



# CREOSOTE

## Regulatory Situation Europe

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- Status Mutual Recognition across Europe
- Status Tree Stakes assessment
- Major Change applications (Biocidal product)
- Free movement of treated articles
- Renewal of authorization (Active Substance)



## Status Approvals

- CA struggle with creosote dossier
- Every CA has its own timeline
- CA lack resources for a timely evaluation
- To obtain priority for application requires perseverance
  
- Eight official decisions
- Several draft decisions by other MS
- Sharing of draft and final decisions
  
- Several draft decisions require major change application



# Status Approvals

## Official Decisions (15 March 2017)

	Status	sleepers	poles	stakes h/c	stakes full	equestrian Fencing	highway fencing	marine	bridges
Austria	official			wine and fruit growing					
Croatia	official								
Finland	official			Export only					
Ireland	official								
Netherlands	official								
Poland	official								
Sweden	official								
Switzerland	official								

	approved
	not yet approved (requires application for change)
	not approved



- Status Mutual Recognition across Europe
- **Status Tree Stakes assessment**
- Major Change applications (Biocidal product)
- Free movement of treated articles
- Renewal of authorization (Active Substance)



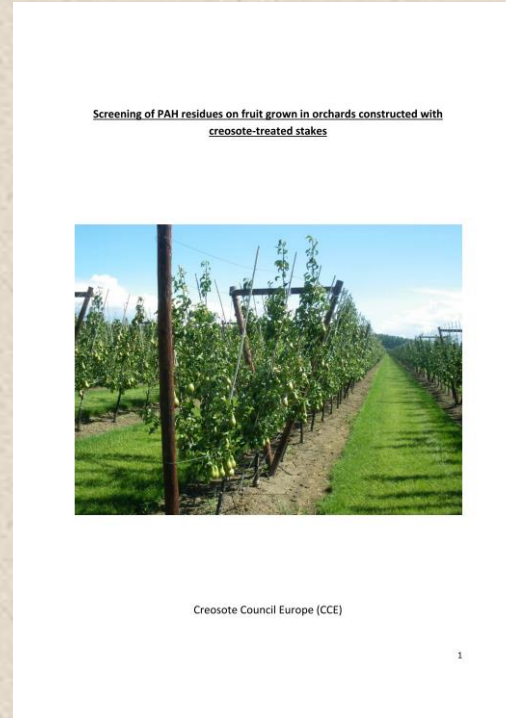
## Status Tree Stakes assessment

### Background:

- A use requires an assessment by the RMS (Sweden/Poland)
- Authorization in CMS via mutual recognition after assessment RMS
- In the case of use as fruit tree stakes and in vineyards, potential residues in fruit and grapes needed to be addressed.
- Background: possible risk to consumer health
- Started 2014
- Final report June 2016



## Status Tree Stakes assessment

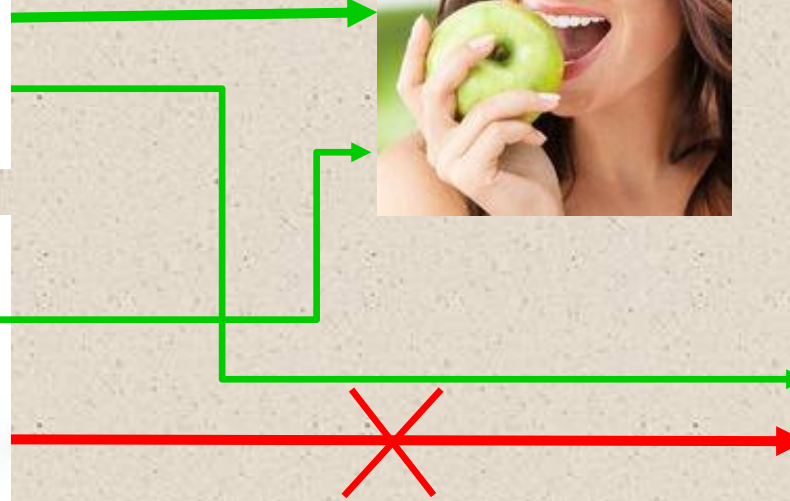


Screening of PAH residues on fruit grown in orchards constructed with creosote-treated stakes



## Status Tree Stakes assessment

### Conclusion



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





## Status Tree Stakes assessment

### Result

- Assessment of creosoted tree stakes is now complete
- Use can be authorised by CMS
- Authorisation requires major change application



- Status Mutual Recognition across Europe
- Status Tree Stakes assessment
- **Major Change applications (Biocidal product)**
- Free movement of treated articles
- Renewal of authorization (Active Substance)



## Application for change using Article 19(5)

- Article 19(5)

a biocidal product may be authorised where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

- Article 8 (procedure for major change of products)

1. Submission of application
2. Payment of fee (within 30 days)
3. Validation of application (compliant with requirements)(within 30 days)
4. Incomplete application: submit additional info (max 90 days)
5. Validation of additional information (within 30 days)
6. Evaluation of application (within 180 days)
7. Agreement on draft assessment report (within 90 days of receipt)
8. Acceptance of major change (within 30 days)



## Application for change using Article 19(5)

### Agricultural stake/support & Fencing posts

- Authorization requires application for major change
- Application for change process can take over 1 year
- Phase out period for non approved uses:
  - 180 days for making the product available
  - 365 days for its use

Difference in timelines can lead to possible gap in supply to the market.

