Probabilistic risk assessment of patulin in apple juice for preschool children in Flanders

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Patulin

- *Penicillium expansum*
- Apples and apple-based products
- Toxicity

- Bacteria
- Animal cells and tissues

TDI: 0.4 µg/kg bw/day
Influence of organic farming on patulin?

2 possible impacts

Reduced use of fungicides

More mould growth

Reduced use of insecticides

More insect damage

More fungal invasion
Occurrence of patulin in apple juice (AJ) in Belgium

Baert et al. 2006.
Patulin levels in contaminated samples

Baert et al. 2006.

Mean (µg/l): 10.2 43.1 10.5
Objectives

• Evaluate influence of patulin levels on public health

Exposure  TDI

Focus: small children and apple juice

• Evaluation of lowering regulatory limit

• Evaluation of lowering AJ consumption
Exposure assessment

Contamination (µg pat/g AJ) \times Consumption (g AJ/kg bw/day) = Intake
Exposure assessment

Contamination
(µg pat/g AJ)

Consumption
(g AJ/kg bw/day)

µg/g AJ

g AJ/kg bw/day

Contamination x Consumption = Intake
Exposure assessment - Probabilistic

Contamination
(µg pat/g AJ)

Consumption
(g AJ/kg bw/day)

Contamination x Consumption = Intake
Exposure assessment - **Probabilistic**

**Contamination**

\( (\mu g \text{ pat/g AJ}) \)

\[ \text{Cumul. Prob.} \]

\[ \mu g/g \text{ AJ} \]

**Consumption**

\( (g \text{ AJ/kg bw/day}) \)

\[ \text{Cumul. Prob.} \]

\[ g \text{ AJ/kg bw/day} \]

**Contamination \times Consumption = Intake**

\( x_1, x_2 \)
Exposure assessment - Probabilistic

Contamination
(µg pat/g AJ)

Consumption
(g AJ/kg bw/day)

Contamination x Consumption = Intake

X₁, X₂, X₃, X₄, X₅, ........
Exposure assessment - Probabilistic

Contamination (µg pat/g AJ)

Consumption (g AJ/kg bw/day)

µg pat/kg bw/day

Cumul. Prob.

Cumul. Prob.

X₁, X₂, X₃, X₄, X₅, ...........
Exposure assessment

\[ \text{Contamination} \times \text{Consumption} = \text{Intake} \]

\[ (\mu g \text{ pat/g AJ}) \times (g \text{ AJ/kg bw/day}) = \mu g/g \text{ AJ} \times \text{g AJ/kg bw/day} \]
Exposure assessment - Probabilistic

Contamination

(µg pat/g AJ)

Consumption

(g AJ/kg bw/day)

Contamination x Consumption = Intake

µg pat/kg bw/day

g AJ/kg bw/day

Cumul. Prob.

Cumul. Prob.

X₁, X₂, X₃, X₄, X₅, ........
Exposure assessment

Contamination (µg pat/g AJ)

Apple juices were analysed on patulin content (Baert et al., 2006)

Consumption (g AJ/kg bw/day)

Epidemiological study on nutritional habits of preschool children in Flanders (2.5-6.5 years) (Huybrechts et al., 2006)

Assumptions:

• A consumer will only drink one type of apple juice
• Consumption pattern of 3 types of AJ is the same
Values below LOD?

Between 10 and 13% of the data ≥ LOD

H1: LOD
H2: LOD/2
H3: 0

Cum. prob.

87%
<table>
<thead>
<tr>
<th></th>
<th>LOD</th>
<th>LOD/2</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>P50</strong>*</td>
<td>0 [0-0]**</td>
<td>0 [0-0]</td>
<td>0 [0-0]</td>
</tr>
<tr>
<td><strong>P90</strong></td>
<td>0.085 [0.077-0.094]</td>
<td>0.043 [0.039-0.047]</td>
<td>0 [0-0]</td>
</tr>
<tr>
<td><strong>P97.5</strong></td>
<td>0.216 [0.181-0.312]</td>
<td>0.125 [0.096-0.197]</td>
<td>0 [0-0.183]</td>
</tr>
<tr>
<td><strong>P99</strong></td>
<td>0.408 [0.261-0.815]</td>
<td>0.341 [0.155-0.782]</td>
<td>0.316 [0-0.775]</td>
</tr>
<tr>
<td><strong>P99.5</strong></td>
<td>0.601 [0.351-1.442]</td>
<td>0.617 [0.213-1.442]</td>
<td>0.627 [0.161-1.442]</td>
</tr>
<tr>
<td><strong>P99.9</strong></td>
<td>1.449 [0.533-3.068]</td>
<td>1.443 [0.506-3.246]</td>
<td>1.445 [0.522-3.245]</td>
</tr>
</tbody>
</table>

* 50th percentile  ** [90% confidence interval]
Values below LOD?

