assessment information generated in the Chemical safety assessment and reporting tool (Chesar) to the relevant IUCLID sections.
22 January 2014 - News alert
Recommendations on best practice for interaction during substance evaluation published
The Member States, the European Commission and ECHA have agreed on recommendations regarding harmonising the interaction between the evaluating Member State and the registrants under substance evaluation.
22 January 2014 - News alert
Revised ECHA Consultation Procedure for Guidance published
ECHA has published a second revision of its Consultation Procedure for Guidance, as endorsed by the ECHA Management Board at its December 2013 meeting.
03 January 2014 - Press release
Authorisation to use a substance of very high concern - first opinions adopted
ECHA's scientific committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) have adopted their opinions on an application for authorisation to use a substance of very high concern (SVHC).
17 December 2013 - News alert
ECHA publishes a new guidance document concerning biocides
The European Chemicals Agency (ECHA) has published a new guidance for the Biocidal Products Regulation (BPR) on human health risk assessment, Volume III, Part B.
› More news
VAT Downstream Users
Committee for Socio-Economic Analysis
Registered Substances
Committee for Risk Assessment
Board of Appeal
OECD QSAR Toolbox
Directors' Contact Group SIEF
Candidate list of SVHCs
Member State Committee
Authorisation list
Work programme 2014
eChemPortal HelpNet Forum CoRAP
Stakeholders
C&L Inventory database PPORD
› Subscribe
Public Consultations
REACH
Testing proposals
Start date: 19/12/2013 Deadline: 03/02/2014
1 testing proposal
Start date: 21/01/2014 Deadline: 17/03/2014
14 testing proposals
Restrictions
Start date: 17/12/2013 Deadline: 14/02/2014
1 consultation on SEAC draft opinion
Start date: 18/09/2013 Deadline: 18/02/2014
2 restriction proposals
Start date: 17/12/2013 Deadline: 17/06/2014
1 restriction proposal
Identification of Substances of Very High Concern
There are currently no ongoing consultations
Draft Recommendation of substances for the Authorisation List
There are currently no ongoing consultations
Applications for authorisation
There are currently no ongoing consultations
CLP
Harmonised classification and labelling
Start date: 16/12/2013 Deadline: 03/02/2014
10 CLH proposals
BPR
Potential candidates for substitution
Start date: 17/12/2013 Deadline: 15/03/2014
1 consultation



- Type the name of the substance
- Note that the box legal disclaimer must be ticked
- Click on Search
- Then click on View

Examples of C&L, result:



Summary Of Classification and Labelling

Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

General Information

EC Number	CAS Number	Index Number	International Chemical Identification
401-190-1	101200-48-0	607-177-00-9	tribenuron methyl (ISO) 2-[4-methoxy-6-methyl-1,3,5-triazin-2-yl(methyl)carbamoylsulfamoyl]benzoic acid methyl ester methyl 2-(3-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-3-methylureidosulfonyl)benzoate

ATP Inserted / Updated: CLP00/ATP01

CLP Classification (Table 3.1)

Classification		Labelling			Specific Concentration limits, M-Factors	Notes
Hazard Class and Category Code (s)	Hazard Statement Code (s)	Hazard Statement Code (s)	Supplementary Hazard Statement Code (s)	Pictograms, Signal Word Code (s)		
Skin Sens. 1	H317	H317		GHS07 GHS09 Wng	M=100	
Aquatic Acute 1	H400					
Aquatic Chronic 1	H410	H410				

Signal Words	Pictograms	
Warning		
	Exclamation mark	Environment

DSD Classification (Table 3.2) and Seveso II Data

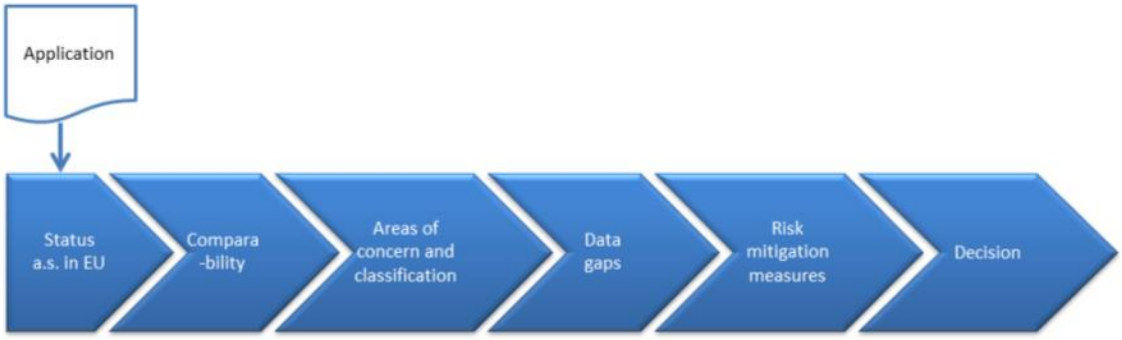
Classification	Risk Phrases	Safety Phrases	Indication of danger	Concentration Limits	
				Concentration	Classification
R43 N; R50-53	43 50/53	(2) 24 37 46 60 61	Xi N	C ≥ 0,25 %	N; R50-53
				0,025 % ≤ C < 0,25 %	N; R51-53
				0,0025 % ≤ C < 0,025 %	R52-53

Seveso Data				
Seveso Substance	Main Seveso Category	Other Seveso Categories	Seveso Concentration	Categories
No	-	-	-	-

Appendix 1, examples

The examples given below are intended to in more detail show where and which type of information that can be found in the EU documentation. The aim is however not to give a complete guidance on how the information can be used for decision making. In order to base a decision on this information national consideration needs to be taken into account.

The three examples are showing relevant documents and text, applied in a stepwise assessment procedure, see flowchart below.



