

# Recent developments and current activities in the physico-chemical evaluation of plant protection products

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# content

introduction

legislation

Regulations, basic substances, candidates for substitution, adjuvants, labelling

guidance documents

change of composition, equivalence of a.s., ...

on-going harmonization

packaging, tank mixtures, ...

conclusion





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# legislation: a bit of history

## 1. Directive 91/414/EEC

annex I: list authorized a.s.

annex II: requirements a.s.

annex III: requirements formulations

## 2. Regulation (EC) no 1107/2009

differences:

- implementation
- procedures
- requirements





# legislation: current

Regulation (EC) no 1107/2009

Regulation 540/2011: list authorized a.s.

Regulation 544/2011: requirements a.s.

Regulation 545/2011: requirements  
formulations

Regulation 547/2011: labelling  
formulations





# legislation: current/future

Regulation (EC) no 1107/2009

Regulation 540/2011: list authorized a.s.

Regulation **283/2013**: requirements a.s.

Regulation **284/2013**: requirements  
formulations


Regulation 547/2011: labelling  
formulations





# legislation: future

Regulation (EC) no 1107/2009

- basic substances
- candidates for substitution
- adjuvants 





# legislation: future

Regulation (EC) no 1107/2009

= harmonization

+ simplification (eventually)







# legislation: classification

## Regulation (EC) no 1272/2008: CLP

- classification, labelling and packaging of substances & mixtures
- evaluation formulations = on-going work (June 2015)
  - H(azard) & P(recautionary) statements  
vs. R & S phrases
  - pictograms
  - signal words





# legislation: classification

Regulation (EC) no 1272/2008: CLP

- flammability
- aspiration hazard



# legislation: classification

## Regulation (EC) no 1272/2008: CLP

### - flammability: liquids (flash point)

DSD			CLP		
	FP (°C)	BP (°C)	FP (°C)	BP (°C)	
<b>F+; R12</b>	<0	≤35	<23	≤35	Flam. Liquid 1, H224
<b>F; R11</b>	<21	-		>35	
<b>R10</b>	≥21 and ≤55		≥21 and <23	≤35	Flam. Liquid 1, H224
				>35	Flam. Liquid 2, H225
			≥23 and ≤55	-	Flam. Liquid 3, H226
<b>n.c.</b>	>55 and ≤60		>55 and ≤60		

Notes:

(1) *n.c.*: not classified under DSD

(2) *FP*: flash point

(3) *BP*: boiling point



# legislation: classification

Regulation (EC) no 1272/2008: CLP

- aspiration hazard

R65 → Asp. Tox. 1, H304

- viscosity  $\leq 20.5 \times 10^{-6} \text{ m}^2/\text{s}$  @ 40°C

- > 10% hydrocarbon content

- surface tension **not involved**



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# guidance docs (GDs)

to harmonize interpretation of legislation

several DG Sanco GDs available 

3 recent physchem-related examples:

- composition change
- parallel trade
- equivalence of a.s.



# GDs: composition change

SANCO/12638/2011 

- implemented from March 2013
- currently **rev 2**.

1. non-significant change = notification

= exchanging co-formulant with same amount and chemically identical

2. significant change

= all other changes to co-formulants  
studies may be required



# GDs: parallel trade

SANCO/10524/2012 

- implemented from ?
- Art. 52 of Regulation 1107/2009
- trade is acceptable if ‘identical’:
  1. common origin
  2. composition
  3. (re-)packaging





# GDs: equivalence of a.s.

SANCO/10597/2003 

- acceptability of new sources of a.s. or changes in existing ones
- recent revision: procedure
- Art. 38 of Regulation 1107/2009
- RMS commenting



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# harmonization

e-consultations

on-going e-consultations/harmonizations:

- packaging extrapolation
- tank mixtures, seed treatment, analytical methods, equivalence of a.s., ...



# harmonization: packaging

2 year shelf life study in commercial packaging material

- physchem characteristics different in different packaging materials?
  - unlikely...
- seepage data sufficient?



# harmonization: packaging

extrapolate!

- shelf life study in worst case material
- depending on formulation type
  - solid vs. liquid
  - water- or solvent-based
- none or only seepage data from other packaging



# harmonization: tank mixtures

2.9

*“Physical and chemical compatibility with other plant protection products with which it is to be authorized”*

6.2

*“Where proposed label claims include recommendations...”*

→ harmonized or national?



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# conclusion

slowly but surely to...

## harmonization!

- more EU level co-operation
  - zonal evaluation
  - guidance
  - e-consulation





Thank  
you  
for  
your  
attention!

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