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EFSA in focus PLANTS

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> Key topics

Assessing the impact of pesticides on birds and mammals

EFSA has suggested a scientific approach for assessing the risks to birds and mammals of exposure to pesticides. It developed this approach by evaluating the impact of pesticides according to a large range of scenarios including different crops and different types of pesticide use.

This multi-step approach first begins by using fundamental, conservative data (e.g. from acute laboratory studies) in assessing the risk of mortality and the reproductive effects from a given pesticide. If the risk from this assessment is not acceptable according to EU legislation, then, data from more complex studies are assessed in the next step, to add more realism and to reduce uncertainty.

Under the EU system of peer-review, industry seeking authorisation to market pesticides must provide information to enable Member States to assess the direct impact of these pesticides on birds and mammals. Various guidance documents, which EFSA is responsible for revising, and proposing, exist to help Member States and industry fulfil these obligations.

"This important EFSA opinion will help industry and Member States safeguard birds and mammals from any potential negative effects of pesticides by contributing to the improved scientific assessments of their possible risks," said Prof Tony Hardy, Chair of the EFSA Panel for Plant Protection Products and their Residues (PPR) behind this work. *"But it is, of course, only one of the many aspects that EFSA and the PPR Panel is working on to provide advice and guidance to Europe's risk managers on the possible risks to users, the public and the environment from pesticides and their residues."*

The opinion is part of the overall revision of guidance documents which EFSA is working on, together with the European Commission and Member States. The opinion contains explanations on the range of options available for higher-tier risk assessments.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902014630.htm

> Join EFSA's Scientific Committee or Panels p2

Call to renew EFSA's Scientific Committee and Panel members now open: Membership has benefits

In terms of food safety, EFSA spans the entire food chain. EFSA brings together leading scientific experts from across Europe to provide the independent risk assessment advice that Europe's risk managers need to protect consumers, workers and the environment.

So, what drives national experts to join EFSA's Scientific Committee or Panels? *"There are many good reasons,"* says Henrik Wegener, Director of the Danish National Food Institute. *"Experts get exposed to topical problems first hand. They become exposed to much broader problems and to the risk assessments, and to some extent the solutions, than if they were at home. That means they become better equipped for those discussions that will also happen at home."*

According to Prof Wegener, by meeting a lot of high ranking experts and by sharing knowledge, experts become sharper, more efficient and faster in accessing up-to-date information. This helps them to quickly conduct risk assessments to give science-based advice to national authorities.

For example, *"Experts in Panels get very in-depth training in the principles and framework of risk assessments."* And according to him, it is EFSA's rigorous risk assessments system that consistently results in scientific advice of the highest standards, based on the latest information available.

Added value

For national institutes, given the rigourous selection procedure, Prof Wegener also believes becoming an EFSA Panel member lends prestige to the host institution as, of those who apply: *"Only the best experts get to join."* This also has added benefits in terms of starting or being invited to join new research projects. *"It's the same as having people in WHO/FAO expert committees."*

EFSA Panels explained

Currently, EFSA has a Scientific Committee and ten Scientific Panels covering all areas from field to plate. They range from plant health to plant protection and GMOs; from animal feed, animal health and welfare to biological hazards; from contaminants in the food chain to nutrition and healthy diets; from food additives and flavourings to materials in contact with food.

Recently, EFSA published a call to renew members of its Scientific Committee and eight of its Panels. The Authority seeks independent experts for a three-year term, renewable, to start in the summer of 2009. The call closes on 7 January 2009.

But what is the role of EFSA's Panels? Any time the European Commission, European Parliament or national risk managers asks for advice from EFSA, or when EFSA itself seeks answers to a question, it is allocated to the Scientific Committee or a relevant Panel. The Committee or Panel then forms a working group of independent experts to provide the advice. The exact nature of the question will determine who sits in the group. It consists of members who may be supported by external experts. The working group will then develop a draft opinion. The opinion will be based on the information gathered, the outcome of its scientific risk assessment work, plus any feedback from the consultations that EFSA may hold with stakeholders. It will then submit its draft opinion for adoption by the Scientific Committee or Panel.

And the motivation? In the words of Prof Tony Hardy, Chair of the EFSA Panel on Plant Protection Products and their Residues: *"I wouldn't do it if I didn't think it would make a difference."*

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_JoinEFSAScientificCommitteeorPanels.htm

New EFSA body to coordinate pesticide risk assessment

EFSA is setting up a new committee to further strengthen its role in reviewing the safety of active substances used in pesticides together with the European Commission and EU Member States.

"The committee will provide a platform for cooperation and consultation between the different actors involved in pesticide risk assessment in the EU," said Hubert Deluyker, Director of Scientific Cooperation and Assistance at EFSA. *"It will be responsible for planning and monitoring the safety review process from beginning to end – in other words, from the initial application for a certain active substance to be authorised through to the publication of a conclusion by EFSA on the safety of that substance."*

"The main aim is to further streamline the peer review process and clearly define priorities in the face of an ever-growing workload and a changing regulatory environment. In 2007, for example, EFSA published conclusions on 20 different active substances but in 2008 that figure is due to rise to 60 – in other words a three-fold increase year-on-year," he continued. *"At the same time, challenging new deadlines are being discussed which would put further pressure on the peer review system."*

The Pesticide Steering Committee, which will be fully operational from 1 January 2009, will be made up of experts responsible for the pesticide risk assessment process nationally as well as representatives of EFSA and the European Commission.

The committee will help to ensure the best possible use of resources, increase efficiency and further strengthen consumer protection. This will be achieved by facilitating the planning process, by helping to prevent duplication and by promoting the exchange of information between EFSA, the Commission and Member States at every stage.

A practical example of this will be the development of common IT tools enabling file sharing and online access to data across the EU.