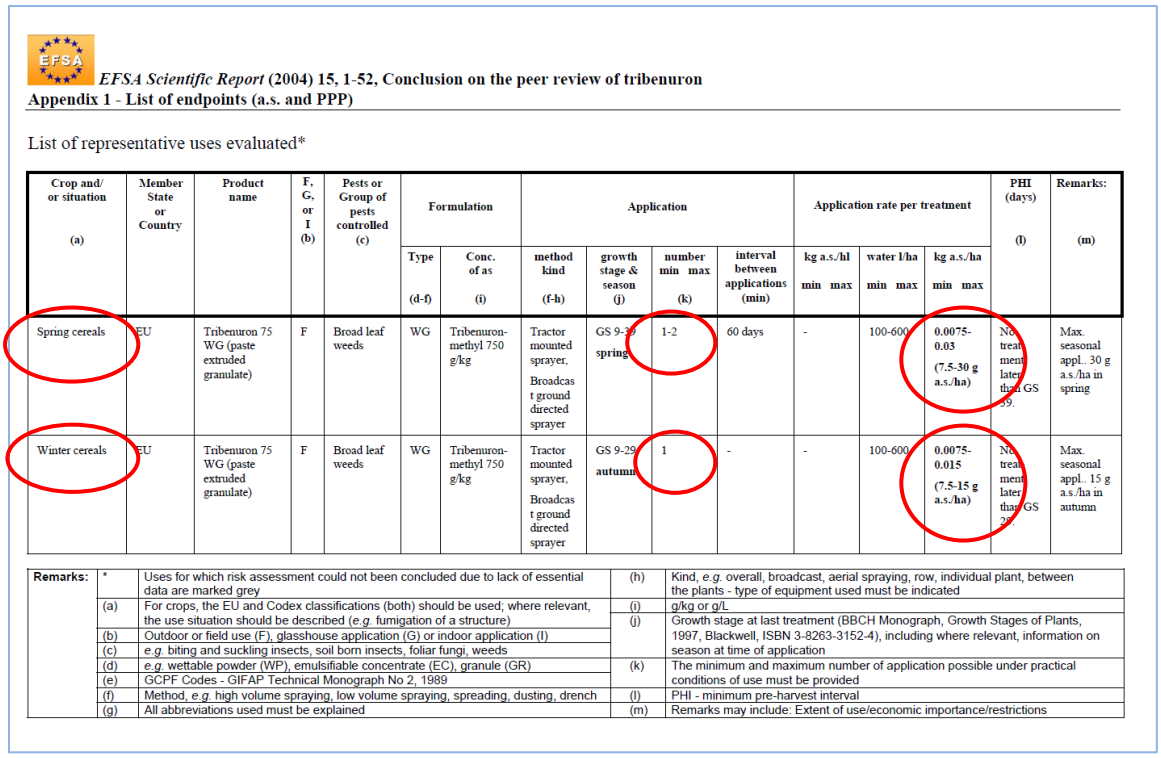
Example 1, Tribenuron

Check status of the active substance in EU

In the EU Pesticide database it is possible to see that tribenuron was approved in March 2006 as active substance in pesticides in the EU.

Check comparability (e.g. use, identity) in EU to the actual use or identity in your region or country

This information can be obtained from the EFSA conclusion. The crops evaluated in the EU risk assessments are spring and winter cereals at dose rates 7.5 – 30 g active substance/ha and at maximum 2 applications (as highlighted in the picture below). In this table the uses that were evaluated in the EU processes is shown.



EFSA Scientific Report (2004) 15, 1-52, Conclusion on the peer review of tribenuron
Appendix 1 - List of endpoints (a.s. and PPP)

List of representative uses evaluated*

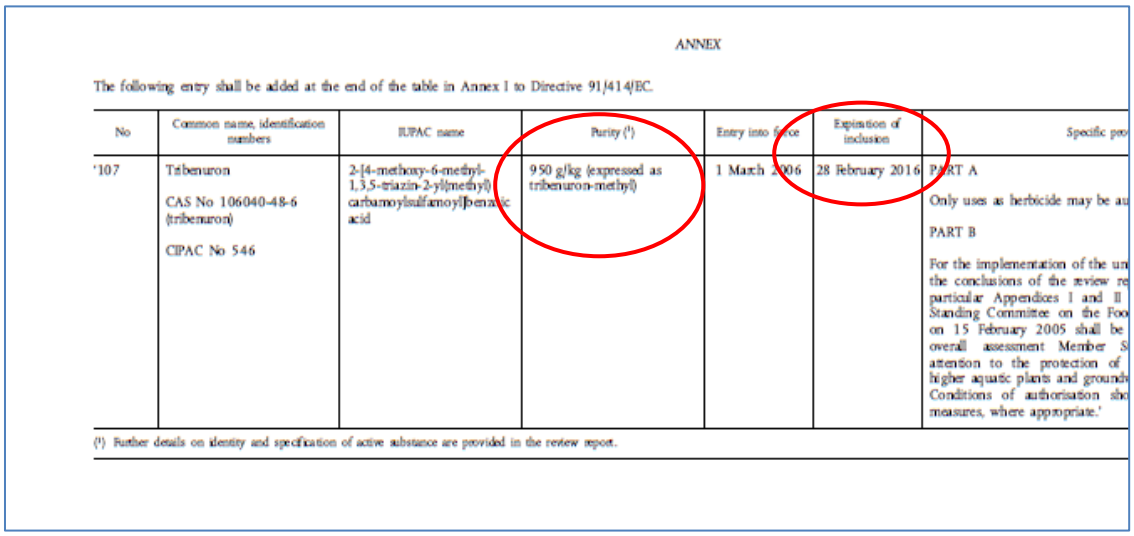
Crop and/ or situation (a)	Member State or Country	Product name	F, G, or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hl min max	water l/ha min max	kg a.s./ha min max		
Spring cereals	EU	Tribenuron 75 WG (paste extruded granulate)	F	Broad leaf weeds	WG	Tribenuron-methyl 750 g/kg	Tractor mounted sprayer, Broadcast ground directed sprayer	GS 9-39 spring	1-2	60 days	-	100-600	0.0075-0.03 (7.5-30 g a.s./ha)	No treatment later than GS 39.	Max. seasonal appl.. 30 g a.s./ha in spring
Winter cereals	EU	Tribenuron 75 WG (paste extruded granulate)	F	Broad leaf weeds	WG	Tribenuron-methyl 750 g/kg	Tractor mounted sprayer, Broadcast ground directed sprayer	GS 9-29 autumn	1	-	-	100-600	0.0075-0.015 (7.5-15 g a.s./ha)	No treatment later than GS 29.	Max. seasonal appl.. 15 g a.s./ha in autumn

Remarks:				
	*	Uses for which risk assessment could not been concluded due to lack of essential data are marked grey	(h)	Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
	(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)	(i)	g/kg or g/L
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(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
	(c)	*e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds		
	(d)	*e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		
	(f)	Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
	(g)	All abbreviations used must be explained	(m)	Remarks may include: Extent of use/economic importance/restrictions

Furthermore, valuable information can be obtained from the Commission Directive 2005/54/EC, which can be found via the EU pesticide database.

For example that tribenuron is approved until 2017. The purity is agreed to ≥ 950g/kg and the FAO specification is 950 g/kg [546/TC (2002)], see figure below.

In the Commission Directive it can be understood that based on the information currently available, the review has concluded that for the active substance notified by the main data submitter, none of the manufacturing impurities considered are of toxicological or environmental concern.



ANNEX

The following entry shall be added at the end of the table in Annex I to Directive 91/414/EC.

