Harmonization of Russian pesticide MRLs with Codex standards

Valerii Rakitskii, Olga Egorova

• Federal Service for Surveillance on Consumer Rights Protection and Human Well-being (Rospotrebnadzor)

• F.F.Erisman Federal Scientific Center of Hygiene of Rospotrebnadzor
Legislation of harmonization of Russian MRLs to Codex


- Federal law No. 52-FZ of March 30, 1999 «On Sanitary-and-Epidemiological Public Well-Being»

- Decision of the Commission of the Customs Union No. 299 of 28 May 2010 «On Application of Sanitary Measures in the Customs Union»


- Decision of the Commission of the Customs Union No. 625 “On Ensuring the Harmonization of Regulations of the Customs Union in the Application of Sanitary, Veterinary and Phytosanitary Measures with International Standards” of 7 April 2011.
Introductory remarks

• Toxicological assessment of pesticides and their hazardous metabolites
• Complex hygienic regulation principles are used
• Pesticide residue data based on field trials in 3 soil-climatic zones covering 2 growing seasons at maximum use rate and number of treatment
• The validated analytical method should be provided
• MRLs may be set for group like cereals or pome fruits
• When MRL is established a Codex level standards is considered
• Risk assessment of dietary exposure to pesticide residues (hazardous metabolites)
• The MRL authorization is a part of a multi-step procedure that provides the opportunity for discussion and comment by national regulating authorities of EurAsEC and other
Scheme of MRLs harmonization for pesticides which are authorized in the RF

- **ADI**
- **Water**
- **Diet (MRLs)**
- **Atmospheric air**

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

**MRL values (Codex Alimentarius, EU)**

**Development or adaptation of the analytical control method in a particular food product**
Scheme of MRL harmonization in imported products for pesticides which are not authorized in the RF

1. Submission of toxicological dossier on a pesticide A.I.
2. Development of ADI
3. Development of MRL
4. Submission of foreign data on residue tolerance for a pesticide in a particular agricultural product
5. MRL values (Codex Alimentarius, EU)
6. Development or adaptation of the analytical control method in a particular food product
## Guidelines on Human Health Risk Assessment From Exposure to Environmental Chemicals [G 2.1.10.1920-04]

### Hygienic Standards

- **HS-1.2.3111-13** “Hygienic Standards of Pesticides Content in Environmental Objects (List)” with amendments
- **MI 1.2.2960-11** “Scientific Justification for MRLs of Pesticides in Food Products”
- **MI 1.2.3216-14** “The risk assessment of Pesticide Residues in Food Product For Human”

### Example: Chlorantraniliprole, ADI – 2.0 mg/kg bw

#### Risk assessment of non-carcinogenic effects at food intake

<table>
<thead>
<tr>
<th>Commodity</th>
<th>MRL, mg/kg</th>
<th>Chlorantraniliprole, mg/kg</th>
<th>Daily intake contribution, kg/day</th>
<th>Contribution to the exposure value, %</th>
<th>Risk assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Median residue</td>
<td>90%-percentile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pome fruits</td>
<td>0.5</td>
<td>0.17</td>
<td>0.46</td>
<td>0.125</td>
<td>33,0</td>
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<tr>
<td>Potato</td>
<td>0.1</td>
<td>0.02</td>
<td>0.06</td>
<td>0.470</td>
<td>14,6</td>
</tr>
<tr>
<td>Grapes*</td>
<td>1.0</td>
<td>0.051</td>
<td>0.019</td>
<td>0.200</td>
<td>15,9</td>
</tr>
<tr>
<td>Tomato*</td>
<td>0.6</td>
<td>0.088</td>
<td>0.019</td>
<td>0.120</td>
<td>16,4</td>
</tr>
<tr>
<td>Stone fruits*</td>
<td>1.0</td>
<td>0.091</td>
<td>0.27</td>
<td>0.070</td>
<td>9,9</td>
</tr>
<tr>
<td>Pepper*</td>
<td>1.0</td>
<td>0.066</td>
<td>0.34</td>
<td>0.075</td>
<td>7,7</td>
</tr>
<tr>
<td>Cucumber*</td>
<td>0.3</td>
<td>0.032</td>
<td>0.1</td>
<td>0.050</td>
<td>2,5</td>
</tr>
<tr>
<td>Σ exp</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk assessment</th>
<th>HQ med</th>
<th>HQ90%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

- ADI – 2.0 mg/kg bw, *- imported commodities
- HQ ≤ 1. Non-carcinogenic risk of atranilamid derivative is acceptable under the agricultural practice (use rate, application rate and waiting times)

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THE ACHIEVEMENT OF HARMONIZATION

During last decade about 1,500 MRLs of 162 active ingredients have been reconsidered. 66 of them are new A.I.

Guidelines on MRL establishment and risk assessment have been developed based on international approaches including 11 harmonized analytical methods of control for 66 individual commodities.

Harmonization process of Russian MRLs resulted in improvement and updating of some terms and definitions.

Compliance principle of Russian MRLs to the Codex ones has led to a significant increase in the level of acceptance of Codex MRLs.
Uniform sanitary and epidemiological and hygienic requirements for products subject to sanitary and epidemiological supervision (control);

Section 15. Requirements for pesticides and agrochemicals, EurAsEC, 2015, Moscow

The decision of the Board of the Eurasian Economic Commission N 149 of November 10, 2015 "On Amendments to the Customs Union Commission Decision N 299 d.d. 28 May 2010 "

Единые санитарно-эпидемиологические и гигиенические требования к продукции (товарам), подлежащей санитарно-эпидемиологическому надзору (контролю)

Раздел 15. Требования к пестицидам и агрохимикатам
MRL setting policy of Codex Alimentarius Commission is based on high protection level for the consumer.

Harmonization process for Russian MRLs with international standards is very important, it is being conducted and will continue within the framework of valid legal norms.
Thank you for your time

pesticide@yandex.ru