The committee is just one of the many elements in EFSA's increasingly important role in the field of pesticides (See p3).

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902093448.htm

> EFSA at work

Pesticide peer review, EFSA and the Member States

With around 900 active substances used in plant protection products in the various Member States, but not necessarily authorised for use in all countries, Europe needed a harmonised approach to safeguard consumers, workers and the environment while providing consistency for industry. To ensure this, Europe's pesticide peer review programme was created.

Since 2003 EFSA has worked closely with Member States to scientifically assess the risks within the European Commission's Europe-wide peer review programme of active substances used in plant protection products. The Commission then uses these assessments when deciding whether to place active substances on the positive EU list or not.

Active substances in plant protection products are the chemicals or micro-organisms that enable the product to do its job. Herbicides destroy unwanted plants while insecticides protect the plant against insects which harm plants or reduce crop yields.

Peer review in practice

At EFSA a dedicated unit, the Pesticide Risk Assessment and Peer Review Unit (PRAPeR), has overall responsibility for managing the peer review process. But it first begins with Member States.

Under EU law active substances cannot be used in plant protection products unless they are on the EU list of approved substances. Before a substance can be placed on this list, industry has to prove that it can be used safely regarding human health, the environment and residues in the food chain. The applicant submits an extensive dossier to the agency in Member States responsible for pesticide risk assessments. A Member State then writes a draft assessment report.

Once complete, it is sent to experts at EFSA and other Member States - the 'peers'- for comment. The industry applicant and experts at the Member State that drafted the report can respond to the comments. The comments and draft report are made publicly available for consultation.

EFSA and Member States then discuss the feedback before EFSA drafts the conclusion which is then submitted to the Member State for comment. EFSA then finalises the conclusion which is sent to the Commission and made publicly available online. It is up to the Commission to decide whether to include the active substance in the positive list or not. All told, the process takes at least three years.

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Today and tomorrow

In 2007, EFSA published conclusions on 20 different active substances. In 2008 that figure is expected to rise to 60. To help manage this increased workload, from 1 January 2009, a new Pesticide Steering Committee will begin work. Made up of national pesticide risk assessment experts as well as EFSA and European Commission representatives, it will help ensure the best possible use of resources, increase efficiency and further strengthen consumer protection.

By the end of 2009, the peer review programme, which began in 1993, will have reviewed all active substances that were on the EU market in 1993. Until then, some substances awaiting the decision to be on the EU list or not, may still be authorised for use in the EU nationally. Existing substances that were not on the list may no longer be used in the EU. New active substances, outside of the existing programme, are peer reviewed in the same way as existing active substances.

On issues that cannot be resolved by peer review, or when further scientific guidance is needed EFSA's Panel on Plant Protection Products and their Residues (PPR) steps in. Such topics include toxicology, the fate and behaviour of

pesticides or the risks to bird and mammals. Alongside the PRAPeR unit, the PPR Panel helps ensure plant protection products in Europe provide the right level of protection to plants without harming humans or the environment.

http://www.efsa.europa.eu/EFSA/ScientificPanels/efsa_locale-1178620753812_PRAPER.htm

Guiding Europe's pesticide risk managers

The Pesticides Directive is the regulatory framework under which plant protection products in all European Union (EU) countries are governed. For Europe's pesticide risk managers it is their principal point of reference. But for risk managers to make informed decisions they need sound scientific advice. This is where EFSA steps in.

"EFSA is an independent risk assessment organisation separate from the risk managers," explains Prof Tony Hardy, Chair of the EFSA Panel responsible for plant protection products and their residues (PPR Panel). *"Therefore EFSA evaluates the risks and provides advice to risk managers in the European Commission and Member States.*

"[EFSA] is the risk assessor not the risk manager," he adds. *"It does not take regulatory decisions. It is not part of the decision process; that belongs to the risk managers."*

The Commission and the European Parliament are the risk managers at European level. Nationally, Member States have pesticide authorities that act as the risk managers. For example, in the UK, it is the Pesticides Safety Directorate. These national competent authorities work closely with the Commission, drawing on EFSA's guidance and advice.

As risk managers, the Commission, European Parliament and Member States can all ask EFSA for advice. And to deliver the best advice, EFSA first engages in dialogue with these risk managers to better understand the context, what is being asked and what is required before providing targeted, independent expert advice.

EFSA itself can also seek answers to questions of its own. For example, within EFSA the Pesticide Risk Assessment and Peer Review Unit, (PRAPeR), which is responsible for assessing the safety of active substances in plant protection products (see p3), may ask the PPR Panel's advice on particular active substances, for example cyprodinil, or on generic issues of pesticide use as in the case of its opinion on lowering the uncertainty factor for assessing risks to aquatic organisms.

The Panel may consult Member States and industry, in particular during the development of guidance documents. Often this is through online consultations where anyone can comment but it may also involve direct consultation through workshops where the Panel presents and explains its advice or guidance. Stakeholders ranging from industry to NGOs, from Member State representatives to Commission officials, for example, are invited to attend.

Advising and guiding

The Panel has helped to revise the annexes of the EU's Pesticides Directive (formally Directive 91/414/EEC) by reviewing the data requirements for assessment. The Panel then published scientific advice on six sets of data requirements ranging from physical and chemical properties to toxicological properties. These are being used by European Commission and Member States to revise the annexes.

According to Prof Hardy, over the years, the Panel's role and work has changed. In 2006 the Commission decided to transfer the responsibility for updating existing and elaborating new guidance documents to EFSA. As a result, direct questions about particular issues are less frequent while generic guidance questions are growing.

This has led the Panel to consult Member States about which of the existing guidance documents should be revised in order of priority and where they felt there were gaps. This has helped

shape the Panel's work programme for the coming years. All told there are more than 25 guidance documents on pesticides and some important gaps have been identified such as guidance on the exposure of operators to pesticides. Currently, the Panel is working on nine different guidance documents.