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific pro
'107	Tribenuron CAS No 106040-48-6 (tribenuron) CIPAC No 546	2-[4-methoxy-6-methyl-1,3,5-triazin-2-yl(methyl) carbamoylsulfamoyl]benzoic acid	950 g/kg (expressed as tribenuron-methyl)	1 March 2006	28 February 2016	PART A Only uses as herbicide may be au PART B For the implementation of the un the conclusions of the review re particular Appendices I and II Standing Committee on the Foo on 15 February 2005 shall be overall assessment Member S attention to the protection of higher aquatic plants and groundv Conditions of authorisation sho measures, where appropriate.'

(1) Further details on identity and specification of active substance are provided in the review report.

Check Areas of concern and classification

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: Production and distribution chain
Unit D.3 - Chemicals, contaminants and pesticides

Tribenuron
SANCO/10671/04 final
15 February 2005

Review report for the active substance **tribenuron**
Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 February 2005
in view of the inclusion of tribenuron in Annex I of Directive 91/414/EEC

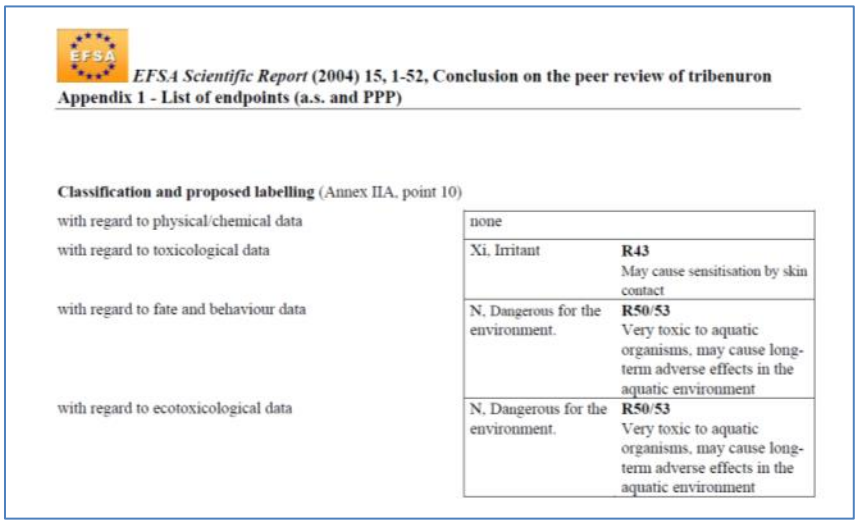
1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of tribenuron, made in the context of the work programme for review of existing active substances provided for in Article

Information on which areas that needs to be considered in particular for the national authorisation of tribenuron, i.e. areas for which risk mitigation measures might be needed, can be found in the Review report (which can be found via the EU pesticide database. The European Commission gives the following message to the Member States in the Review Report under the heading “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 tribenuron”:

"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, varied or withdrawn, as appropriate:

- Member States should pay particular attention to the protection of non- target terrestrial plants, higher aquatic plants and groundwater in vulnerable situations. Risk mitigation measures should be applied, where appropriate".



EFSA Scientific Report (2004) 15, 1-52, Conclusion on the peer review of tribenuron
Appendix 1 - List of endpoints (a.s. and PPP)

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	none	
with regard to toxicological data	Xi, Irritant	**R43** May cause sensitisation by skin contact
with regard to fate and behaviour data	N, Dangerous for the environment.	**R50/53** Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
with regard to ecotoxicological data	N, Dangerous for the environment.	**R50/53** Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Above, the proposed classification in the EFSA Conclusion from 2004 and the current harmonized classification from 2008 is found below. This example shows that the classification was proposed in the old EU classification system in 2004 and the final decision on a harmonized classification is made 2008 according to the new EU implementation of GHS called CLP.

Summary Of Classification and Labelling

Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

General Information

EC Number	CAS Number	Index Number	International Chemical Identification
401-190-1	101200-48-0	607-177-00-9	tribenuron methyl (ISO) 2-[4-methoxy-6-methyl-1,3,5-triazin-2-yl(methyl)carbamoylsulfamoyl]benzoic acid methyl ester methyl 2-(3-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-3-methylureidosulfonyl)benzoate

ATP Inserted / Updated: CLP00/ATP01
CLP Classification (Table 3.1)

Classification		Labelling			Specific Concentration limits, M-Factors	Notes
Hazard Class and Category Code (s)	Hazard Statement Code (s)	Hazard Statement Code (s)	Supplementary Hazard Statement Code (s)	Pictograms, Signal Word Code (s)		
Skin Sens. 1	H317	H317		GHS07 GHS09 Wng	M=100	
Aquatic Acute 1	H400					
Aquatic Chronic 1	H410	H410				

Signal Words	Pictograms	
Warning		
	Exclamation mark	Environment

DSD Classification (Table 3.2) and Seveso II Data

Classification	Risk Phrases	Safety Phrases	Indication of danger	Concentration Limits	
				Concentration	Classification
R43 N; R50-53	43 50/53	(2) 24 37 46 60 61	Xi N	C ≥ 0,25 %	N; R50-53
				0,025 % ≤ C < 0,25 %	N; R51-53
				0,0025 % ≤ C < 0,025 %	R52-53

Seveso Data				
Seveso Substance	Main Seveso Category	Other Seveso Categories	Seveso Concentration	Categories

Check data gaps

No data gaps have been identified for the uses evaluated, this information can be inferred from the Review report under the heading “List of studies to be generated “

Check risk mitigation measures

EFSA Scientific Report (2004) 15, 1-52, Conclusion on the peer review of tribenuron

Particular conditions proposed to be taken into account to manage the risk(s) identified

