



# Harmonization of MRLs of Pesticides in Food Products between the RF and the EU

FBES "Federal Scientific Center for Hygiene named after F.F. Erisman"  
of the Rospotrebnadzor  
Research Institute for Pesticides Hygiene, Toxicology and Chemical Safety

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# 2008 – up to the present time



Federal Service for  
Supervision in  
Protection of Consumer  
Rights and  
Man Well-being

European Commission



General Directorate for  
Healthcare and  
Consumer Protection of the  
European  
Commission





- **Consultation of Russia and European experts on the basis of the EFSA.**

**Detailed discussion of methodical approaches of scientific foundations for maximum acceptable levels (MAL) of pesticides residues in food products.**

*October 7, 2008, Italy, Parma*

- **Two meetings of EU and RF experts on issues of harmonization of the maximum acceptable levels (MAL) and maximum residue levels (MRL) in plant products (MAL/MRL).**

*May 26 – 27, 2010, Moscow*

*April 28, 2011, Moscow*

State sanitary-epidemiological  
standardization of the Russian Federation

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## 1.2 Hygiene, toxicology and sanitary service

# Scientific Grounds for Maximum Acceptable Levels of Pesticide Residues in Food Products

Methodical instructions  
MI 1.2.2960-11

The official publication

Moscow, 2011

MI 1.2.2960-11

APPROVE

Head of the Federal Service for Supervision  
in Protection of Consumer Rights and Man Well-being,  
Chief state sanitarian physician of RF

G.G. Onishenko

July 29, 2011

## 1.2. Hygiene, toxicology and sanitary service

### Scientific grounds for maximum acceptable levels of pesticide residues in food products

Methodical instructions  
MI 1.2.2960-11

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#### I. Scope of use

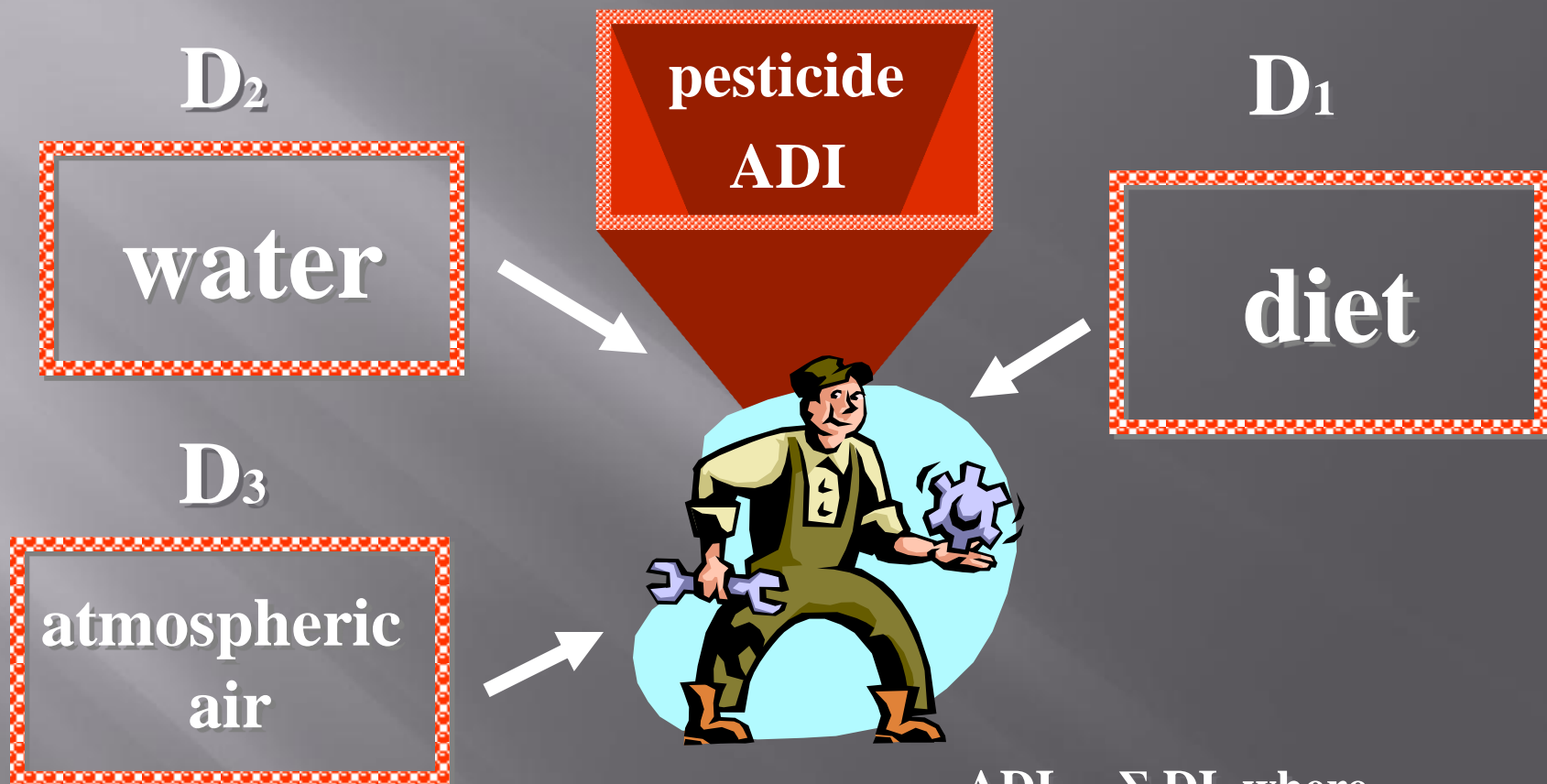
1.1. In the methodical instructions, requirements to scientific foundations for the values of maximum acceptable levels of pesticides residues in food products are established.

