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Agricultural Situation

The EU harmonization of MRLs: update

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Report Highlights:

The European Union is in the process of significantly adjusting its pesticide policies. US growers/shippers who export product to Europe should be aware of these changes which are scheduled to take effect in July 2008.

The ongoing EU MRL harmonization has reached a final phase. The new framework, Regulation 396/2005, is expected to be fully applicable by July 2008. From that time on, all EU MRLs will be harmonized at the EU level and national MRLs will no longer exist. This report highlights important information to facilitate compliance with the new harmonized MRL legislation.

Includes PSD Changes: No
Includes Trade Matrix: No
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Executive Summary

- Annexes II, III and IV to framework Regulation 396/2005 were notified to the WTO in August 2007 (see at the [Commission's website](#) for the draft versions of the Annexes)
- The EU Standing Committee approved the annexes as notified in October 2007 and they will be published in the Official Journal in the same format in January 2008.
- The publication of these Annexes in the Official Journal is a step forward in the EU MRL harmonization process since the framework Regulation 396/2005 will be fully applicable, following the standard six month implementation period or approximately July 2008. Once implemented, all MRLs will be harmonized at the EU Community-wide level and Member State MRLs will no longer exist.
- The Commission recognizes the need for limited updating, especially for Annex III, before July 2008. The Commission would like to include more recently approved MRLs in the implemented Annex III in July and is also considering comments received in response to the WTO notification in August. Several US commodities groups have commented on the proposed EU MRLs and these are under consideration.
- Proposed amendments for Annex III are due to be voted at the Standing Committee meeting in March 2008. Therefore, any comments with regard to Annex III can and should be submitted to the Commission before the end of February 2008. (For more details, please contact the US Mission to the EU).
- U.S. exporters should compare existing US MRLs for their products against the MRLs set forth in Annex II, III, and IV. They should also check existing import tolerances if they are not covered by the current version of Annex III. Any active substance not mentioned in Annexes II, III or IV will be subject to the 'default' MRL of 0.01 parts per million (ppm) when Regulation 396/2005 comes into force, which could become an irritant to trade.
- All the comments or proposed amendments concerning MRLs in Annex III received after the deadline of March will go through the regular MRL application/setting procedure which will take at least a year.
- The Commission does **not** provide any transitional measures for products used on crops planted before Regulation 396/2005 becomes fully applicable. Producers should be aware of any products that could be affected by the new Regulation. It is recommended that any crop protection products be checked against the Annexes of the Regulation 396/2005 before application **this growing season.**

This report focuses on the EU MRL legislation and the ongoing harmonization transition. It highlights recent events and necessary steps to be taken by US exporters to prevent future trade irritants. The following pages provide a full overview of the MRL situation in the EU.

How are EU pesticide MRLs regulated?

The pesticide legislation covering the residues for food is currently in a transitional phase. The current situation in the EU is still characterized by a dual system where EU and national MRLs (Maximum Residue Levels) for pesticides coexist, but full harmonization of all MRLs in the EU is expected by July 2008. By that time, the framework [Regulation 396/2005](#) will replace the existing Directives which currently contain the EU's partially harmonized MRLs. The new system will harmonize all MRLs at the EU level.

The marketing and use of plant protection products is regulated by EU Directive 91/414. Active substances are being reviewed under this Directive and can only be used in plant protection products when they are included in a positive EU list. Once a substance is included in the positive list, the use of products containing them can be authorized. This permission for use associated with inclusion/non-inclusion in 91/414 pertains to uses in the EU only and not to uses in the United States.

What is Regulation 396/2005?

Regulation 396/2005 will provide full harmonization of all MRLs at the Community-wide level, but it will only be fully applicable six months after the first four Annexes¹ to this Regulation have been published in the Official Journal (OJ).

Annex I is the only one already established, while Annexes II, III and IV were notified to the WTO in August 2007. The EU Standing Committee² approved the annexes as notified in October 2007 and they will be published in the same format in the OJ in January 2008 (see at the [Commission's website](#) for the draft versions of the Annexes). Regulation 396/2005 will be fully applicable 6 months later in July 2008. Once implemented, EU Member State MRLs will no longer exist.

Annex I, established by [Regulation 178/2006](#), is the only one of the four annexes of Regulation 396/2005 that has been officially established so far and simply **lists** the **commodities** to which MRLs apply.

Annex II will contain **existing MRLs** that were already harmonized at EU level and will replace the EU's four current MRL Directives.

Annex III will contain **temporary MRLs** and consist of two parts:

-**Part A** will contain the MRLs for 167 active substances most of which have not yet been harmonized at EU level, including those for active substances awaiting a decision for inclusion in Annex I of Directive 91/414 and some import tolerances. (The substances appearing here mostly originated from previously existing member-state MRLs.)

-**Part B** will contain all draft Temporary MRLs for active substances already harmonized at the EU level (and therefore included in Annex II) but in and on new commodities (for example some tropical products not previously established) established in Annex I (= new pesticide/crop combinations). These MRLs will eventually be shifted to Annex II of Regulation 396/2005.