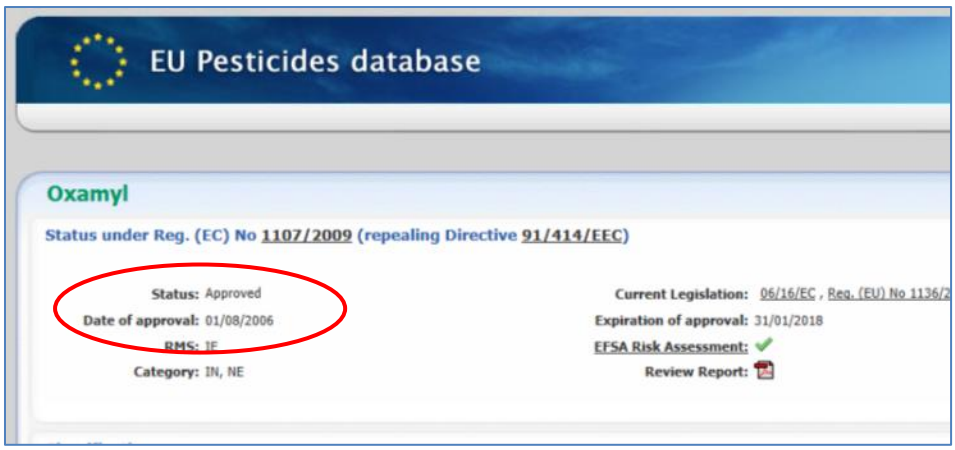
- Appropriate risk mitigation measures (e.g. a 5 meter no spray bufferzone) are required with regard to the risk for non target terrestrial plants and higher aquatic plants (refer to points 6.2 and 6.8).
- Under certain conditions (e.g. alkaline soils), appropriate risk mitigation measures may need to be considered to prevent groundwater contamination from tribenuron-methyl (refer to point 5.2.2.).
- Withholding period from application until harvest of grain and straw is recommended. Forage data demonstrated that at least up to 12 unidentified compounds were present at harvest in forage samples, partially at significant levels; therefore, forage should not be fed. If cereal forage is intended for use as animal feeding stuff, metabolite identification in forage should be dealt with at Member State level (refer to points 4.1.1). Resultant requirements concerning e.g. toxicological aspects and potential occurrence of residues in food of animal origin should be dealt with at Member State level.
- The residue definition should be restricted to the representative uses (cereals). If for future uses residue levels (and/or metabolite) become significant, this would need to be reviewed (refer to points 4.1.1).

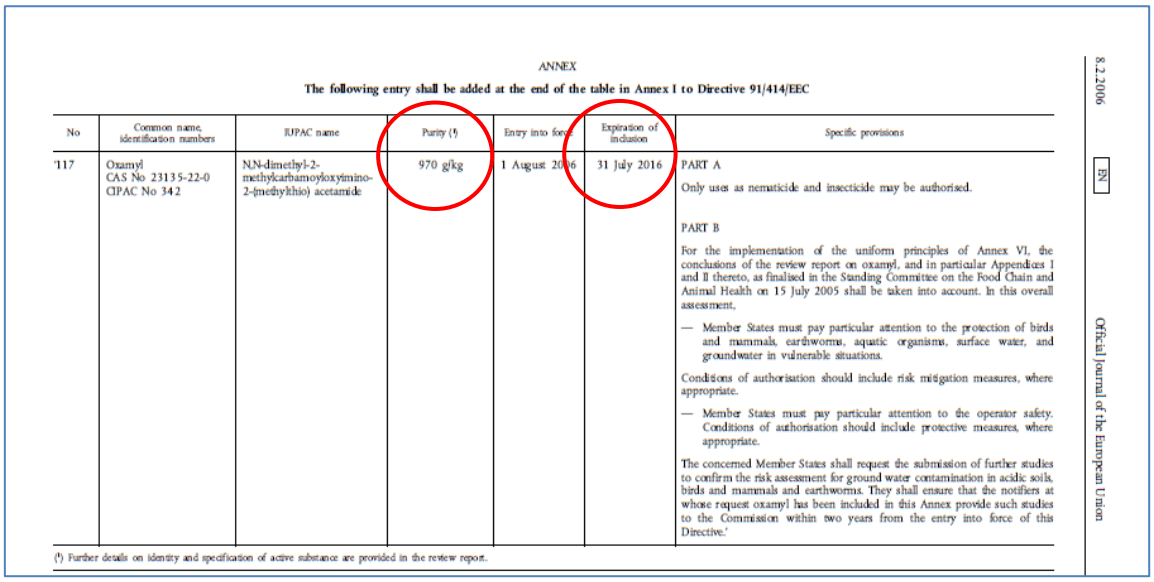
For the uses evaluated in for EU the risk mitigation measures listed above were considered essential. For national authorization other risk mitigation measure might however be needed depending on national conditions and product use

Example 2, Oxamyl – Extensive risk mitigation

Check status of the active substance oxamyl in EU

From the EU pesticide database it is noted that oxamyl was approved, in August 2006.





ANNEX

The following entry shall be added at the end of the table in Annex I to Directive 91/414/EEC

No	Common name, identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
'117	Oxamyl CAS No 23135-22-0 CIPAC No 342	N,N-dimethyl-2-methylcarbamoyloxyimino-2-(methylthio) acetamide	970 g/kg	1 August 2006	31 July 2016	PART A Only uses as nematicide and insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on oxamyl, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 July 2005 shall be taken into account. In this overall assessment, — Member States must pay particular attention to the protection of birds and mammals, earthworms, aquatic organisms, surface water, and groundwater in vulnerable situations. Conditions of authorisation should include risk mitigation measures, where appropriate. — Member States must pay particular attention to the operator safety. Conditions of authorisation should include protective measures, where appropriate. The concerned Member States shall request the submission of further studies to confirm the risk assessment for ground water contamination in acidic soils, birds and mammals and earthworms. They shall ensure that the notifiers at whose request oxamyl has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.'

(1) Further details on identity and specification of active substance are provided in the review report.

8.2.2006 EN Official Journal of the European Union

Oxamyl is approved until 2016 according to info in Commission directive (found via the EU pesticide data base. In the annex to the commission directive it can be seen that the purity is agreed to ≥970g/kg and there is no FAO specification available for the moment (2011). The review has established that for the oxamyl notified by the main data submitter none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

Check comparability (e.g. use, identity) in EU to the actual use or identity in your region or country

EFSA Scientific Report (2005) 26, 1-78, Conclusion on the peer review of oxamyl
Appendix 1 – List of endpoints (a.s. and PPP)

List of representative uses evaluated*

Crop and/or situation (a)	Member State or Country	Product name	F/G/I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Potato, main crop	NE; SE	Vydate	F	Nematodes and some other insect pests	GR	100	Evenly soil incorporated to a depth of 10 cm	At planting	1	Not relevant.	-		4.0-5.5 kg/ha. [Depending on soil type.]	--	
Potato, early potatoes	NE; SE	Vydate	F	Nematodes and some other insect pests	GR	100	Evenly soil incorporated to a depth of 10 cm	At planting	1	Not relevant.	-		4.0 kg/ha	12 weeks	

Remarks:				
	*	Uses for which risk assessment could not been concluded due to lack of essential data are marked grey	(h)	Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
	(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)	(i)	g/kg or g/L
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(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
	(c)	*e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds		
	(d)	*e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		
	(f)	Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
	(g)	All abbreviations used must be explained	(m)	Remarks may include: Extent of use/economic importance/restrictions

The crops evaluated in the risk assessments is potato at dose rates 4.0-5.5 k g active substance /ha and with maximum 1 application. However, no definitive conclusion on the risk assessment could be reached for the uses evaluated due to lack of data, see further below under the heading “Check data gaps”. In this case for oxamyl the uses are shaded in grey.

