Failing to apply the precautionary principle in pesticide authorisation: the costly consequences for whom?

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ENSSER PP Conference  
Centre for Interdisciplinary Research, Bielefeld  
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Treaty on the Functioning of the European Union- Article 191

Reg 1107/2009 (Pesticide Regulation)

- Art. 1(4). “The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment.”

- Art. 13(2). Risk management decision must comply with the conditions of the precautionary principle as laid down in General Food Law (Reg 178/2002)
Reg. 178/2002 (General Food Law) Art. 7 on PP.

1. “In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.”

Risk managers: European Commission and Member States
Legal requirements - pesticides

Plant Protection Product Regulation (PPPR) 1107/2009:

- High level of protection for ALL
  - Humans, animals, environment
- Protect the vulnerable
  - Pregnant women, children, babies
- Apply the precautionary principle
- Consider active substances, products and residues (food & environment)
- Consider mixture effects (cocktails)

Mutagens, Carcinogens, Toxic to Reproduction, Endocrine Disruptors, PBTs
Failing to implement PP

Legal paradox: pesticide products are designed to be toxic to living organisms and are applied on open spaces

- They adversely affect non-target organisms in the environment and may lead to population effects
- The possibility of harmful effects to humans and animals is very high
Environmental exposure to pesticides and the sublethal effects on farmland bird populations

Pesticide authorization

Organic chemicals in ecosystems: an occupational increase

Neurobehavioral Deficits, Diseases, and Associated Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union

The effects of insecticides on butterflies -- A review
Increasing number of active substances

Availability of active substances

Total number of approved active substances per year

<table>
<thead>
<tr>
<th>Year</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value</td>
<td>400</td>
<td>450</td>
<td>470</td>
<td>490</td>
<td>500</td>
<td>510</td>
<td>520</td>
<td>530</td>
</tr>
</tbody>
</table>
European Statistics on sales

EU: Releasing 380,000 tonnes a.s./year

All sales 2017

- Zone A
- Zone B
- Zone C

Sales A.S. (tonnes)

- 2011
- 2012
- 2013
- 2014
- 2015
- 2016
- 2017

- Fungicides
- Herbicides
- Insecticides
European Statistics

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>EU land</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total EU agricultural area</td>
<td></td>
<td>40 %</td>
</tr>
<tr>
<td>Pesticide use</td>
<td></td>
<td>92 %</td>
</tr>
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Sales (tonnes A.S.)

Eurostats, 2017
European Statistics

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</table>
### Toxicity of authorised active substances

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
<th>Type Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total A.S. approved</td>
<td>466</td>
<td>All</td>
</tr>
<tr>
<td>Carcinogens 2 (suspected)</td>
<td>23</td>
<td>HB (9), FU (10), IN (3), PG (1)</td>
</tr>
<tr>
<td>Reproductive toxicity 1b</td>
<td>10</td>
<td>HB (3), FU (4), IN (1), RO (2)</td>
</tr>
<tr>
<td>Reproductive toxicity 2</td>
<td>20</td>
<td>HB (8), FU (9), IN (1)</td>
</tr>
<tr>
<td>Two PBT</td>
<td>49</td>
<td>HB (15), FU (23), IN (8), PG (2), RO (1)</td>
</tr>
<tr>
<td>Candidates for substitution</td>
<td>63</td>
<td>All</td>
</tr>
<tr>
<td>Endocrine disruption (ED)</td>
<td>27</td>
<td>-screening exercise- HB (10), FU (13), IN (3)</td>
</tr>
<tr>
<td>ED properties (potential)</td>
<td>104</td>
<td>-screening exercise-</td>
</tr>
</tbody>
</table>
“Acting in accordance with the precautionary principle means taking action when you know there is a risk but you cannot assess precisely the level of risk.”

