CREOSOTE

Regulatory Situation
Europe

Ralph Meulepas
Creosote Council Europe

WEI – European Institute for Wood Preservation
• Status Mutual Recognition across Europe
  - Summary
  - Pending actions
  - Fruit Stakes Use
  - Overview

• Renewal of authorization (Active Substance)
  - Status
  - Brexit
  - Expiry Dates
## Summary

<table>
<thead>
<tr>
<th></th>
<th>WEI Congress March 2017</th>
<th>WEI Congress September 2017</th>
<th>WEI Congress March 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Official decisions</td>
<td>8</td>
<td>17</td>
<td>20</td>
</tr>
</tbody>
</table>

- Netherlands is only MS to not approve any use
- Approvals Belgium and UK granted
- Fruit stake use under pressure
- Major change applications ongoing in two MS
- Approval some MS still pending
Status specific Member States

Background / pending actions

- Netherlands
  - Formal Complaint

- Spain (resolved)
  - Species approved: Pine (while mainly oak is used)

- Sweden
  - Major change application (Horse Fencing)

- UK
  - Major change application (Fruit stakes / Fencing)
Fruit Stakes
Fruit Stakes

TDI: Tolerable Daily Intake

- In the scenario where **fruits are grown in direct contact with stakes** the exposure for toddlers is not acceptable.
### Fruit Stakes

When 1 in 200 apples has come into contact with creosoted stake
And
You eat 1 apple a day

What is the likelihood of eating 1 contact apple everyday for one year?

<table>
<thead>
<tr>
<th>Event</th>
<th>Odds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eating 13 contaminated apples a year</td>
<td>18.000.000 to 1</td>
</tr>
<tr>
<td>Eating a contaminated apple on 3 consecutive days</td>
<td>8.000.000 to 1</td>
</tr>
<tr>
<td>Being killed by lightning</td>
<td>2.000.000 to 1</td>
</tr>
<tr>
<td>Getting a royal flush in the first hand of poker</td>
<td>649.740 to 1</td>
</tr>
<tr>
<td>Odds of dating a supermodel</td>
<td>88.000 to 1</td>
</tr>
<tr>
<td>Die in a car accident</td>
<td>15.000 to 1</td>
</tr>
</tbody>
</table>

**Conclusion: worst scenario used is unrealistic**
Fruit Stakes

CCE objectives:

- Improve the unrealistic worst case scenario to a more realistic worst case scenario.
- Protect both fully treated stakes and bottom treated stakes

CCE addressed two major flaws:

1) Risk Mitigation Measures
   - Washing
   - Rejection of discolored/malformed apples
   - Peeling

2) Only very small part (<0,5%) of the fruit has come in contact with a creosoted stake
Fruit Stakes

KEMI:

No response on unrealistic worst case scenario

But....

proposed amendment (RMM):
"Fruit and berries grown in direct contact with creosote-treated wood during cultivation should be discarded"
Fruit Stakes

Several MS (a.o. Germany and Czech Republic) objected:

- Deeply sceptical the proposed RMM is realised in practice

- NEW objection: Potential skin contact with creosoted stake during fruit picking (seasonal workers & general public).

Zero Risk is the only acceptable risk
Fruit Stakes

KEMI conclusion:

- Can’t proceed because of objections from concerned Member States
- Also, no ability, or resources, to drive this issue further without a submitted application.
- Approval via article 37:
  Any of the Member States concerned may, in particular, propose in accordance with the first subparagraph to refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted for a biocidal product containing an active substance to which Article 5(2) or Article 10(1) applies.

