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Update on the EU Pesticide MRL Harmonization 2006

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Report Highlights:

U.S. industries should pay attention to implementing measures that will lead to fully harmonized EU pesticide MRLs. As part of this process, the European Commission collected data on unharmonized MRLs from its Member States. Based on this Member State information a list was created with the highest national MRL for all reported crop/active substance combinations. The publication of the list on the European Commission's website is intended for informational purposes and gives all involved parties an opportunity to check the status of substances of concern. These lists are not adopted yet and are as such not definitive. This report provides links to the Member State MRL list and explains how this publication fits into the Commission's MRL harmonization process.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
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[E3]

Which MRLs lists are currently applicable?

EU MRLs (see directives) plus national unharmonized for pesticide residues were only set at Community level for about 150 plant protection products. EU harmonized MRLs can be found in the following directives:

- [Council Directive 86/362/EEC](#), as amended, establishes MRLs for pesticides in cereals and cereal products
- [Council Directive 86/363/EEC](#), as amended, establishes MRLs for pesticides in products of animal origin
- [Council Directive 90/642/EEC](#), as amended, establishes MRLs for pesticides in products of plant origin, including fruits and vegetables

The complete list of EU MRLs in force is also available from the European Commission's website: [EU MRLs sorted by pesticide](#) [EXCEL](#) (240 kb) updated 04/11/2004.

The following EU MRL updates have not yet been included in the Commission's table of Nov 4, 2004:

Amendments to Council Directives:		
86 / 362 / EEC on cereal and cereal products	86 / 363 / EEC on products of animal origin	90 / 642 / EEC on fruit and vegetables
		2004/115/EC
2005/37/EC		2005/37/EC
2005/46/EC	2005/46/EC	2005/46/EC
2005/48/EC	2005/48/EC	2005/48/EC
2005/70/EC	2005/70/EC	2005/70/EC
		2005/74/EC
2005/76/EC		2005/76/EC
2006/4/EC		2006/4/EC
		2006/9/EC
2006/30/EC	2006/30/EC	2006/30/EC

See also: http://europa.eu.int/comm/food/plant/protection/pesticides/legislation_en.htm

Unharmonized products are still covered by Member State legislation. If there is a national MRL for a specific pesticide/commodity combination in the importing Member State (while there is no EU legislation in place for that combination) and the product being imported is consistent with it, it can be marketed in that country. Importers wishing to market the product in other Community Member States may face problems.

If there is no EC legislation in place and there is no national MRL in force in the importing Member State, then the exporter needs to obtain an "import tolerance".

Which MRL lists will be applicable in the future?

The European Commission collected data on unharmonized MRLs from its Member States. Based on this Member State information, a list was created with the highest national MRL for all reported crop/active substance combinations. National MRLs in force on March 31, 2005 were used for the preparation of this list as reported by the 25 EU Member States. It was last updated on Sep 29, 2005.

Although these provisional lists will not be adopted as such, they will lay the foundation of the definitive MRL lists. Once they are finalized, they will be published as the annexes to [Regulation 396/2005](#). The new EU regulation foresees that all MRL's, including import tolerances, will apply EU wide, removing the trade problems that were the result of the

current situation whereby Member States can set their own national MRL's in the absence of Community MRL's.

Structure of Regulation (EC) No 396/2005

This new regulation is a framework regulation and was published in March 2005. The Regulation provided for the development of four annexes. Only when all of these annexes are in force, the regulation will become fully applicable. When fully implemented it will have replaced the Directives that are currently in force.

The four annexes consist of:

Annex I: List of products and product groups for which harmonized MRLs will apply

Annex II: 'Definitive' tolerances which have been considered at EU level. This annex will include the EU MRLs that are included in the EU directives that apply currently.

Annex III: Temporary MRLs.

Annex IV: List of Active Substances for which no MRL's are required

The new regulation provides for the creation of two categories of EU MRLs. 'Definitive' tolerances (listed in Annex II of the new Regulation) which would have been considered at EU level and 'temporary' tolerances (listed in Annex III of the new Regulation). The temporary MRLs relate to tolerances that have not yet been considered at EU level. They are a mix of MRLs set by member States or those required to facilitate the import of treated produce from outside the Community. Consumer safety implications would be assessed before a temporary MRL would be included in the Regulation. Temporary MRLs will gradually be reviewed and, where appropriate, transferred to the 'definitive' list.

Status of the implementation of Regulation 396/2005

[Regulation 178/2006](#) was published in order to establish Annex I listing the food and feed products to which maximum levels for pesticide residues apply. This annex gives an overview of the products and product groups to which the MRLs apply and meanwhile determines the structure of the published MRL lists. Up until now, it is the first Annex that has been officially completed.

Regulation 396/2005 will only enter into force six months after adoption of its Annexes I-IV. Until such time, the national MRL of each Member State for each pesticide/crop combination remains in force and operators/stakeholders should comply with the relevant national legislation.

Next Steps in the Harmonization Procedure

The main focus of the efforts is currently on Annex III in order to establish the list of temporary MRLs. This list covers all current temporary MRLs (not considered at EU level yet) as well as the currently unharmonized national MRLs including import tolerances.