Check areas of concern and classification

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: Production and distribution chain
Unit D.3 - Chemicals, contaminants and pesticides

Oxamyl

SANCO/10212/05 final rev 1

17 June 2011[1]

Review report for the active substance **oxamyl**

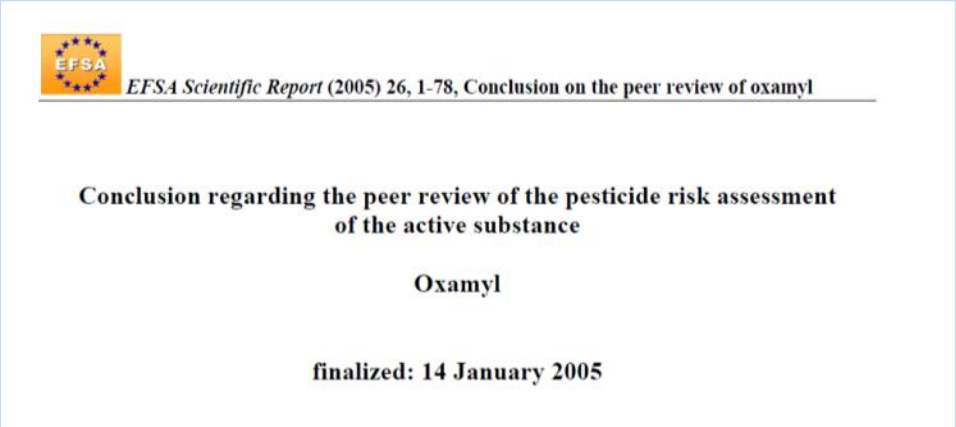
Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 July 2005
in view of the inclusion of oxamyl in Annex I of Directive 91/414/EEC

Information on which areas that need to be considered in particular for the national authorisation of oxamyl can be found in the Review report. The European Commission gives the following message to the Member States in the Review report:

"On the basis of the proposed and supported uses 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, varied or withdrawn, as appropriate:

- Member States must pay particular attention to the protection of birds and mammals, earthworms, aquatic organisms , surface water, and groundwater in vulnerable situations. Conditions of authorisation should include risk mitigation measures, where appropriate.

- Member States must pay particular attention to the operator safety. Conditions of authorisation should include protective measures, where appropriate."


EFSA Scientific Report (2005) 26, 1-78, Conclusion on the peer review of oxamyl

Conclusion regarding the peer review of the pesticide risk assessment of the active substance

Oxamyl

finalized: 14 January 2005

Further information on areas of concern can be found in the EFSA conclusion. The following **critical areas of concern** were identified in the EFSA conclusion report:

- For the operator exposure, it is necessary to consider the use of Personal protective equipment (PPE) and respiratory protective equipment (RPE) during mixing and loading as well as during application and an additional limitation of the treated area to 4.6 ha/day in order to derive an estimated operator exposure below the AOEL.
- Risk assessment with respect to ground water contamination and soil ecotoxicology by the parent and metabolites needs to be completed for acidic soils.
- A high risk to birds and mammals from the use of oxamyl and the need to address this risk further was identified. A full risk assessment can only be concluded when the outstanding data is evaluated.

- For the 3 run-off stream scenarios from the FOCUSsw[4] step 3 scenarios evaluated, the trigger was still breached indicating a high risk to aquatic organisms under these circumstances. Risk mitigation measures need to be taken into account at MS level to address this risk. The aquatic risk assessment has been conducted on the assumption that direct contamination (i.e. 'drift' of small granules) of surface water is not possible. A restriction highlighting the need to avoid the use of application machinery (i.e. pressurised systems) that may result in direct contamination of adjacent surface waters is proposed.
- The long term risk to earthworms is considered high as the TER[5] (1.7<TER<1.9 for an incorporation depth of 10 cm, 3.5<TER<3.8 for an incorporation depth of 20 cm) breaches the Annex VI trigger value of 5. The need to address this risk further was identified.

EFSA Scientific Report **(2005) 26, 1-78, Conclusion on the peer review of oxamyl**
Appendix 1 – List of endpoints (a.s. and PPP)

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data

Classification:	Very toxic by inhalation and if swallowed
Label:	
Symbol:	T+;
Indication of danger:	Very Toxic
Risk phrase:	R26/28 Very toxic by inhalation and if swallowed
Safety phrases:	S2, Keep out of the reach of children
	S36/37, Wear suitable protective clothing and gloves
	S45, In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)

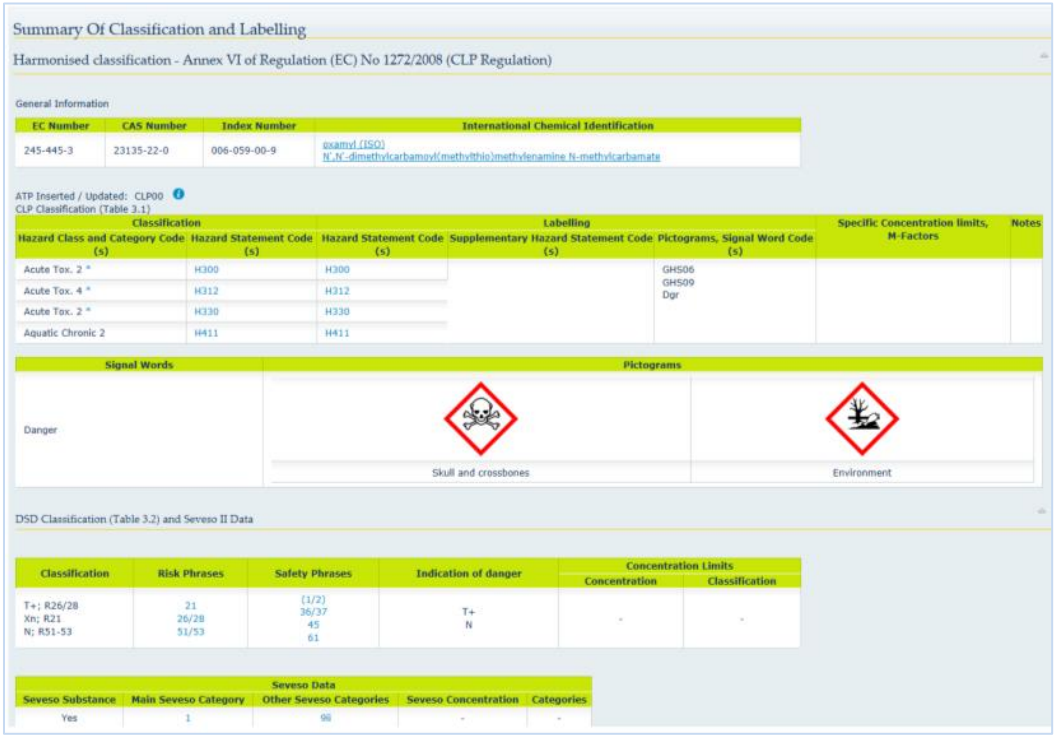
Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data

Classification:	Dangerous for the environment
Label:	
Symbol:	N
Indication of danger:	Dangerous for the environment
Risk phrase:	R50/53– Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Safety phrases:	S61

Above, the proposed classification in the EFSA Conclusion from 2004 and the harmonised classification from 2008 is found below.