1.2. The methodical instructions are intended for specialists of bodies and organizations of the Federal service for supervision in protection of consumer rights and man well-being and also of research organizations of hygienic profile accredited, according to the stated order, for conduction of the work on hygienic standards development.

1.3. The methodical instructions have been developed for the reason of realization of measures of people health protection from adverse pesticides effects and prevention of contamination of food raw products and food stuffs with pesticides residues.

1.4. Safety of the people health, not the protection of crop rotation, is the priority, i.e. absence of pesticides residues in food products in quantities giving unacceptable risk for human health.

# Principle of complex hygienic regulation



$$ADI = \sum DI, \text{ where}$$

ADI – acceptable daily intake for an individual,

$D_1$  - acceptable dose which can get into a body with diet,

$D_2$  - acceptable dose which can get into a body with water,

$D_3$  - acceptable dose which can get into a body with atmospheric air.



# Acceptable daily intake for man (ADI)

$$\text{ADI} = \frac{\text{NOELch.or.}}{\text{Reserve factor}} \text{ (mg/kg b.w.)}$$

where: **NOELch.or.** – A value of no observed effect level dose determined in chronic toxicological experiment with peroral effect

**RF** – reserve factor (min = 100)

When a substance is characterized by the specific and delayed effects, the reserve factor for hazardous pesticides increases up to 200 – 500 and in some cases - to 1 000 and more

# Process of harmonization of MRL values for plant products with EU standards

**1. Process of harmonization of MRL values between RF and EU is very important and it is being permanently realized within the framework of legislative and normative-legal documents valid in the territory of RF.**

**2. For pesticides registered according to the stated order and applied in the territory of RF, procedure of MRL development and authorization, and their analytical ensuring is being strictly regulated by present legislation of RF and unflinching realized.**

**3. For pesticides which do not have state registration in RF but can get into a human body with imported food-stuffs, suppliers must observe the following requirements:**

- to submit information concerning the used pesticides during their manufacture, storage and transportation;**
- to submit data on MRL values in a concrete type of product (standards established by Codex Alimentarius Commission, EU, national body of an exporting country etc;**
- to submit a published method of analytic control of a pesticide active ingredient in than type of food product and analytical standard.**

**The above information will be the basis of conduction, according to the stated order, sanitary-epidemiological expertise of the certain type of a food-product. According to the expertise results, a decision will be arrived at concerning a possibility of import and conditions of use of that type of a food product.**



# Scheme of MRLs harmonization in imported products for pesticides which are not authorized in the RF

Submission of toxicological dossier on a pesticide a.i.



Development of ADI



Development of MRL



Submission of foreign data on residue tolerance for a pesticide in a particular agricultural product



MRL values (Codex Alimentarius, EU)



Development or adaptation of an analytical control method in a particular food product



# Scheme of MRLs harmonization in imported products for pesticides which are authorized in the RF

ADI

water

diet (MRLs)

atmospheric  
air

Submission  
of foreign data  
on residue tolerance for  
a pesticide in a  
particular agricultural  
product

MRL values  
(Codex Alimentarius,  
EU)

Development or  
adaptation of an  
analytical control method  
in a particular food  
product



**Federal  
Scientific  
Center for  
Hygiene name  
after  
F.F. Erisman**

State sanitary-epidemiological standardization of  
the Russian Federation

State sanitary-epidemiological rules and standards

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1.2. Hygiene, toxicology and sanitary service

## **Hygienic Standards for Pesticides Content in Environmental Objects (List)**

Hygienic standards  
HS 1.2.2701 - 10

The official publication

Moscow, 2010

# Supplement No 1 to HS 1.2.2701-10

Annex

Approved  
by decree of Chief state  
sanitarian physician of RF  
of July 7, 2011 No 92

Hygienic standards of pesticides contents in environmental objects  
Supplement No 1 to HS 1.2.2701-10  
Hygienic Standards  
HS 1.2.2890 11

Active ingredient	ADI (mg/kg) of human body weight	MAC/TAC in soil (mg/kg)	MAC/TAL in water bodies (mg/dm <sup>3</sup> )	MAC/TSEL in air of working zone (mg/m <sup>3</sup> )	MAC/TSEL in atmospheric air (mg/m <sup>3</sup> )	MRL/PMRL in products (mg/kg)
1. Azoxystrobin	0,03	/0,4	0,01/	/1,0	/0,01	Potatoes - 0.05
2. Aluminium phosethyl	3,0	/0,5	0,3/	2,0/	/1,0	Tomato - 100.0 Cucumber - 75.0
3. Bixaphen	0.02	/0.9	0.005/ (general sanitary)	/1.0	/0.002	Grain of cereals - 0.5
4. Cyprosulfamide	0.08	/0.24	0.07/(general sanitary)	/0.8	/0.01	Maize (grain & oil) - 0.1



# Results of activity on harmonization of MRL values

Under economic agreements the following have been harmonized:

Ist Priority  
List - 20  
MRLs for 9  
a.i.  
2009-2010

IIInd Priority  
List - 19  
MRLs for 13  
a.i.  
2010-2011

IIIId Priority  
List - 23 MRLs  
for 15 a.i. (from  
25 MRLs for 16  
a.i.)  
2011-2012



# Problem Issues at Harmonizing the Standards:

➤ Significant divergence in values of pesticides MRL set by Codex Alimentarius Commission, EU, EPA etc;

➤ Essential corrections (even during a year) of standards approved by international and national bodies on the basis of data on human risks;



# TASKS:

- In the scheduled order, continuation of the work on harmonization of pesticides MALS (for new active ingredients, new crops, on priority lists, MRLs corrections etc).
- Harmonization of risk assessment methods.
- Permanent improvement of analytical methodical basis.





**Thank you for  
your time!**