A landmark piece of work

For Prof Hardy, a recent landmark has been the Panel opinion on the science behind the guidance document on assessing the risks to birds and mammals of pesticides. (see p1) *"It was an enormous piece of work, completed in just fours days short of two years. It involved lots of consultation of Member States as regulators and risk managers. It also included a way to relate to industry as users of the guidance and, obviously, the European Commission as risk managers."*

"It is a major piece of soundly-based scientific work but it recognises that EFSA is not in a position to take risk management decisions that are required for a guidance document," he continues. The next stage is getting the advice from risk managers to create the final guidance document. To do this a small group, consisting of European Commission, technical experts from the PPR Panel and Member State representatives, will look at the opinion and take risk management decisions based on different options explained in the opinion. These will eventually lead to the fully revised guidance document, by mid to late 2009.

As for the future, the PPR Panel will need to keep the guidance documents up to date. *"Science moves forward all the time,"* explains Prof Hardy. Developments in science, and analytical and modelling techniques need to be taken into account so they can be built into the guidance documents that Member States and industry use. *"It's a balancing act. The guidance can't stand still nor change all the time. There is a periodic need to bring them up to date,"* he adds.

All told, says Prof Hardy: *"EFSA adds a sound independent rigour to the evaluation and risk assessment of plant protection products."* That's EFSA's added value. And in the context of the renewal of EFSA's Panel Members, Prof Hardy is confident that the *"Spirit of excellence will continue and will continue to make a positive contribution to the regulatory process."*

Based on an interview with Prof Tony Hardy, Chair of EFSA's PPR Panel.

http://www.efsa.europa.eu/EFSA/ScientificPanels/efsa_locale-1178620753812_PPR.htm

> Meeting reports

Environmental and consumer groups meet EFSA to discuss GMOs

8 July 2008, Parma - *Parma, Italy*

Following the meeting held in February 2006, representatives from non-governmental organisations (NGOs) active in genetically modified organisms (GMOs) and consumer groups came to EFSA on 8 July 2008 to further learn and to discuss about EFSA's work on GMOs.

In a constructive atmosphere, the discussions evolved around the various procedural and scientific aspects of GMO risk assessments. The following issues were discussed:

- the transparency of EFSA's scientific working processes;
- EFSA initiatives on cooperation with Member States during the risk assessment process (including environmental risk assessments);
- actions taken by EFSA on the independence of its scientific experts;
- the incorporation of the latest scientific advances in guidance to applicants;
- the availability and robustness of scientific data and the involvement of stakeholders.

Specific points were raised about how scientific uncertainties are reported in the EFSA opinions and on the determination of the potential long-term impact on human health and the environment as being part of the risk assessment.
In addition, participants also asked for further information on the update to EFSA's environmental risk assessment guidance for applicants. Amongst others, the current guidance includes sections on the assessment to be carried out on non-target organisms (mainly insects that are not the target of the insect-resistance GM plants, but also other organisms which could be unintentionally affected by a genetic modification), the statistical and biological criteria used in its risk assessment, and the set-up for field trials. These sections will be further detailed. Also discussed was public access to documents and the composition of the broad pool of ad hoc experts the GMO panel is associated with.

At the end of the meeting, all participants agreed to continue the dialogue and to meet again in 2009. Meanwhile, dialogue and consultations with the scientific community and with stakeholders will continue.

The meeting, chaired by EFSA's Executive Director, Catherine Geslain-Lanéelle, took place with Greenpeace, Friends of the Earth and BEUC (the European Consumers' Organisation).

http://www.efsa.europa.eu/EFSA/efsa_locale1178620753812_1178718079693.html

> Events

Workshop on pesticide persistence in soils

12-14 May 2009 - *Ispra, Italy*

EFSA will run a workshop on pesticide persistence in soil on 12-14 May 2009 in Ispra, Italy.

The European Commission's Joint Research Centre (JRC) will host the event at their premises in Ispra. The main objective will be to present the EFSA's draft of the revised guidance document on persistence of pesticides in soil to EFSA's stakeholders (Member States, industry representatives, consulting companies and others) to collect their feedback during the revision process. In particular, issues linking environmental exposure to assessments of the ecotoxicological effects in soil will be considered. This will also be of great relevance for EFSA's upcoming revision of the Guidance Document on Terrestrial Ecotoxicology. Around 50-60 stakeholders are expected to attend.

http://www.efsa.europa.eu/EFSA/ScientificPanels/efsa_locale-1178620753812_PPR.htm

> Calls

Article 36 calls for proposals

Article 36 of EFSA's Founding Regulation allows the Authority to financially support projects and activities that contribute to EFSA's mission. This financial support is exclusively given to a list of competent organisations capable of assisting EFSA in its work. The list was drawn up on the basis of nominations made by Member States in an EFSA Management Board decision.

Some of the calls below may have closed. The intention is to provide an idea of the type of support EFSA seeks.
For the most recent list of Article 36 calls, please visit:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_call_for_proposals.htm

Call for a systematic review of pest risk models using climatic data and plant phenology

With the growth in global trade and the effect of climate change, the risk of harmful plant pests increases. As such there is a growing need for more detailed pest risk assessments. The process of conducting a pest risk assessment includes the choice and application of plant epidemiological models that take also climate data and plant phenology into consideration. These models are used to predict the risk of establishment, spread or development of plant pests. But there are considerable differences in the methods and terminology used, and new modelling approaches are continually being developed. In recognition of this, EFSA launched a call for a systematic review of existing pest risk models to establish an inventory with a harmonised and transparent structure to be able to evaluate and compare the models before they will be used in a specific application.