The Commission compiled all the information from all the Member States and a comparison was made between all Member State MRLs and the Codex MRLs. From this data, a draft harmonized list was created maintaining the highest MRL for each crop/active substance combination.

The list only comes into force after it has been reviewed by EFSA, and subsequently adopted by the Commission. It has already been submitted to EFSA for consumer safety assessment. Based on the outcome of that assessment, a list of temporary MRLs will be proposed by the Commission as Annex III to Regulation EC (No) 396/2005.

How should these lists be read?

The lists with MRL information of the Member states are published on the DG SANCO website and were last updated at the end of 2005.

The first two lists contain the same information but organized in a different way. In the first list the pesticides are ranked alphabetically. The list contains the highest MRL for each pesticide/crop combination observed as well as the Member State(s) where it is legally applicable.

The commodities or crops are organized in four different levels (similar to the structure of Regulation 178/2006 or Annex I). The product groups correspond to level 1. For example group 1 is fruit, group 2 are vegetables and so on. Within each product group three other levels can be distinguished following a certain taxonomy:

- Level 1: Fruit
- Level 2: Berries and small fruit
- Level 3: Cane fruit
- Level 4: Raspberries

See also

http://europa.eu.int/comm/food/plant/protection/resources/mrl_pending_alphabetically.xls

The use of these different levels makes it possible to organize the MRL information in a different way. Not all MRL values are printed in the other lists but it becomes possible to determine all values by following a few simple rules:

- The value on the highest level has a priority over all values on lower levels. For example a value displayed on level 1 for vegetables will apply to all vegetables.
- Two different values for two commodities with the same level number (as is the case for level 2 in example 1) but within the same group also apply to all lower levels (levels 3 & 4 in this case) up to the next commodity with the level 2. In the example, the MRL value of 10 ppm applies to all stem vegetables, including asparagus, cardoons, celery, fennel, leek, rhubarb and others. The MRL value of 5 ppm applies to all fungi, including cultivated and wild mushrooms.

See also http://europa.eu.int/comm/food/plant/protection/resources/mrl_pending_group.xls

Example 1

LEVEL	COMMODITY	MRL VALUE
2	(vii) STEM VEGETABLES	10
4	Asparagus	
4	Cardoons	
4	Celery	
4	Fennel	
4	Leek	
4	Rhubarb	
4	Others	
2	(viii) FUNGI	5
3	(a) Cultivated mushrooms	
3	(b) Wild mushrooms	

If the category "Others" is displayed in bold it means that some MRL values differ and are highlighted in grey. In the table below the commodities "Aniseed" and "Caraway" are highlighted in grey because their MRL value of 3ppm differs from the value displayed for the commodity "Others" which is set at 5 ppm.

Example 2

LEVEL	COMMODITY	AS X
1	7. Miscellaneous Products	
2	(i) TEA (leaves and stems, dried, fermented or otherwise, from the leaves of Camellia sinensis)	1
2	(ii) HOPS (dried), including hop pellets and unconcentrated powder	1
2	(iii) Spices dried and/or processed	
4	Aniseed	3
4	Caraway	3
4	Coriander seed	5
4	Cumin seed	5
4	Nutmeg	5
4	Pepper, black and white	5
4	Others	5
2	(iv) Herbal infusions	1
2	(v) Sugar plants	10
4	Sugar beet (top)	
4	Sugar beet (rot)	
4	Sugar beet (leaves)	
4	Sugar cane	
2	(vi) Cocoa	2

There is also a list that contains national MRL's of active substances that have not been reviewed under Directive 91/414/EEC and for which a decision was taken not to include them in the annex. The MRLs for either prohibited substances and for products with no specific MRL will be set by default at 0.01 mg/kg.

For substances withdrawn from the market, it is still possible to obtain an import tolerance if data can be provided showing that its residues do not endanger consumer health.

Import tolerances

The Commission produced a detailed document on the issue of import tolerances (see [G/SPS/GEN/557](#)).

There are three cases where "import tolerances" would be required, namely if a trader wants to import a commodity:

- (1) containing residues of a substance used in the European Communities but where the commodity is not produced in the European Communities e.g. papayas. In this case there would usually be expertise in the rapporteur Member States;
- (2) treated with a substance no longer or not yet used in the European Communities. In this case, there would normally not be expertise in the European Communities and full toxicological and residues data would be required.
- (3) treated with a substance in use in the European Communities but where the foreign Good Agricultural Practice (GAP) allows higher residues than the European Communities' critical GAP. In this case, marginal data specific to the GAP for the

crop would be needed since a dossier and rapporteur Member State would be available.

Under the new regulation 396/2005 import tolerances will still be set by a Member State but will apply EU wide. For substances included in Directive 91/414/EEC, they will be transferred to Annex II. For substances not included, they will be transferred to Annex III.

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Related reports from USEU Brussels:

Report Number	Title	Date Released
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/scriptsw/attacherep/default.asp .		