[4] FOCUS surface water is a modelling tool used to predict concentration of pesticides in the surface water for EU risk assessment.
[5] Toxicity/Exposure Ration is used as a trigger for acceptable effects for the EU risk assessment



Summary Of Classification and Labelling

Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

General Information

EC Number	CAS Number	Index Number	International Chemical Identification
245-445-3	23135-22-0	006-059-00-9	oxamyl (ISO) N',N'-dimethylcarbamoyl(methylthio)methylenamine N-methylcarbamate

ATP Inserted / Updated: CLP00
CLP Classification (Table 3.1)

Classification		Labelling			Specific Concentration limits, M-Factors	Notes
Hazard Class and Category Code (s)	Hazard Statement Code (s)	Hazard Statement Code (s)	Supplementary Hazard Statement Code (s)	Pictograms, Signal Word Code (s)		
Acute Tox. 2 *	H300	H300		GHS06 GHS09 Dgr		
Acute Tox. 4 *	H312	H312				
Acute Tox. 2 *	H330	H330				
Aquatic Chronic 2	H411	H411				

Signal Words	Pictograms	
Danger	Skull and crossbones	Environment

DSD Classification (Table 3.2) and Seveso II Data

Classification	Risk Phrases	Safety Phrases	Indication of danger	Concentration Limits	
				Concentration	Classification
T+; R26/28 Xn; R21 N; R51-53	21 26/28 51/53	(1/2) 36/37 45 61	T+ N	-	-

Seveso Data				
Seveso Substance	Main Seveso Category	Other Seveso Categories	Seveso Concentration	Categories
Yes	1	96	-	-

This example shows that the classification was proposed in the old EU classification system in 2004 and the final decision on a harmonized classification is made 2008 according to the new EU implementation of GHS called CLP.

Check data gaps

The data that is missing in order to make perform an appropriate risk assessment for all areas can be found under the heading “List of studies to be generated” in the Review report, in this case:

The concerned Member States shall request the submission of further studies to confirm the risk assessment for ground water contamination in acidic soils, birds and mammals and earthworms.

Further details of which studies that are missing can be found in the EFSA conclusion under the heading “Check Data Gaps”, in this particular case e.g.:

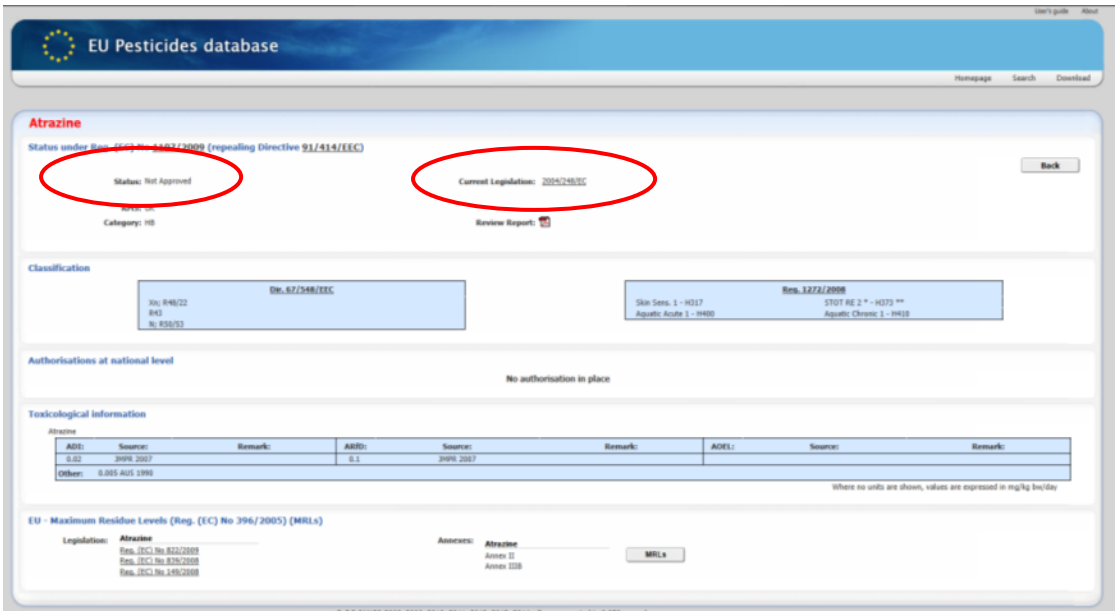
- boiling point or temperature of decomposition
- auto-flammability of the dry technical material
- identity of impurities
- data on rotational crop residue trials ('cold studies') to address the proposed time restriction of 120 days after oxamyl application (relevant for all representative uses evaluated; not essential for risk assessment; no submission date proposed by the notifier)
- degradation in acidic soils must be addressed;
- modelling to fully characterise the risk of oxamyl and its metabolites in soil and groundwater at different pHs is needed
- a refined avoidance study using oxamyl 10GR (Vydate ®) and conducted with relevant birds for European agricultural landscapes under more realistic exposure conditions
- full study report providing information on the number of granules available on the soil surface.
- the full report of the study on the release of the active ingredient from the granule (DuPont-3025);
- earthworm field study;

