EU Legal framework for pesticides – recent decisions

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- **Approval**
  - Active Substance
  - One Use with Formulated Product

- **Authorisation**
  - Use of PPP (GAP)

- **Sustainable Use**
  - Use
    - Use of PPP
    - Use of PPP (GAP)
    - Application Equipment, Training, Information, IPM...

- **MRL**
  - Residues

**Regulated at EU level**

**Regulated at Member State level**

PPP Placing on the Market Regulation (EC) 1107/2009

PPP Residues Regulation (EC) 396/2005
"Approval" vs. "Authorisation"

Active substance

Formulated Product
EU zonal system

North

Center

South
Separation risk assessment / risk management

1. Application
   Industry → Data dossier

2. Risk Assessment
   1 Member State (RMS) → Draft Assessment Report
   European Food Safety Authority (EFSA) + all Member States → Expert meetings,
   "Conclusion on the peer review"
   EFSA

3. Risk management
   Commission + all Member States → (Restricted) approval / Non-approval
Active Substances = Approval at EU level

• Application for approval
  • Data requirements
• Evaluation shared between 28 Member States: for each substance => one Rapporteur MS
  • Uniform principles of evaluation
• Peer review by the European Food Safety Authority
• Approval => List of approved substances
• Total length of the procedure = 2.5 to 3 years
• First approval for 10 years – renewal for up to 15 years
Approval Criteria

PPP containing the active substance must (during proper use):

a) Be sufficiently effective;

b) Have no immediate or delayed harmful effect on human health, including on vulnerable groups, or animals health, directly or through drinking water, food, feed or air, or consequences in the workplace or through other indirect effects taking into account known cumulative or synergistic effects when the scientific methods are available, or on groundwater;

c) Have no unacceptable effects on plants or plant products

d) Not cause unnecessary suffering and pain to vertebrates to be controlled;

e) Not have unacceptable effects on the environment with particular regard to:
   - fate and distribution
   - impact on non-target species
   - impacts on biodiversity and the eco-sytem
Availability of active substances

Development of the number of available active substances in the EU between 1993 and 2010

- Active substances to be evaluated
- Approved active substances
- Approved NAS

Food Safety
Availability of active substances

Total number of approved active substances per year

- 2011: 400
- 2012: 450
- 2013: 500
- 2014: 550
- 2015: 600
- 2016: 650
- 2017: 700
- 2018: 750
Recent restrictions / non-renewal of approvals where unacceptable impacts on the environment played a role

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Risks to</th>
</tr>
</thead>
<tbody>
<tr>
<td>imidacloprid, clothianidin, thiamethoxam</td>
<td>bees</td>
</tr>
<tr>
<td>thiram</td>
<td>birds and mammals</td>
</tr>
<tr>
<td>chlorpropham</td>
<td>non-target arthropods</td>
</tr>
<tr>
<td>propiconazole</td>
<td>Groundwater pollution</td>
</tr>
<tr>
<td>propineb</td>
<td>bees</td>
</tr>
<tr>
<td>diquat</td>
<td>birds</td>
</tr>
<tr>
<td>oxasulfuron</td>
<td>earthworms, aquatic organisms, soil macro- and micro-organisms, not-target terrestrial plants</td>
</tr>
<tr>
<td>pymetrozine</td>
<td>Groundwater pollution and risks to aquatic organisms</td>
</tr>
</tbody>
</table>
Thank you for your attention!

For further information:

https://ec.europa.eu/food/plant/pesticides_en
https://ec.europa.eu/food/plant/pesticides/refit_en
https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en
https://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides_en

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