EFSA sought proposals to establish an electronic inventory of quantitative models describing the spread, establishment or development of plant pests on crops in Europe. In submitting proposals, applicants were required to focus on model structure, the parameters used and data sets. As first step the project should restrict the search to the most applicable models for actual predictive measurements. This means to models including climatic data and / or plant phenology as input factors, but in the future EFSA will update and enlarge the inventory continuously.

The call closed on 10 October 2008.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902037425.htm

European bee mortality and bee surveillance

Since 2003 there have been reports in Europe and America of serious losses of bees from beehives. This phenomenon has been called Colony Collapse Disorder (CCD). CCD is characterised by the rapid loss from a colony of its adult bee population.

In order to assess the current situation with regard to bee surveillance programmes in Europe a short questionnaire was distributed to Member States through the EFSA Focal Point network. The questionnaire requested information on monitoring of chemical residues in honey, surveillance programmes monitoring collapse, weakening and mortality in bees and data on honey production and bee populations. The information from the questionnaires was collated in the report Bee Mortality and Bee Surveillance in Europe, published in August 2008.

To follow on from the survey and expand on the findings EFSA launched a call for proposals for an EU-wide collective study in the area of CCD. This requires an EU-wide review of literature on the topic, a description of active surveillance programmes and a collation of historical epidemiological data to facilitate an objective assessment of all possible causes of CCD. The resulting work from the study will prepare the grounds and orientate research towards identified gaps in scientific knowledge.

The call closed on 10 October 2008.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902044762.htm

Call to develop a harmonised approach to characterising risk in pest risk assessments

The methodologies used to conduct pest risk assessment vary and there is a recognised need to introduce harmonisation to ensure consistency in this field. In addition, a more generic approach is needed for characterising and assessing pest risks, to respond more effectively to the threats arising from increased globalisation of trade and climate change. These were two of the key recommendations that emerged from EFSA's Scientific Colloquium on 'Pest Risk Assessment: Science in support of phytosanitary decision-making in the European Community' in December 2007. This led EFSA to launch a call to develop a harmonised approach to characterising the risks in pest risk assessments.

The aim of this call was to further develop the scientific basis for risk characterisation of organisms considered to be possibly harmful. It involves the systematic review and development of the methodologies used for pest risk assessments as well as the analysis of direct and indirect consequences of plant pest introductions.

The call closed on 20 October 2008.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902083521.htm

Calls awarded

CFP/EFSA/PLH/2007/01

Inventory of data sources for phytosanitary pest risk assessment in the European Community

Universita' Cattolica del Sacro Cuore

CFP/EFSA/PRAPeR/2008/01

Collection of Codex Maximum Residue Limits and related information for active substances to be evaluated under Article 12(2) of Regulation (EC) No 396/2005

The Pesticides Safety Directorate, British Government Agency

For all calls awarded see: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_call_for_proposals.htm

Public consultation on new guidance about emissions of pesticides from protected crop systems

EFSA has launched an open consultation on its plan to create an inventory for protected crop systems (e.g. greenhouses and cultivations grown under cover) and to provide a new guidance document for estimating the importance of emission routes and the emissions of plant protection products from protected crop systems.

At present, there is no definition that separates emissions from plant protection products applied to protected crop systems as opposed to field applications. Neither is there agreement on the definitions of individual protected/covered crop systems like a specific type of greenhouse. Nevertheless, several active ingredients have been listed in EU pesticide legislation (Directive 91/414/EEC) with reference to their use in greenhouses.

Therefore the guidance document that will be provided following this consultation will fill a gap in the environmental risk assessment scheme and allow a future working group to develop emission and exposure scenarios for protected crop systems.

The consultation closes on 15 December 2008.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902135564.htm

Public consultation on the existing guidance documents for aquatic and terrestrial ecotoxicology

EFSA has launched an open consultation on the existing guidance documents for aquatic ecotoxicology and for terrestrial ecotoxicology under existing EU pesticide legislation. These documents provide guidance to notifiers and Member States on how to conduct assessments of aquatic and terrestrial ecotoxicology in the context of the review of active substances for inclusion in the current EU pesticide legislation.

The consultation closes on 15 December 2008.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902135509.htm

Public consultation on EFSA's updated guidance document for assessing the risks of GM plants, and the derived food and feed

In 2008 EFSA held a public consultation on its updated guidance document for the risk assessment of genetically modified (GM) plants, and the derived food and feed. The previous guidance document was originally adopted in 2004 and updated already in 2006. Now it has been further updated, following several years of experience in assessing the risks of GMO applications and the outcome of EFSA's own self-tasking activities.

The updated guidance document will be used by the European Commission and Member States to establish legally binding detailed guidelines for the European Union.

As part of that process, the outcome of this public consultation will be sent to the Commission and to Member States.

EFSA will publish an evaluation report on the comments received and be consulted prior to the adoption of the legal framework.

The consultation closed on 21 September 2008.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902010430.htm

Public consultation on the draft statistical considerations for the safety evaluation of GMOs

Recently EFSA concluded its public consultation on its proposed statistical guidelines for analysing compositional data from trials of genetically modified organisms (GMO).

The current EFSA guidance document for the risk assessment of GM plants describes the principles, but does not specify strict rules for the design of experiments or the analysis of results. As a result, in 2006, EFSA began a self-task activity to investigate whether more detailed guidance could be provided regarding the use of appropriate statistical models for analysing data from field trials, and of data field trials for compositional studies and animal feeding trials, and their design. These guidelines are the result.

The consultation closed on 21 September 2008.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902010687.htm

Public consultation on the risk assessment of GM plants used for non-food or non-feed purposes

EFSA launched a public consultation on its draft opinion on the risk assessment of genetically modified (GM) plants used for non-food or non-feed purposes which are becoming increasingly common.