Health Commissioner Vytenis Andriukaitis
Annual Conference of Safe Food Advocacy
Europe
Brussels 2017
Failing to implement PP

- Risk assessment – eliminating the evidence on adverse effects
- Active substance versus products
- Pesticide mixtures

https://citizens4pesticidereform.eu/
Risk assessment

- Data requirements are based *predominately* on industry-sponsored studies
- Confidential – *foreseen to change in 2021*
- Poor reporting of adverse effects
- Adverse effects dismissed for “unscientific reasons” (e.g. historical controls, secondary effects)
Dismissing adverse effects

▪ Carcinogenicity (glyphosate)
Dismissing adverse effects

- Carcinogenicity (glyphosate)
  - Adult animals
  - Tumours in 5 mice studies – statistically significant following revision

**Graphs:**

- **2001**: Virus infection (ML)
- **1983**: Spontaneous & toxic (R)
- **1993**: Spontaneous & toxic (HS)
- **1997**: Spontaneous & toxic (ML)

**Legend:**

- Historical controls (pool 22 years) CD-1 mice
Data requirements are based *predominately* on industry-sponsored studies.

However, according to 1107/2009 Art. 8(5):

“All **Scientific peer-reviewed open literature, as determined by the Authority, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier shall be added by the applicant to the dossier.”
Published Vs industry studies

Example: Studies on the genotoxicity of glyphosate

Source: Helmut Burtscher-Schaden, European Parliament hearing, PEST Committee 2018
Risk assessment

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Active Substance Vs Product

- Products are not assessed as thoroughly for chronic toxicity as active substances
- Human/mammalian chronic toxicity of products is extrapolated from the RA of active substances

Assessment by Member State

EU assessment
Active Substance Vs Product

European Court of Justice ruling (Case C-616/17):

- Are the general rules governing the approval of glyphosate unlawful?

- On active substance:
  - The identification of the active substances is not sufficient

- On products:
  - the effects caused by the interaction between a given active substance and, inter alia, the other constituents of the product must be considered

- Current testing of plant protection products are not suffice to exclude long-term carcinogenicity and toxicity
On cumulative and synergistic effects

Legal requirements

1107/2009, Art. 4 (2a & 3b): Pesticide products (3b) and their residues (2a) “shall have no harmful effect on human health, including that of vulnerable groups, or animal health... ...taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available; or on groundwater”

396/2005, Art. 14. Decisions on applications concerning MRLs: Account shall be taken of (2b) “the possible presence of pesticide residues arising from sources other than current plant protection uses of active substances, and their known cumulative and synergistic effects, when the methods to assess such effects are available;
Effects of pesticide mixtures are not assessed in utero exposure to 18 chemicals < LOAEL caused cumulative effects on male reproductive development.

Exposure of rats to mixture of 13 chemicals < NOAELs caused hepatotoxicity.
<table>
<thead>
<tr>
<th>Fruit or Vegetable</th>
<th>With residues</th>
<th>With multiple residues</th>
<th>Max residues/sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apples</td>
<td>67%</td>
<td>46%</td>
<td>17</td>
</tr>
<tr>
<td>Lettuce</td>
<td>58%</td>
<td>36%</td>
<td>13</td>
</tr>
<tr>
<td>Peaches</td>
<td>75%</td>
<td>53%</td>
<td>15</td>
</tr>
<tr>
<td>Strawberries</td>
<td>76%</td>
<td>63%</td>
<td>15</td>
</tr>
<tr>
<td>EU (Average)</td>
<td>47.2%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

European Food Safety Authority (2015)
On cumulative and synergistic effects

EFSA pilot study on chronic effects on thyroid:

- Based on probabilities and assumptions, uses industry studies
- Applies the precautionary principle to conclude there is no risk
- Concludes “Consumer risk from dietary cumulative exposure is below the threshold that triggers regulatory action for all the population groups covered”

Temporary solution: Apply an additional safety factor of 10
Windows of opportunity

- New Commission – European Green Deal- zero pollution ambition
- European Parliament Pest Committee 2019 report
- Pesticide and MRL Regulations REFIT (review) results – overdue
  - pesticide use data (volumes and impacts)
  - set measurable pesticide use reduction targets
  - give priority to non-chemical alternatives
  - protect and restore biodiversity
Thank you!

Let's work together towards a healthier future