Check risk mitigation measures

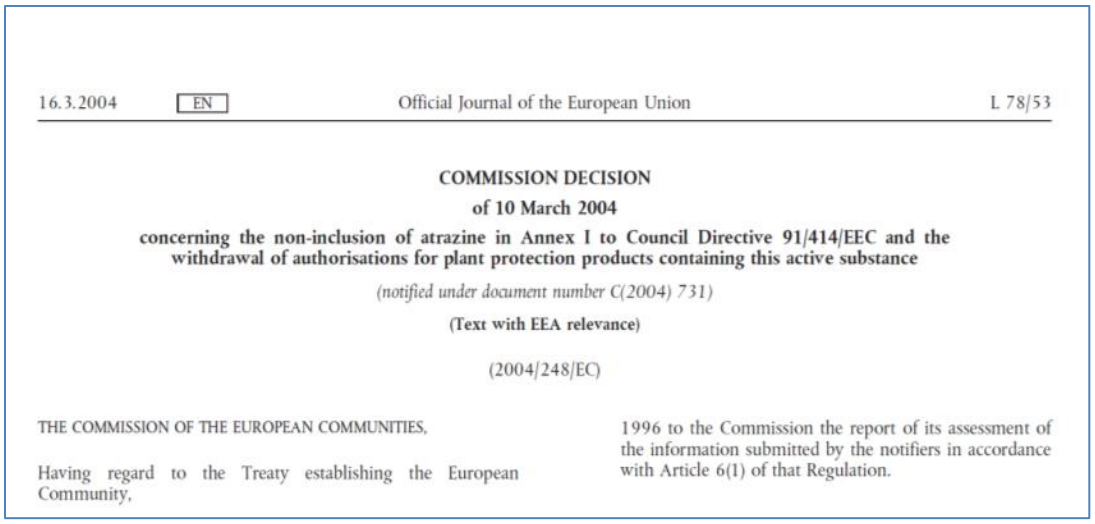
- The operator exposure is below AOEL if PPE and respiratory equipment (RPE) is used during mixing and loading as well as during application, based on an treated area of 4.6 ha/day.
- A label recommendation should be in place, which recommends that rotational crops should not be planted within 120 days of an oxamyl application to soil. This is required to minimize the possibility of residues being detected which will exceed the limit of quantification for oxamyl which is the likely the MRL.
- Potential environmental relevance of metabolite IN-N0079 in soil may need to be assessed for soils containing ferrous ion (Fe (II) (Anaerobic conditions are usually required).
- Potential ground water contamination should be considered under vulnerable conditions.
- A restriction highlighting the need to ensure that immediate incorporation of applied granules is required to ensure that the potential risk to birds and mammals is minimised.
- Risk mitigation measure have to be taken into account at MS level to address the risk to aquatic organisms, e.g. for run-off stream scenarios.

Example 3, Atrazine – Withdrawal

Check the status of the active substance atrazine in EU in the EU pesticide data base.



In the data base it is stated that atrazine is not approved according to the Commission decision, se section 4.1 on how to access the documents.



16.3.2004 EN Official Journal of the European Union L 78/53

COMMISSION DECISION

of 10 March 2004

concerning the non-inclusion of atrazine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance

(notified under document number C(2004) 731)

(Text with EEA relevance)

(2004/248/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

1996 to the Commission the report of its assessment of the information submitted by the notifiers in accordance with Article 6(1) of that Regulation.

The reasons for the non-inclusion and withdrawal of authorisations are found in the Commission Decision:

Assessments made on the basis of the information submitted have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing atrazine satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. In particular available monitoring data were insufficient to demonstrate

that in large areas concentrations of the active substance and its breakdown products will not exceed 0.1 µg/l in groundwater. Moreover it cannot be assured that continued use in other areas will permit a satisfactory recovery of groundwater quality where concentrations already exceed 0.1 µg/l in groundwater. These levels of the active substance exceed the limits in Annex VI to Directive 91/414/EEC and would have an unacceptable effect on groundwater.

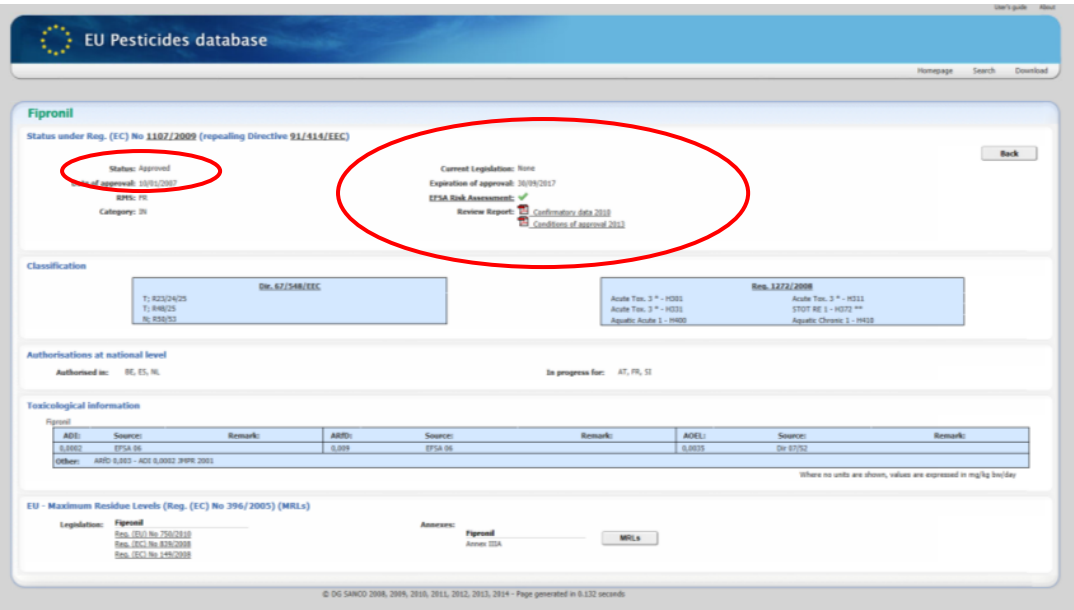
Example 4, Fipronil - Special case (restrictions)

Fipronil, is a 'special case', restriction due to risks to bees. This case is also relevant for neonicotinoids like thiamethoxam and chlothianidin.

Check the status of the active substance

From the EU pesticide database you can get the information that fipronil was approved, in August 2007. However, under the point "Commission Legislation" it is noted "none", which indicates that there are no legal documents supporting this approval. If this occurs it can be due to that the database has not yet been updated according to the latest decisions.

In this particular case this inadequacy is due to risk to pollinators. A review process was initiated by reports that were submitted describing unforeseen effects on bees before the repeated review (see figure 1). The reports were discussed, peer reviewed and a new EFSA conclusion report was published. The conclusions activated an amended decision published in the new Commission Implementing Regulation.



