



CREOSOTE

Regulatory Situation Europe

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- **Status Mutual Recognition across Europe**
 - Summary
 - Pending actions
 - Fruit Stakes Use
 - Overview
- Renewal of authorization (Active Substance)
 - Status
 - Brexit
 - Expiry Dates



Summary

	WEI Congress March 2017	WEI Congress September 2017	WEI Congress March 2018
Official decisions	8	17	20

- 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)

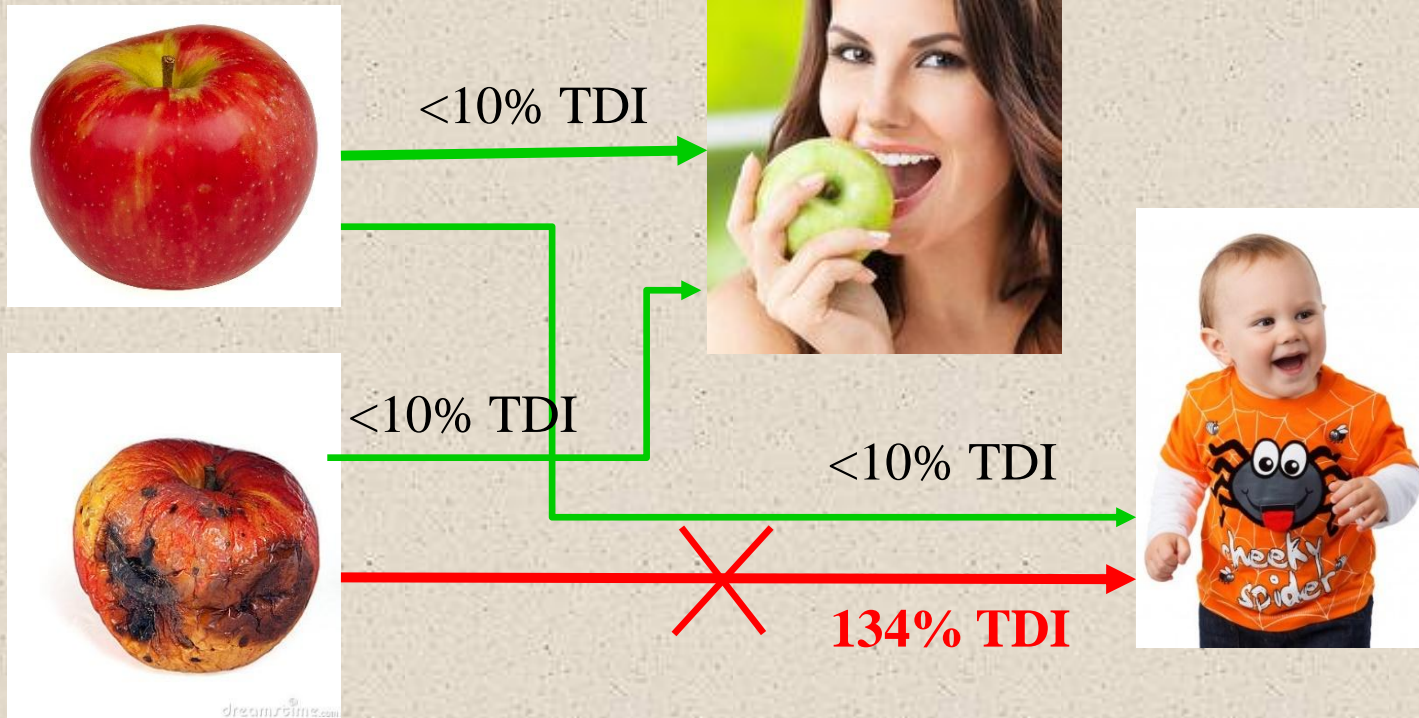


Fruit Stakes



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?

	ODDS
Eating 13 contaminated apples a year	18.000.000 to 1
Eating a contaminated apple on 3 consecutive days	8.000.000 to 1
Being killed by lightning	2.000.000 to 1
Getting a royal flush in the first hand of poker	649.740 to 1
Odds of dating a supermodel	88.000 to 1
Die in a car accident	15.000 to 1

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)

Date									
28-2-20	Status	sleepers	poles	stakes h/c	stakes full	equestrian Fencing	highway fencing	marine	bridges
Austria	official			wine and fruit growing					
Belgium	official								
Bosnia-Hercegovina	official								
Bulgaria	official								
Croatia	official								
Finland	official			Export only					
France	official								
Germany	official								
Greece	official								
Hungary	official								
Ireland	official								
Latvia	official								
Netherlands	official	Formal complaint launched							
Norway	official								
Poland	official								
Spain	official								
Slovenia	official								
Sweden	official					Major Change			
Switzerland	official								
UK	official			Major Change					

	approved
	Major Change application ongoing
	not approved
	(temporarily) removed from approval



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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





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.