Between 10 and 13% of the data $\geq$ LOD

H1: LOD

H2: LOD/2

H3: 0

H4: uniform (min, max)

Cum. prob. 87%

LOD

Pat. conc.
<table>
<thead>
<tr>
<th>Values below the LOD? - exposure (µg/kg bw/day) for organic apple juice</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>P50*</td>
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</table>

* 50th percentile  ** [90% confidence interval]
Assessment of patulin exposure (µg/kg bw/day)

<table>
<thead>
<tr>
<th></th>
<th>Organic AJ</th>
<th>Convent. AJ</th>
<th>Handcraft. AJ</th>
</tr>
</thead>
<tbody>
<tr>
<td>P83*</td>
<td>0 [0-0]**</td>
<td>0 [0-0]</td>
<td>0 [0-0]</td>
</tr>
<tr>
<td>P97.5</td>
<td>0.135 [0.053-0.229]</td>
<td>0.095 [0.057-0.133]</td>
<td>0.102 [0.047-0.151]</td>
</tr>
<tr>
<td>P99</td>
<td>0.350 [0.143-0.822]</td>
<td>0.156 [0.106-0.206]</td>
<td>0.150 [0.084-0.229]</td>
</tr>
<tr>
<td>P99.5</td>
<td>0.615 [0.249-1.472]</td>
<td>0.202 [0.141-0.287]</td>
<td>0.195 [0.109-0.290]</td>
</tr>
<tr>
<td>P99.9</td>
<td>1.471 [0.526-3.066]</td>
<td>0.328 [0.210-0.548]</td>
<td>0.298 [0.156-0.460]</td>
</tr>
</tbody>
</table>

*83th percentile  ** [90% confidence interval]
### Percentage of the population exceeding the TDI

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<th>Handcraft. AJ</th>
</tr>
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<tbody>
<tr>
<td><strong>Percentage</strong></td>
<td>0.9%</td>
<td>0.1%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Confidence Interval</strong></td>
<td>[0.3-1.8%]*</td>
<td>[0-0.3%]</td>
<td>[0-0.2%]</td>
</tr>
</tbody>
</table>

* [90% confidence interval]
Risk management measure: **Lowering the regulatory limit**

**European legislation Nr. 1425/2003**

fruit juices and fruit nectar: **50 µg kg\(^{-1}\)**

Effect on exposure when only apple juice with <50µg pat/kg is available
Risk management measure: Lowering the regulatory limit

European legislation Nr. 1425/2003  
fruit juices and fruit nectar: 50 µg kg\(^{-1}\)  
future: new evaluation

Effect on exposure when only apple juice with <50µg pat/kg is available

Effect on exposure when limit would be 25 µg kg\(^{-1}\)
Lowering the regulatory limit: patulin exposure ($\mu$g/kg bw/day) for organic apple juice

<table>
<thead>
<tr>
<th>Current sit.</th>
<th>&lt;50$\mu$g/kg</th>
<th>&lt;25$\mu$g/kg</th>
</tr>
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<tr>
<td>P50*</td>
<td>0 [0-0]**</td>
<td>0 [0-0]</td>
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<tr>
<td>P97.5</td>
<td>0.135 [0.053-0.229]</td>
<td>0.118 [0.045-0.186]</td>
</tr>
<tr>
<td>P99</td>
<td>0.350 [0.143-0.822]</td>
<td>0.226 [0.107-0.443]</td>
</tr>
<tr>
<td>P99.5</td>
<td>0.615 [0.249-1.472]</td>
<td>0.379 [0.173-0.647]</td>
</tr>
<tr>
<td>P99.9</td>
<td>1.471 [0.526-3.066]</td>
<td>0.682 [0.320-1.402]</td>
</tr>
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</table>

* 50th percentile     ** [90% confidence interval]
## Lowering the regulatory limit: Percentage of pop. exceeding TDI

<table>
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<tr>
<th></th>
<th>&lt;50µg/kg</th>
<th>&lt;25µg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Current sit.</strong></td>
<td>0.9%</td>
<td>0.5%</td>
</tr>
<tr>
<td></td>
<td>[0.3-1.8%]*</td>
<td>[0.1-1.2%]</td>
</tr>
</tbody>
</table>

* [90% confidence interval]

Due to high apple juice consumption: up to 1.2l/day
Risk management measure: **Lowering apple juice consumption**

Fruit juice:
- less fibres \[\longleftrightarrow\] fresh fruit
- more sugar \[\longleftrightarrow\] mineral water

Advised: limit fruit juice consumption to ± 200ml a day
**Lowering apple juice consumption:** Percentage of pop. exceeding TDI

<table>
<thead>
<tr>
<th>Organic AJ</th>
<th>Current sit.</th>
<th>AJ cons. &lt;200ml/day</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.9% [0.3-1.8%]∗</td>
<td>0.8% [0.2-1.7%]</td>
</tr>
</tbody>
</table>

∗ [90% confidence interval]
## Lowering apple juice consumption:
### Percentage of pop. exceeding TDI

<table>
<thead>
<tr>
<th></th>
<th>Organic AJ</th>
<th>Conventional AJ</th>
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<tr>
<td><strong>Current sit.</strong></td>
<td>0.9%</td>
<td>0.1%</td>
</tr>
<tr>
<td><strong>AJ cons. &lt;200ml/day</strong></td>
<td>0.8%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>AJ contam. &lt;25µg/kg</strong></td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

* [90% confidence interval]
Conclusion

• A proper treatment of data <LOD is not be underestimated

• A uniform distribution with uncertain bounds can be used to handle data <LOD

• Children consuming organic AJ: 0.9% [0.3-1.8%] exceed TDI

• ↓ regulatory limit to 25 µg/kg: 0% [0-0.3%] exceed TDI

• Reduction of AJ consumption was less effective to reduce patulin exposure