**We can't let this happen**



## Application for change using Article 19(5)

How to prevent possible supply gap

- Preparation of dossier well in advance
- Have all information in place
- Communication with CA prior to submission
- Fee payments asap
- Follow up on information requests asap



- Status Mutual Recognition across Europe
- Status Tree Stakes assessment
- Major Change applications (Biocidal product)
- **Free movement of treated articles**
- Renewal of authorization (Active Substance)



## Free movement of treated articles

The BPR covers biocidal products

- How to use it
- What articles may be treated with it

However, limited coverage of the treated wood

- Labelling
- Rules on import relating to the active substance



## Free movement of treated articles

Labels on treated wood must include:

- A statement that the treated article incorporates biocidal products
- The biocidal property
- The name of all active substances contained in the wood
- Instructions for use, including any precautions to be taken because of the preservative used

Import rules relating to active substances:

- All the active ingredients in the preservative that it was treated with must be approved for EU use in wood preservatives.
- EU approval of active substances is specific in terms of technical quality and supplier

However...





## Free movement of treated articles

- The BPR does not impose rules on movement of treated articles between Member States nor, other than labelling and active substance rules, on import from outside the EU.
- That leaves us with the REACH Annex XVII rules...



## Free movement of treated articles

- REACH Annex XVII imposes restrictions on where wood treated with creosote may be used:
- Wood treated in industrial installations or by professionals according to subparagraph (a) which is placed on the market for the first time or retreated in situ may be **used for professional and industrial use only**, for example on railways, in electric power transmission and telecommunications, for fencing, for agricultural purposes (for example stakes for tree support) and in harbours and waterways.



## Free movement of treated articles

- Treated wood referred to under paragraph 2(b) and (c) shall not be used:
  - — inside buildings, whatever their purpose,
  - — in toys,
  - — in playgrounds,
  - — in parks, gardens, and outdoor recreational and leisure facilities where there is a risk of frequent skin contact,
  - — in the manufacture of garden furniture such as picnic tables,
  - — for the manufacture and use and any re-treatment of:
    - — containers intended for growing purposes,
    - — packaging that may come into contact with raw materials, intermediate or finished products destined for human and/or animal consumption,
    - — other materials which may contaminate the articles mentioned above.



## Free movement of treated articles

### Result:

Wood treated with creosote either in a MS in accordance with national authorisation, or outside the EU, in both cases using an approved creosote may be imported into and used in in a MS (in accordance with REACH) regardless of conditions imposed under a national BPR authorisation of creosote.

### From CA-Sept16-Doc.6.2:

Under this legal framework, the EU approval of an AS obstructing the free movement of wooden articles treated with creosote on the basis of the BPR would exceed the powers conferred to the Commission by the co-legislators and **is therefore not possible.**



## Free movement of treated articles

	sleepers	poles	stakes h/c	stakes full	equestrian Fencing	highway fencing
Sweden	approved	approved	not approved	not approved	not approved	not approved
Finland	approved	approved	Export only			

approved
not yet approved (requires application for change)
not approved

- Impregnation of wood for equestrian fencing in Sweden is restricted.
- Wood impregnated in Finland (treated article) can be imported and used for equestrian fencing in Sweden.



## Free movement of treated articles

A final point on exporting:

- BPR authorisation is not required for use of a wood preservative used solely for treatment of wood for export out of the EU...



- Status Mutual Recognition across Europe
- Status Tree Stakes assessment
- Major Change applications (Biocidal product)
- Free movement of treated articles
- **Renewal of authorization (Active Substance)**



## Renewal of authorization (Active Substance)

- Joint submission CCE
- Evaluating Competent Authority: UK HSE
- Expiry date AS approval 30 April 2018
  
- Application was submitted in time (end of October 2016)
- Tackled several IT issues during submission
- ECHA has forwarded dossier to UK HSE (February 2016)

Authorization process includes

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





## Renewal of authorization (Active Substance)

- BP authorization focused on Member States where creosote is used for **impregnation of wood**
- Support is also needed not only from member states that treat wood but also from member states that **import treated wood**
- No information on any use in 12 European Member States! (Mostly former European MS)
- End User Input Limited



## Downstream and End User input

Impact and Influence of Downstream Users and End Users on creosote authorization process cannot be underestimated!

It is crucial in a successful authorization process.

- Outcome of 2008 stakeholder consultation resulted in Active Substance Authorization
- Biocidal Product Approvals (2016/2017)

Sweden	Finland
Swedish Transport Administration	Finnish Transport Agency
Skanova (telecom network operator)	Finnish Energy (energy sector branche organisation)
Vattenfall AB (electricity grid)	Fingrid Oyj (high voltage grid)
	Centre for Economic Development, Transport and the Environment (bridges)



## Datagaps

Austria	insufficient data
Belgium	data available
Bulgaria	no data
Croatia	no data
Cyprus	no data
Czech Republic	insufficient data
Denmark	no data
Estonia	no data
Finland	data available
France	data available
Germany	data available
Greece	no data
Hungary	insufficient data
Ireland	data available
Italy	insufficient data

Latvia	insufficient data
Lithuania	no data
Luxembourg	no data
Malta	no data
Netherlands	data available
Norway	data available
Poland	data available
Portugal	insufficient data
Romania	no data
Slovakia	no data
Slovenia	no data
Spain	data available
Sweden	data available
Switzerland	insufficient data
United Kingdom	data available

no data
insufficient data
data available

- Get support from **ALL** MS that **impregnate wood or use creosoted wood**
- Every vote counts



Thank you for your attention

**Questions?**