Previous guidelines focused on the risk assessment of GM plants intended for food and feed.

EFSA is responsible for carrying out the scientific risk assessment of GMO applications submitted for EU market authorisation to the European Commission. In September 2004, EFSA published guidance for the preparation and presentation of GMO applications submitted. This was updated in 2006 and is being updated again in 2008. However, this is a generic guidance document covering GM plants, and derived food and feed. More and more genetically modified (GM) plants are being developed to manufacture non-food or non-feed products such as medicinal or industrial products, vaccines and antibodies, diagnostic products, as well as industrial enzymes and raw materials for the production of biopolymers, biofuels, paper and starch.

This opinion that was under consultation covered plants developed for non-food or non-feed purposes. The data requirements and risk assessment criteria for those plants were evaluated and further elaborated where needed.

The consultation closed on 21 September 2008.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178716609288.htm

> Latest mandates received

Mandates accepted Jun-Oct 2008

Information on all other on-going requests is available in EFSA's register of questions:
http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf?nocache=1226997647104

Genetically Modified Organisms (GMO)

New information submitted by Austria in the context of a safeguard measure adopted under Article 23 of Directive 2001/18/EC on oilseed rape lines Ms8, Rf3 and Ms8xRf3

Requestor: **European Commission**
Reception Date: **01 Aug 2008**
Deadline: **31 Mar 2009**
Question Number: **EFSA-Q-2008-743**

Information submitted by Austria in support of a safeguard measure adopted under Article 23 of Directive 2001/18/EC on maize lines MON863

Requestor: **European Commission**
Reception Date: **03 Sep 2008**
Deadline: **31 Mar 2009**
Question Number: **EFSA-Q-2008-742**

Request to review recent scientific studies relating to the impact on the environment of the cultivation of two genetically modified maize plants: 1507 and Bt11

Requestor: **European Commission**
Reception Date: **28 Jul 2008**
Deadline: **15 Dec 2008**
Question Number: **EFSA-Q-2008-679**

Application for authorisation of genetically modified maize event GA21 and derived food and feed for import use including cultivation (EFSA-GMO-UK-2008-60)

Requestor: **United Kingdom**
Reception Date: **16 Jul 2008**
Deadline: **22 Apr 2009**
Question Number: **EFSA-Q-2008-481**

Application for authorisation of genetically modified PL73 *Escherichia coli* (LM) for feed use (dried killed bacterial biomass) (EFSA-GMO-FR-2008-61)

Requestor: **France**
Reception Date: **07 Aug 2008**
Deadline: **02 Apr 2009**
Question Number: **EFSA-Q-2008-669**

RONOZYME ProAct (serine protease) for chickens for fattening

Requestor: **European Commission**
Reception Date: **04 Jul 2008**
Deadline: **27 Apr 2009**
Question Number: **EFSA-Q-2008-431**

Application for authorisation of genetically modified PT73 *Escherichia coli* (TM) for feed use (dried killed bacterial biomass) (EFSA-GMO-FR-2008-59)

Requestor: **France**
Reception Date: **05 Jun 2008**
Deadline: **23 Jan 2009**
Question Number: **EFSA-Q-2008-412**

Plant Heath (PLH)

Plant health risk of *Thaumetopoea processionea* L., the oak processionary moth, for the EU territory

Requestor: **European Commission**
Reception Date: **20 Oct 2008**
Deadline: **20 Apr 2009**
Question Number: **EFSA-Q-2008-709**

Guidance document on a harmonised framework for the assessment of risks of organisms harmful to plants and plant products

Requestor: **EFSA**
Reception Date: **22 Sep 2008**
Deadline: **31 May 2009**
Question Number: **EFSA-Q-2008-690**

Pesticide Risk Assessment and Peer Review (PRAPeR)

Chlormequat (Chloride)

Application to modify the existing MRL for chlormequat in pears from 0.2 mg/kg to 0.1 mg/kg. From 31July 2009 the LOQ of 0.05* mg/kg should apply; Request for the lowering of current tMRL of 0.2 mg to of 0.1mg/lkg and extension of this tMRL until 31 July 2014

Requestor: **European Commission**
Reception Date: **07 Oct 2008**
Deadline: **07 Jan 2009**
Question Number: **EFSA-Q-2008-741**

Tetraconazole

Application to modify the existing MRL for tetraconazole in apricots from 0.02* mg/kg to 0.1 mg/kg

Requestor: **European Commission**
Reception Date: **06 Oct 2008**
Deadline: **06 Jan 2009**
Question Number: **EFSA-Q-2008-740**

Isoxaflutole

Application to modify the residue definition for MRL setting from isoxaflutole to the sum of isoxaflutole and RPA 202248, expressed as isoxaflutole

Requestor: **European Commission**
Reception Date: **26 Sep 2008**
Deadline: **26 Mar 2009**
Question Number: **EFSA-Q-2008-739**

Trifloxystrobin

Application to modify the existing MRL for trifloxystrobin in passion fruit from 0.02* mg/kg to 5 mg/kg

Requestor: **European Commission**
Reception Date: **26 Sep 2008**
Deadline: **26 Dec 2008**
Question Number: **EFSA-Q-2008-738**

Pymetrozine

Application to modify the existing MRL for pymetrozine in chinese cabbage from 0.2 mg/kg to 1 mg/kg

Requestor: **European Commission**
Reception Date: **26 Sep 2008**
Deadline: **26 Dec 2008**
Question Number: **EFSA-Q-2008-737**

Prothioconazole

Application to modify the existing MRL for prothioconazole-desthio in head cabbage from 0.02* mg/kg to 0.05 mg/kg

Requestor: **European Commission**
Reception Date: **26 Sep 2008**
Deadline: **26 Dec 2008**
Question Number: **EFSA-Q-2008-736**

