

Implementation of CLP and the safety data sheets Responsible Care . Contribution to sustainable chemical industry in the Balkan region 10 - 11 October 2013 Sofia

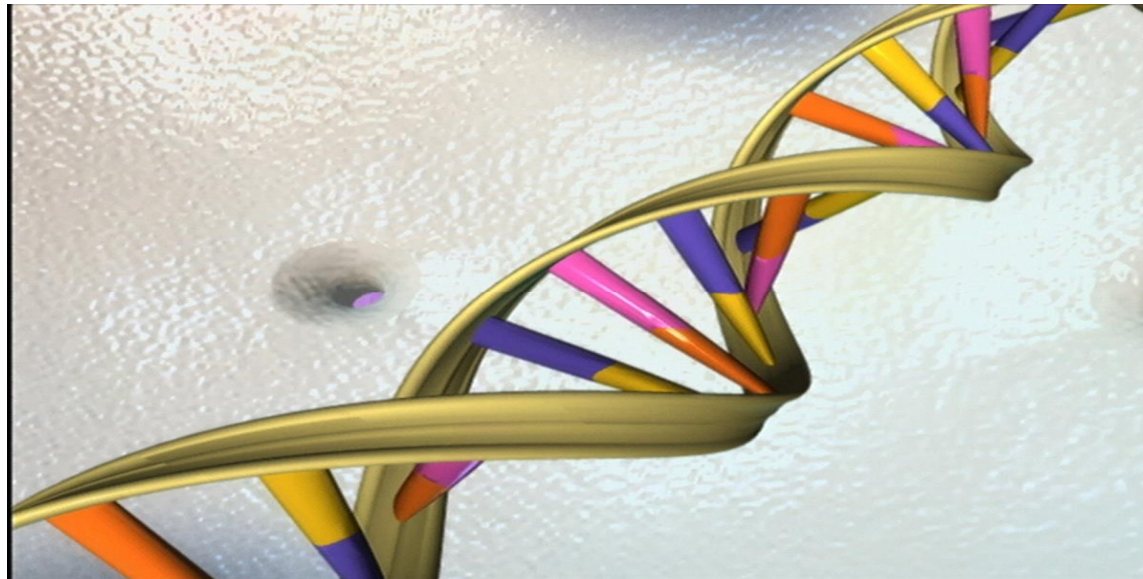


Dr. Erwin Annys

ment REACH – CLP/GHS



- “ Regulation (EC) Nr. 1907/2006 refers to
 - “ Directive 67/548/EEC : 97 times
 - “ Directive 1999/45/EC: 38 times
- “ Regulation (EC) Nr. 1272/2008 refers to
 - “ Regulation (EC) Nr. 1907/2006: 67 times