Poland:

- cMS comments impact the Polish decision
- Fruit stakes will also be removed
Fruit Stakes

Outcome

- No (re-)approval expected in cMS opposing fruit stake use (Germany, Austria, Czech Republic) in short term

- Only short term option: BPR article 37

- Major change application in Sweden required to reopen discussion
## Status Approvals

### Official Decisions (14 March 2018)

<table>
<thead>
<tr>
<th>Date</th>
<th>Status</th>
<th>sleepers</th>
<th>poles</th>
<th>stakes h/c</th>
<th>stakes full</th>
<th>equestrian Fencing</th>
<th>highway fencing</th>
<th>marine</th>
<th>bridges</th>
</tr>
</thead>
<tbody>
<tr>
<td>28-2-2018</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Austria**: official
- **Belgium**: official
- **Bosnia-Hercegovina**: official
- **Bulgaria**: official
- **Croatia**: official
- **Finland**: official
- **France**: official
- **Germany**: official
- **Greece**: official
- **Hungary**: official
- **Ireland**: official
- **Latvia**: official
- **Netherlands**: official
- **Norway**: official
- **Poland**: official
- **Spain**: official
- **Slovenia**: official
- **Sweden**: official
- **Switzerland**: official
- **UK**: official

- **wine and fruit growing**
- **Export only**
- **Formal complaint launched**
- **Major Change**
- **Major Change application ongoing**
- **not approved**
- **(temporarily) removed from approval**
• Status Mutual Recognition across Europe
  - Pending actions
  - Fruit Stakes Use
  - Overview

• Renewal of authorization (Active Substance)
  - Status
  - Brexit
  - Expiry Dates
Renewal of authorization (Active Substance)

- Joint submission CCE
- Evaluating Competent Authority: UK HSE

- UK HSE is evaluating the application. Expected to be ready in 2018.

Authorization process includes

- **Public Consultation!**
- **Member State voting**
Brexit
Brexit

PARDON ME SIR, MAY I SUGGEST YOU TO TAKE A PARACHUTE WITH YOU?

THANKS, THE FLAG WILL DO!

You guys are taking a huge risk!
Brexit

• Withdrawal Date: 30 March 2019

• UK HSE is eCA until withdrawal date.

• If work UK HSE is not completed by 30 March 2019 another CA has to take over.
Brexit

- Creosote has been scheduled on the work programme of the Biocidal Product Committee
- Discussion in the WG 12-22 November 2018
- Discussion/adoption of opinion in the BPC on 25 February – 01 March 2019
- Opinion of the Biocidal Product Committee might indeed be finalized before Brexit.
• After Brexit the European Commission still has to take a decision on the renewal application (on the basis of the BPC’s opinion).

Is the renewal of AS authorization process completed before Brexit?
Expiry dates
Expiry dates

- Expiry date AS approval was 30 April 2018

- Commission has postponed the expiry date in December to allow the full evaluation to take place (Decision 2017/2334)

- Expiry date is now 31 October 2020
Exparsity date timeline

Biocidal Product

Active Substance

Annex I Inclusion 2010

Authorisation granted

Authorisation period applied for (renewal)

Authorisation period to be applied for in the future (renewal)
Expiry date timeline

Example: marine use Sweden

Biocidal Product

Active Substance

Annex I Inclusion 2010

March 2016
March 2021
March 2026
March 2031
March 2036

Annex I
Inclusion

2010

April 2020
April 2025
2030
2035

Start of phase out period

Authorisation granted
Authorisation not granted
Authorisation period to be applied for in the future (renewal)
Authorisation period applied for (renewal)
Expiry date timeline

History:
What if

| Biocidal Product | 2013 | April 2020 |
| Active Substance | March 2016 | March 2021 |
|                  | 2026 |

Annex I Inclusion
2010

Start of phase out period

- Authority granted
- Authorisation not granted
- Authorisation period to be applied for in the future (renewal)
- Authorisation period applied for (renewal)

WEI – European Institute for Wood Preservation
Expiry dates

- Biocidal Product: 29 March 2021
- Active Substance: 31 October 2020
- Renewal of expiry date every five years
Thank you for your attention

Questions?
Thank you for your attention

Questions?
Thank you for your attention

Questions?
Figure 1. Flowchart of the biocidal active substance approval process.