Pencycuron

Application to modify the existing MRL for pencycuron in potatoes from 0.1 mg/kg to 0.2 mg/kg

Requestor: **European Commission**
Reception Date: **26 Sep 2008**
Deadline: **26 Dec 2008**
Question Number: **EFSA-Q-2008-735**

Mandipropamid

Application to modify the existing MRL for mandipropamid in red mustard from 0.01* mg/kg to 10 mg/kg and in leaves and sprouts of brassica spp from 0.01* mg/kg to 10 mg/kg

Requestor: **European Commission**
Reception Date: **26 Sep 2008**
Deadline: **26 Dec 2008**
Question Number: **EFSA-Q-2008-734**

Latest mandates received

Mancozeb

Application to modify the existing MRL for dithiocarbamates(dithiocarbamates expressed as cs2, incl.maneb, mancozeb, metiram, propineb, thiram and ziram) in garlic from 0.1 mg/kg to 0.5 mg/kg

Requestor: **European Commission**
Reception Date: **26 Sep 2008**
Deadline: **26 Dec 2008**
Question Number: **EFSA-Q-2008-733**

Lambda-Cyhalothrin

Application to modify the existing MRLs for lambda cyhalothrin in currants (red, black and white) from 0.1 mg/kg to 0.2 mg/kg, in gooseberries from 0.1 mg/kg to 0.2 mg/kg, in blueberries from 0.02* mg/kg to 0.2 mg/kg and in cranberries from 0.02* mg/kg to 0.2 mg/kg

Requestor: **European Commission**
Reception Date: **26 Sep 2008**
Deadline: **26 Dec 2008**
Question Number: **EFSA-Q-2008-732**

Indoxacarb

Application to modify the existing MRL for indoxacarb (sum of r and s isomers) in brussels sprouts from 0.02* mg/kg to 0.1 mg/kg

Requestor: **European Commission**
Reception Date: **26 Sep 2008**
Deadline: **26 Dec 2008**
Question Number: **EFSA-Q-2008-731**

Fluroxypyr

Application to modify the existing MRL for fluroxypyr (fluroxypyr incl.its esters expressed as fluroxypyr) in leek from 0.05* mg/kg to 0.2 mg/kg

Requestor: **European Commission**
Reception Date: **26 Sep 2008**
Deadline: **26 Dec 2008**
Question Number: **EFSA-Q-2008-730**

Fluoxastrobin

Application to modify the existing MRL for fluoxastrobin in potatoes from 0.05* mg/kg to 0.1 mg/kg

Requestor: **European Commission**
Reception Date: **26 Sep 2008**
Deadline: **26 Dec 2008**
Question Number: **EFSA-Q-2008-729**

Cyflufenamid

Application to modify the existing MRL for cyflufenamid in oats grain from 0.02* mg/kg to 0.1 mg/kg

Requestor: **European Commission**
Reception Date: **26 Sep 2008**
Deadline: **26 Dec 2008**
Question Number: **EFSA-Q-2008-728**

Azoxystrobin

Application to modify the existing MRL for azoxystrobin in passion fruit from 0.05* mg/kg to 5 mg/kg

Requestor: **European Commission**
Reception Date: **26 Sep 2008**
Deadline: **26 Dec 2008**
Question Number: **EFSA-Q-2008-727**

Aminopyralid

Application to modify the existing MRL for aminopyralid in bovine kidney from 0.01* mg/kg to 0.3 mg/kg

Requestor: **European Commission**
Reception Date: **26 Sep 2008**
Deadline: **26 Dec 2008**
Question Number: **EFSA-Q-2008-726**

Potassium Tri-Iodide

Application to include the active substance in Annex IV to Regulation (EC) No 396/2005

Requestor: **European Commission**
Reception Date: **26 Sep 2008**
Deadline: **26 Dec 2008**
Question Number: **EFSA-Q-2008-724**

Thiram

Application to set new MRLs for parent compound only (for cases of concern) in bananas at 0.2 mg/kg and for total cs2-residue (for screening) in bananas at 0.5 mg/kg

Requestor: **European Commission**
Reception Date: **21 Sep 2008**
Deadline: **21 Dec 2008**
Question Number: **EFSA-Q-2008-723**

Teflubenzuron

Application to modify the existing MRL for teflubenzuron in peppers from 0.5 mg/kg to 1 mg/kg

Requestor: **European Commission**
Reception Date: **17 Sep 2008**
Deadline: **17 Dec 2008**
Question Number: **EFSA-Q-2008-722**

Spirotetramat

Application to set new MRLs for spirotetramat and the metabolites byi 08330-enol, byi 08330-ketohydroxy, byi08330-enol-glc, and byi 08330-mono-hydroxy in lemons at 1 mg/kg, in oranges at 1 mg/kg, in mandarins at 1 mg/kg, in grapefruit at 1 mg/kg, in almonds at 0.5 mg/kg, in walnuts at 0.5 mg/kg, in hazelnuts at 0.5 mg/kg, in pecans at 0.5 mg/kg, in apples at 1 mg/kg, in pears at 1 mg/kg, in cherries at 5 mg/kg, in apricots at 2 mg/kg, in peaches at 2 mg/kg, in plums at 2 mg/kg, in table grapes at 2 mg/kg and in wine grapes at 2 mg/kg.