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

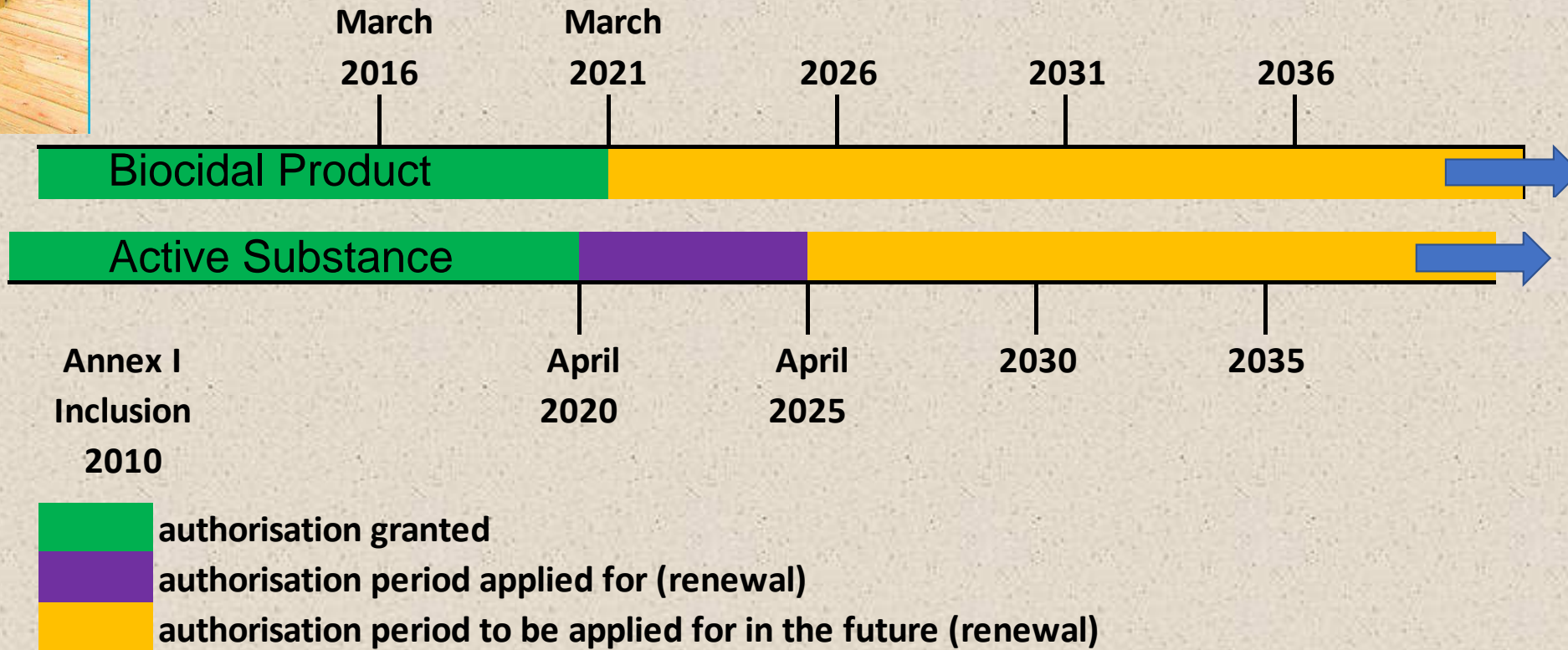


Expiry dates

- 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



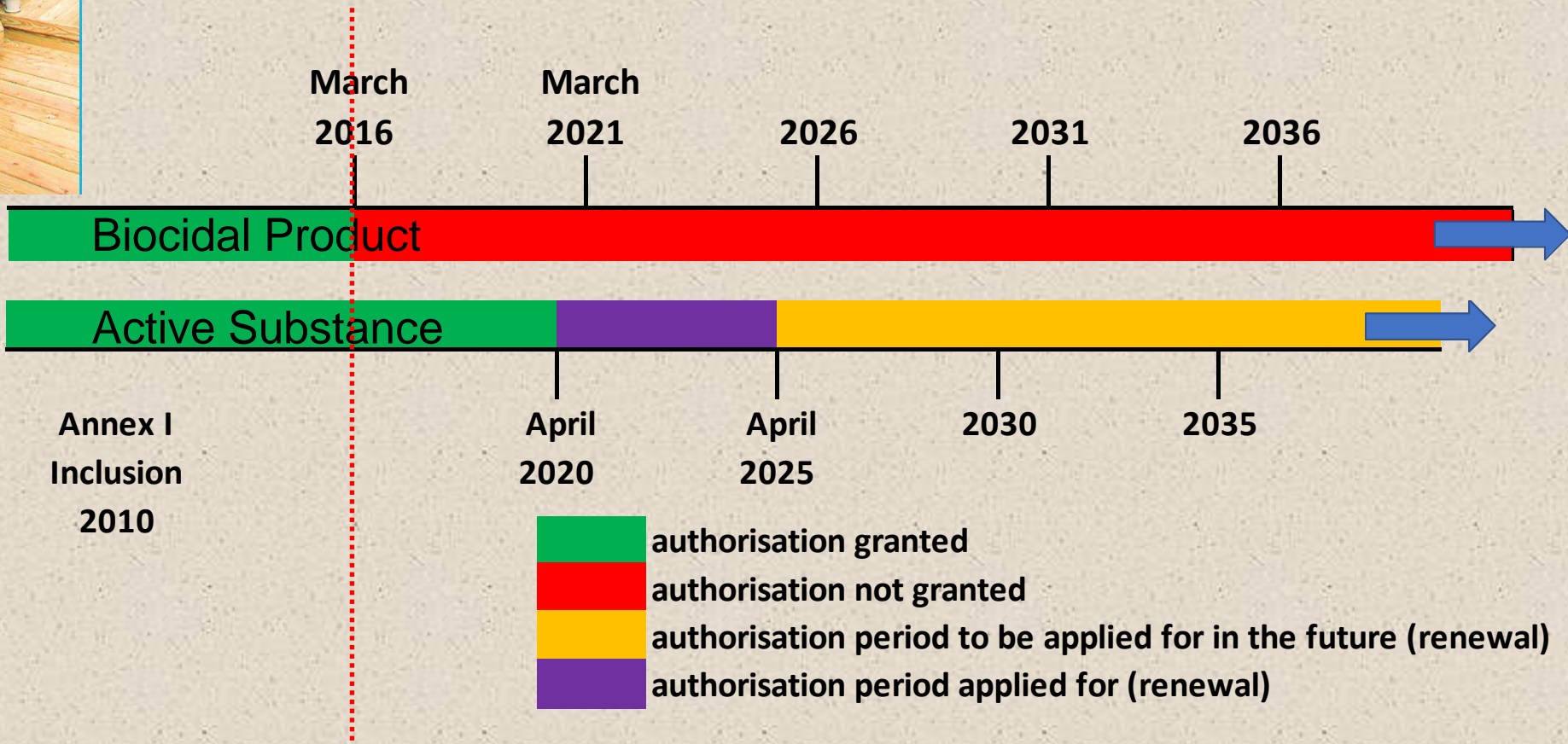
Expiry date timeline





Expiry date timeline

Example: marine use Sweden

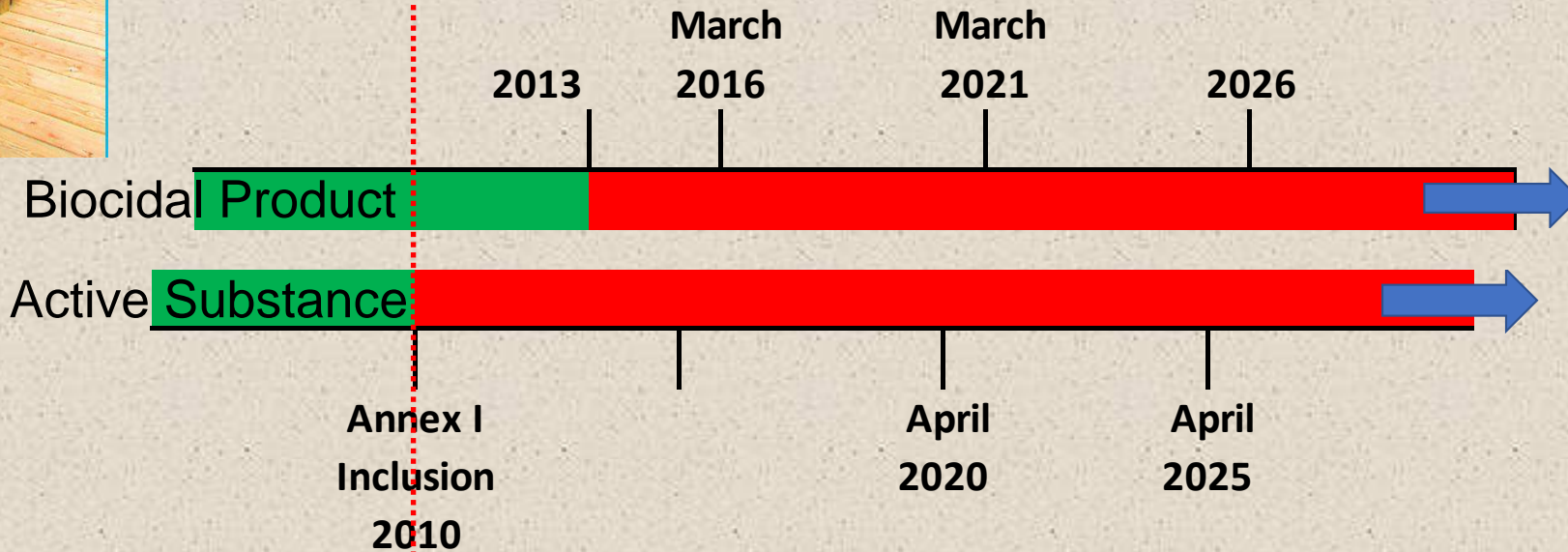


Start of phase out period



Expiry date timeline

History:
What if



2013

March
2016

March
2021

2026

Biocidal Product

Active Substance

Annex I
Inclusion
2010

April
2020

April
2025

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



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

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