The data base is not yet updated in relation to the latest Commission implementing Regulation. This Commission implementing Regulation can however be found by searching on the EURlex data base (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do)

An extract from the document is found below:

L 219/22 EN Official Journal of the European Union 15.8.2013

COMMISSION IMPLEMENTING REGULATION (EU) No 781/2013

of 14 August 2013

amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substance fipronil, and prohibiting the use and sale of seeds treated with plant protection products containing this active substance

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (1), and in particular the first alternative of Article 21(3), Article 49(2) and Article 78(2) thereof,

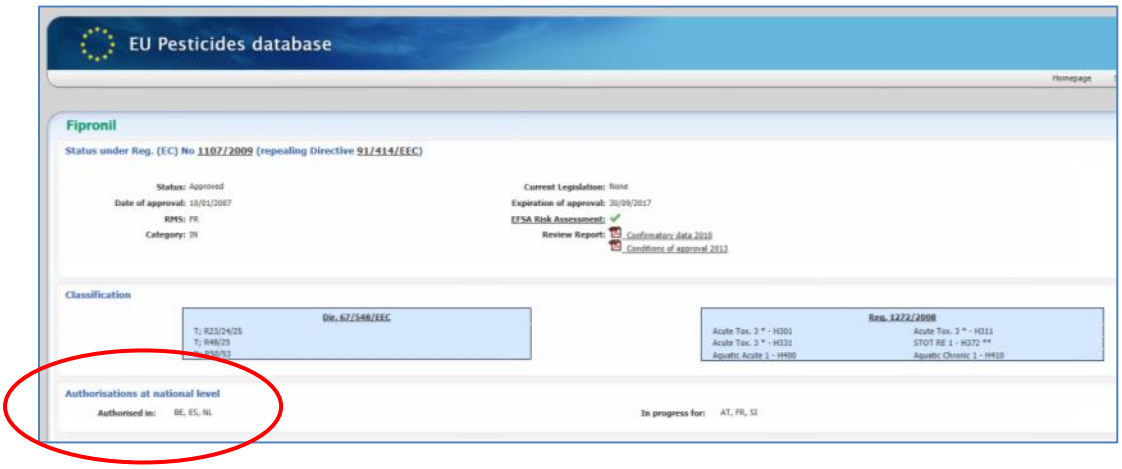
(5) The Authority presented its conclusion on the risk assessment of fipronil as regards bees on 27 May 2013 (6).

(6) The Authority identified for the use as seed treatment in maize, high acute risks for bees from plant protection products containing the active substance fipronil. The Authority identified, in particular, a high acute risk for bees resulting from dust. In addition, unacceptable risks due to acute or chronic effects on colony survival and development could not be excluded for several crops. Furthermore, the Authority identified some missing

It has been decided that new conditions for the use should apply and about the use and sale of seeds treated with fipronil. The reasoning for this could be found in the Regulation:

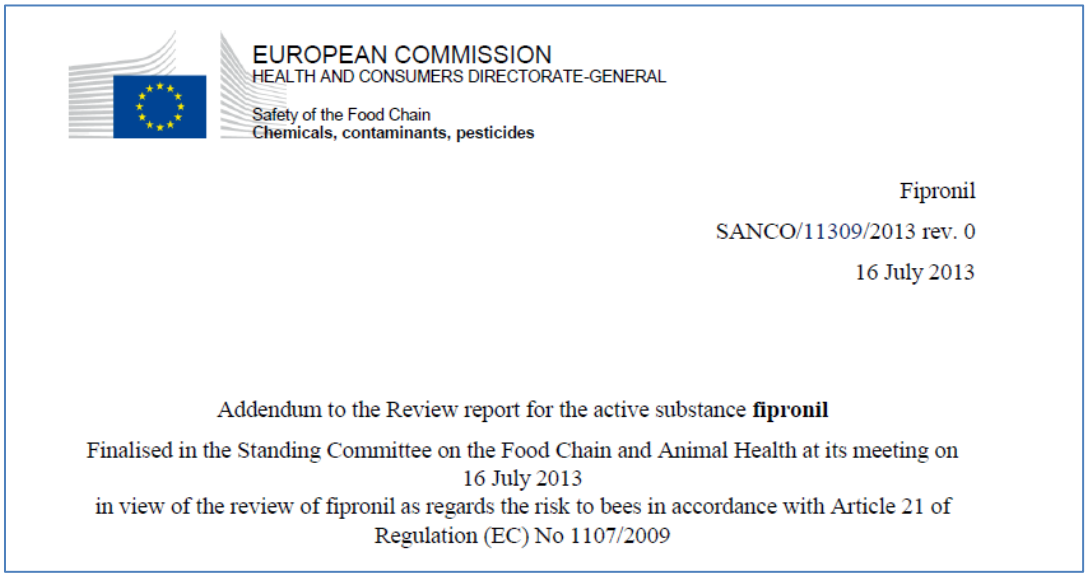
> Based on new information received from Italy concerning risks to honeybees caused by coated maize seeds treated with plant protection products containing fipronil, the Commission decided to review the approval of that active substance. The Commission, in accordance with Article 21(2) of Regulation (EC) No 1107/2009, asked the European Food Safety Authority, hereinafter 'the Authority', for scientific and technical assistance to assess this new information and to review the risk assessment of fipronil as regards its impact on bees.
>
> The Authority presented its conclusion on the risk assessment of fipronil as regards bees on 27 May 2013. The Authority identified for the use as seed treatment in maize, high acute risks for bees from plant protection products containing the active substance fipronil. The Authority identified, in particular, a high acute risk for bees resulting from dust. In addition, unacceptable risks due to acute or chronic effects on colony survival and development could not be excluded for several crops. Furthermore, the Authority identified some missing information for each of the evaluated uses, in particular as regards long term risk to honeybees from dust exposure, from potential exposure to residues in pollen and nectar, from potential exposure to guttation fluid and from exposure to residues in succeeding crops, weeds and soil.

Further information that could be of interest: Check the authorisation status in Member States:



Products containing fipronil have been withdrawn or not authorised in many Member States.

It is also possible to further find information in the review report:


EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Safety of the Food Chain
Chemicals, contaminants, pesticides

Fipronil
SANCO/11309/2013 rev. 0
16 July 2013

Addendum to the Review report for the active substance **fipronil**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 16 July 2013
in view of the review of fipronil as regards the risk to bees in accordance with Article 21 of Regulation (EC) No 1107/2009

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 fipronil.

With regard to the risk to bees, the following issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, amended or withdrawn, as appropriate.

Member States shall pay particular attention to:

– the seed coating shall only be performed in professional seed treatment facilities. Those facilities must apply the best available techniques in order to ensure that the release of dust during application to the seed, storage, and transport can be minimised;

– adequate seed drilling equipment shall be used to ensure a high degree of incorporation in soil, minimisation of spillage and minimisation of dust emission;

– the label of the treated seeds includes the indication that the seeds were treated with fipronil and sets out the risk mitigation measures provided for in the authorisation;
– monitoring programmes are initiated to verify the real exposure of bees to fipronil in areas extensively used by bees for foraging or by beekeepers, where and as appropriate.
Conditions of use shall include risk mitigation measures, where appropriate.

It is also possible to get more information about the risk assessment in the EFSA conclusion on the Peer review of the pesticide risk assessment for bees for the active substance fipronil, see below.