Requestor: **European Commission**
Reception Date: **02 Sep 2008**
Deadline: **02 Dec 2008**
Question Number: **EFSA-Q-2008-720**

Emamectin Benzoate

Application to set new MRLs for emamectin b1a benzoate(expressed as emamectin, free base) in apples at 0.02 mg/kg, in pears at 0.02 mg/kg, in quinces at 0.02 mg/kg, in medlar at 0.02 mg/kg, in loquat at 0.02 mg/kg, in peaches at 0.02 mg/kg, in wine grapes at 0.02 mg/kg, in table grapes at 0.05 mg/kg, in strawberries at 0.05 mg/kg, in tomatoes at 0.01* mg/kg, in aubergines (egg plants) at 0.01* mg/kg, in peppers at 0.02 mg/kg, in melons at 0.01* mg/kg, in pumpkins at 0.01* mg/kg, in watermelons at 0.01* mg/kg, in cucumbers at 0.01* mg/kg, in gherkins at 0.01* mg/kg, in courgettes at 0.01* mg/kg, in cauliflower at 0.01* mg/kg, in broccoli at 0.01* mg/kg, in head cabbage at 0.01* mg/kg, in lettuce at 0.2 mg/kg, in beans (fresh, with pods) at 0.01* mg/kg, in peas (fresh, with pods) at 0.01* mg/kg and in globe artichokes at 0.01* mg/kg.

Requestor: **European Commission**
Reception Date: **02 Sep 2008**
Deadline: **02 Mar 2009**
Question Number: **EFSA-Q-2008-719**

Azoxystrobin

Application to modify the existing MRL for azoxystrobin in turnips from 0.05* mg/kg to 0.2 mg/kg.

Requestor: **European Commission**
Reception Date: **02 Sep 2008**
Deadline: **02 Dec 2008**
Question Number: **EFSA-Q-2008-718**

Fludioxonyl

Application to set a new MRL for fludioxonyl in pomegranate at 3 mg/kg.

Requestor: **European Commission**
Reception Date: **02 Sep 2008**
Deadline: **02 Dec 2008**
Question Number: **EFSA-Q-2008-716**

Clomazone

Application to modify the existing MRL for clomazone in rice grain from 0.01* mg/kg to 0.02* mg/kg.

Requestor: **European Commission**
Reception Date: **02 Sep 2008**
Deadline: **02 Dec 2008**
Question Number: **EFSA-Q-2008-715**

2007 Annual Report on Pesticide Residues according to Article 32 of Regulation (EC)No. 396/2005

Requestor: **EFSA**
Reception Date: **07 Oct 2008**
Deadline: **28 Feb 2009**
Question Number: **EFSA-Q-2008-714**

Omethoate - Request of a scientific opinion on certain MRLs of concern

Requestor: **European Commission**
Reception Date: **04 Jul 2008**
Deadline: **15 Sep 2008**
Question Number: **EFSA-Q-2008-622**

Dimethoate - Request of a scientific opinion on certain MRLs of concern

Requestor: **European Commission**
Reception Date: **04 Jul 2008**
Deadline: **15 Sep 2008**
Question Number: **EFSA-Q-2008-616**

Review of all existing MRLs

Requestor: **EFSA**
Reception Date: **08 Jul 2008**
Deadline: **01 Sep 2009**
Question Numbers:

Zoxamide : **EFSA-Q-2008-649**
Ziram: **EFSA-Q-2008-648**
Warfarin (aka coumaphene): **EFSA-Q-2008-647**
Triticonazole: **EFSA-Q-2008-646**
Trinexapac (aka cimetacarb ethyl): **EFSA-Q-2008-645**
Trifloxystrobin: **EFSA-Q-2008-644**
Triclopyr: **EFSA-Q-2008-643**
Tribenuron (aka metometuron): **EFSA-Q-2008-642**
Triasulfuron: **EFSA-Q-2008-641**
Tolylfluanid: **EFSA-Q-2008-640**
Tolclofos-methyl: **EFSA-Q-2008-639**
Thiram: **EFSA-Q-2008-638**
Thiophanate-methyl: **EFSA-Q-2008-637**
Thifensulfuron-methyl (aka thiameturon): **EFSA-Q-2008-636**
Thiamethoxam: **EFSA-Q-2008-635**
Thiacloprid: **EFSA-Q-2008-634**
Thiabendazole: **EFSA-Q-2008-633**
Tepraloxydim: **EFSA-Q-2008-632**
Sulfosulfuron: **EFSA-Q-2008-631**
Spodoptera exigua nuclear polyhedrosis virus: **EFSA-Q-2008-630**
Spiroxamine: **EFSA-Q-2008-629**
Spinosad: **EFSA-Q-2008-628**
S-Metholachlor: **EFSA-Q-2008-627**
Silthiofam: **EFSA-Q-2008-626**
Rimsulfuron (aka renriduron): **EFSA-Q-2008-625**
Quinoxyfen: **EFSA-Q-2008-624**
Pyrimethanil: **EFSA-Q-2008-623**
Pyridate: **EFSA-Q-2008-622**
Pyraflufen-ethyl: **EFSA-Q-2008-621**
Pyraclostrobin: **EFSA-Q-2008-620**
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Propiconazole: **EFSA-Q-2008-612**
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Pirimicarb: **EFSA-Q-2008-608**
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Picolinafen: **EFSA-Q-2008-606**
Phosmet: **EFSA-Q-2008-605**
Phenmedipham: **EFSA-Q-2008-604**
Pethoxamide: **EFSA-Q-2008-603**

Pendimethalin:	**EFSA-Q-2008-602**
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Paecilomyces lilacinus:	**EFSA-Q-2008-600**
Paecilomyces fumosoroseus:	**EFSA-Q-2008-599**
Oxasulfuron:	**EFSA-Q-2008-598**
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Oxadiargyl:	**EFSA-Q-2008-596**
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Metsulfuron:	**EFSA-Q-2008-593**
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Metalaxyl-M:	**EFSA-Q-2008-586**
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Mepanipyrim:	**EFSA-Q-2008-583**
Mecoprop-P:	**EFSA-Q-2008-582**
Mecoprop:	**EFSA-Q-2008-581**
MCPB:	**EFSA-Q-2008-580**
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lambda-Cyhalothrin:	**EFSA-Q-2008-573**
Kresoxim-methyl:	**EFSA-Q-2008-572**
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Glufosinate:	**EFSA-Q-2008-560**
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Forchlorfenuron:	**EFSA-Q-2008-555**
Foramsulfuron:	**EFSA-Q-2008-554**
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Fenhexamid:	**EFSA-Q-2008-541**