Annex IV will contain the substances for which **no MRLs are required** (exempt from tolerance products). So far, the list only contains [8 substances](#) but it will be amended overtime to include additional products. At present it contains only relevant substances which have been reviewed under Directive 91/414/EEC.

For all substances not included in these four Annexes, the MRL will be set at EU default level of 0.01 ppm. This will eventually lead to the establishment of an Annex V.

¹ The Regulation also provides the possibility to develop other Annexes covering processed products, fumigants, etc.

² The Standing Committee plays a key role in the EU regulatory decision-making process as Committee members are representatives of the EU Member States.

Why is there a need to update Annex III?

Annexes II, III and IV were notified to the WTO in August 2007. The EU Standing Committee approved the annexes as notified, and they will be published in the same format in January 2008.

However, the Commission recognizes the need for a subsequent update, especially for Annex III, before Regulation 396/2005 becomes applicable in July 2008. Annex III included EU national MRLs published up to May 2006. Since that period, several additional MRLs have been approved in Member States. The Commission would like to include these more recent MRLs in the implemented Annex III in July. The Commission is also considering comments received in response to the WTO notification in August. Several US commodities groups commented on the proposed EU MRLs.

Proposed amendments for Annex III are due to be voted at the Standing Committee meeting in March 2008. Some proposals for amending Annex III have already been sent to the European Food Safety Authority (EFSA) and the MRLs passing their evaluation are also scheduled to go to the Standing Committee in March.

How does this MRL policy change affect US exporters? What role can they play? How can they participate in the update process?

US exporters should compare existing US MRLs for their products against the MRLs set forth in Annex II, III, and IV. They should also check existing import tolerances if they are not covered by the current version of Annex III. Any active substance not mentioned in Annexes II, III or IV will be subject to the 'default' MRL of 0.01 parts per million (ppm) when Regulation 396/2005 comes into force, which could become an irritant to trade.

Any comments with regard to Annex III must be submitted to the Commission before the end of February 2008. All the comments or proposed amendments received after the deadline of March will go through the regular MRL application/setting procedure which will take at least a year.

What is the regular application procedure for MRL setting once Regulation 396/2005 is fully applied?

If no amendments are reported, the framework Regulation will become fully applicable and new entries must go through the full regulatory procedure, which will take a year, by law. That is the time foreseen from the time of application to the time of publication of a MRL under the new framework Regulation 396/2005.

Applications made before March 2008 could be finalized within the one year. However, applications made after March 2008 could take more than a year as the EU finalizes Annex III.

MRL setting procedure under Regulation 396/2005 (Source: European Commission)

Applicant	→	Application for MRL	= 1 year
Assigned Rapporteur Member State	→	Evaluation report	
EFSA	→	Reasoned opinion	
Commission	→	Proposal for a Regulation/Decision	
Standing Committee	→	Opinion	
Parliament and Council	→	Right of Scrutiny	
Commission	→	Adoption and publication in the Official Journal	

What about pesticides that were used before July 2008 and are no longer allowed after the new framework Regulation is fully in effect?

The Commission does **not** provide any transitional measures for products used on crops planted before Regulation 396/2005 becomes fully applicable. Producers should be aware of any products that could be affected by the new Regulation. It is recommended that any crop protection products be checked against the Annexes of the Regulation 396/2005 before application **this growing season**.

How can I track EU MRLs?

You can check the status of an active substance in the review procedure of Directive 91/414. According to Article 12 of Regulation 396/2005 EFSA has the obligation to review MRLs within 12 months from the inclusion or non-inclusion in Annex I to Directive 91/414 (check status of active substances under EU review at:

http://ec.europa.eu/food/plant/protection/pesticides/index_en.htm

What about import tolerances?

It is still possible to obtain an import tolerance, even for active substances that have not been evaluated or used in Europe before. Applications for import tolerances must be submitted to the Rapporteur Member State (RMS). The Commission assigns a Member State, if no RMS exists. The RMS reviewed dossiers are evaluated by the EFSA before being forwarded to the Commission for consideration.

Please contact the US Mission to the EU with any additional questions regarding this new regulation.

Visit our website: our website useu.usmission.gov/agri/usda.html provides a broad range of useful information on EU import rules and food laws and allows easy access to USEU reports, trade information and other practical information. More information on pesticides and contaminants can be found at <http://useu.usmission.gov/agri/pesticides.html>. E-mail: AgUSEU.Brussels@usda.gov

Related reports from USEU Brussels:

Report Number	Title	Date Released
E47072	Pesticides update: draft temporary MRL list published - 2007	8/17/07
E36149	UPDATE ON EU PESTICIDE MRLS	12/21/06
E36054	Update on the EU Pesticide MRL Harmonization	04/04/06
E35016	EU Pesticide MRLs Harmonized Shortly	02/03/05

These reports can be accessed through our website useu.usmission.gov/agri or through the FAS website <http://www.fas.usda.gov/scripts/attacherep/default.asp>.