Fenamiphos (aka phenamiphos):	**EFSA-Q-2008-540**
Fenamidone:	**EFSA-Q-2008-539**
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Dinocap:	**EFSA-Q-2008-530**
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Cyazofamid:	**EFSA-Q-2008-516**
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Clothianidin:	**EFSA-Q-2008-514**
Clopyralid:	**EFSA-Q-2008-513**
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Acetamiprid:	**EFSA-Q-2008-485**
2,4-DB:	**EFSA-Q-2008-484**
2,4-D:	**EFSA-Q-2008-483**
1-Methyl-cyclopropene:	**EFSA-Q-2008-482**

Methomyl

Request to conduct a peer review of the pesticide risk assessment presented in the additional report prepared by the Rapporteur Member State following a re-submission application under Commission Regulation (EC) No. 33/2008.

Requestor:	**European Commission**
Reception date:	**22 Sep 2008**
Deadline:	**22 Dec 2008**
Question No:	**EFSA-Q-2008-696**

List of adopted opinions and other documents per unit: June-October 2008

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http://www.efsa.europa.eu/EFSA/ScientificOpinionPublicationReport/efsa_locale-1178620753812_ScientificOpinions.htm

Genetically Modified Organisms (GMO)

Request to review recent scientific studies relating to the impact on the environment of the cultivation of two genetically modified maize plants: 1507 and Bt11

Question number: **EFSA-Q-2008-679**
Adopted on: **29 Oct 2009**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902156411.htm

Safeguard clause invoked by France under Article 23 of Directive 2001/18/EC on MON810 maize. Emerging measures invoked by France under Article 34 of Regulation (EC) No. 1829/2003 on MON810 maize

Question number: **EFSA-Q-2008-077**
Adopted on: **29 Oct 2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902156394.htm

Safeguard clause invoked by Greece under Article 23 of Directive 2001/18/EC on MON810 maize

Question number: **EFSA-Q-2008-313**
Adopted on: **03 Jul 2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902001981.htm

Statement on the need for a 90 day rodent feeding study with genetically modified rice LLRICE62

Question number: **EFSA-Q-2008-342**
Adopted on: **02 Jul 2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902011178.htm

Safeguard clause invoked by Hungary under Article 23 of Directive 2001/18/EC on MON810 maize

Question number: **EFSA-Q-2008-316**
Adopted on: **02 Jul 2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902002009.htm

Application for authorisation of genetically modified MON89788 soybean and derived food and feed (EFSA-GMO-NL-2006-36)

Question number: **EFSA-Q-2006-182**
Adopted on: **02 Jul 2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902000903.htm

Econase XT L and Econase XT P (endo-1,4-beta-xylanase) for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding and piglets (weaned)

Question number: **EFSA-Q-2007-120**
Adopted on **21 May 2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178716685437.htm

Plant Protection Products (PPR)

Risk assessment for birds and mammals - revision of guidance document under Council Directive 91/414/EEC - Scientific Opinion on the science behind the Guidance Document on Risk Assessment for birds and mammals

Question number: **EFSA-Q-2006-064**
Adopted on: **17 Jun 2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902014630.htm

Pesticide Risk Assessment and Peer Review (PRAPeR)

Evaluation of the efficiency of the pesticides peer review process

Question number: **EFSA-Q-2008-399**
Adopted on: **27 Aug 2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902099342.htm

Pesticide conclusions assessing:

Fenpyroximate	**Finalised: 16/10/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902154939.htm	
Copper compounds	**Finalised: 30/09/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902140778.htm	
Diphenylamine	**Finalised 30/09/2008**
Lufenuron	**Finalised 30/09/2008**
Magnesium phosphide	**Finalised 30/09/2008**
Sodium Nitrocompounds	**Finalised 30/09/2008**
Tebufenpyrad	**Finalised 30/09/2008**
Triazoxide	**Finalised 30/09/2008**
Triflumuron	**Finalised 30/09/2008**
Triflusulfuron	**Finalised 30/09/2008**
Zeta-cypermethrin	**Finalised 30/09/2008**
Metamitron	**Finalised: 29/09/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902140866.htm	
Teflubenzuron	**Finalised 29/09/2008**
Aluminium phosphide	**Finalised 29/09/2008**
Calcium phosphide	**Finalised: 29/09/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902140913.htm	
Chlormequat	**Finalised 29/09/2008**
Bensulfuron	**Finalised: 26/09/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902139552.htm	
2,5 dichlorobenzoic acid methylester	**Finalised: 26/09/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902139594.htm	
Tri-allate	**Finalised 26/09/2008**
Penconazole	**Finalised: 25/09/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902154895.htm	
Tebuconazole	**Finalised: 25/09/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902133175.htm	
Triadimenol	**Finalised: 25/09/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902133043.htm	
Cymoxanil	**Finalised: 17/09/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902132974.htm	

Cyromazine **Finalised: 17/09/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902139580.htm

Dimethachlor **Finalised: 17/09/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902154811.htm

Dodemorph **Finalised: 17/09/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902133101.htm

Acetochlor **Finalised: 31/07/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902131508.htm

Aclonifen **Finalised: 31/07/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902139566.htm

Flurprimidol **Finalised: 31/07/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902131308.htm

Sulcotrione **Finalised: 31/07/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902131448.htm

Tetraconazole **Finalised: 31/07/2008**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902131554.htm

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