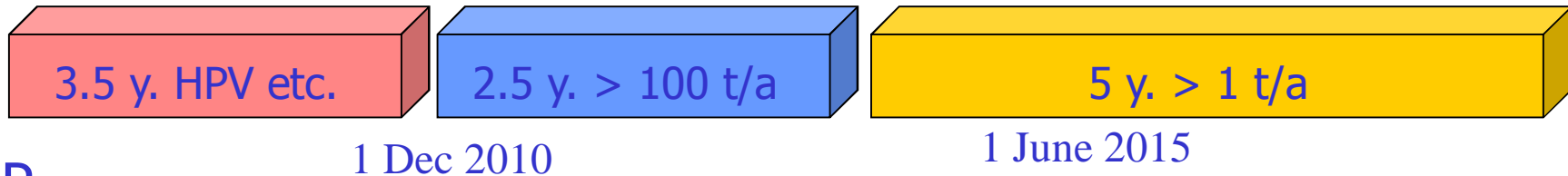


Regulation - timing

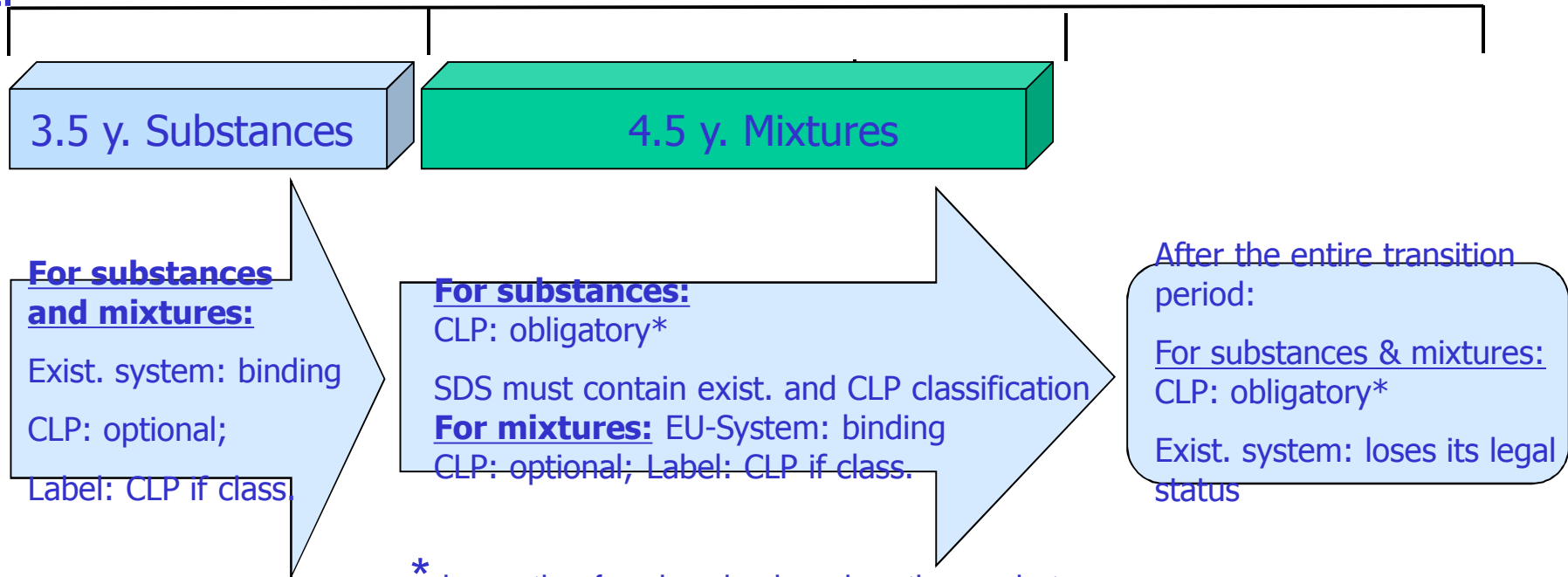


The CLP Regulation entered into force on 20 January 2009

REACH



CLP



* derogation for already placed on the market:

- substances until 1.12.2012 (if pom before 1 Dec 2010)
- mixtures until 1.6.2017 (if pom before 1 June 2015)

Not DSD and DPD!



- “ Not limited to different cut off values (acute toxicity) but as well some differences
 - “ Germ cell mutagenicity
 - “ Reproductive toxicity
 - “ Physico chemical properties
 - “ Sensitisors as introduced by 2nd ATP
 - “ Chronic aquatic toxicity as introduced by 2nd ATP
- “ The changes for mixtures will require a lot of work for companies bringing mixtures on the market
 - “ The classification for mixtures is more complex than it was in the past

on of mixtures



- “ **Different calculations compared to previous legislations**
 - “ **For acute toxicity use of the so called acute toxicity estimates (ATE)**
 - “ **Use of formulas in case of mixtures containing substances without a known toxicity**

on and labelling inventory



- “ Requirement introduced under REACH and taken over by CLP
- “ Industry was confronted with serious surprises as well
 - “ Even for >1000 tpa substances everything was observed
 - “ Less severe classifications
 - “ Much more severe classifications
 - “ But based on what?
 - “ No control possible for industry or for authorities
- “ The deviations are clearly not always related to presence of impurities, different forms,

EC Number	CAS Number	IOPAC Name
203-625-9	108-88-3	toluene

Notified classification and labelling according to CLP criteria

Classification		Labelling			Specific Concentration limits, M-Factors	Not
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	Pictograms Signal Word Code(s)		
Flam. Liq. 2	H225	H225				
Asp. Tox. 1	H304	H304				
Skin Irrit. 2	H315	H315			GHS07 GHS02 GHS08 Dgr	
STOT SE 3	H336	H336				
Repr. 2	H361	H361				
STOT RE 2	H373	H373				
Flam. Liq. 2	H225	H225				
Asp. Tox. 1	H304	H304				
Skin Irrit. 2	H315	H315			GHS07 GHS02 GHS08 Dgr	
STOT SE 3	H336	H336				
Repr. 2	H361					
STOT RE 2	H373					
Flam. Liq. 2	H225	H225				
Asp. Tox. 1	H304	H304				

93/115 entries

STOT RE 1	H372	H372						
		H336						
Flam. Liq. 2	H225	H225						
Asp. Tox. 1	H304	H304						
Skin Irrit. 2	H315	H315	GHS07 GHS02 GHS08 Dgr		80			
Eye Irrit. 2	H319	H319						
STOT SE 3	H335							
Repr. 2	H361	H361						
STOT RE 1	H372	H372						
Flam. Liq. 2	H225	H225						
Asp. Tox. 1	H304	H304						
Skin Irrit. 2	H315	H315	GHS07 GHS02 GHS08 Dgr		61			
STOT SE 3	H336	H336						
Repr. 2	H361	H361						
STOT RE 2	H373	H373						
Flam. Liq. 2	H225	H225						
Asp. Tox. 1	H304	H304						
Skin Irrit. 2	H315	H315	GHS07 GHS02 GHS08 Dgr		59			
STOT SE 3	H336	H336						
Repr. 2	H361	H361						

This should be the first line because normally seen based on the most reliable and controllable information

Organise the clean-up?



“ CLP Article 41 - Agreed entries

- “ Where the notification in Article 40(1) results in **different entries** on the inventory referred to in Article 42 for the same substance, the **notifiers and registrants shall make every effort** to come to an agreed entry to be included in the inventory. The **notifiers shall inform the Agency accordingly.**

Resources for IT suppliers



- “ **Software for classification and labelling and for safety based was including the old Annex I of the DSD with all harmonised classifications and labellings**
- “ **In the past you had as well to consider self-classification, but it was less used**
- “ **Not all endpoints are picked up anymore for industrial chemicals for harmonised classification and labelling under REACH**



EUROPEAN CHEMICALS AGENCY

Forum For Exchange Of
Information On Enforcement

Forum REACH-EN-FORCE 2 Project Report

Obligation of downstream users - formulators of mixtures



- “ Introduced by Directive 91/155/EEC and updated by Directive 2001/58/EC
 - “ Same 16 chapters
 - “ Electronic delivery already mentioned
 - “ Availability in the language where it is put on the market
- “ Repealed by REACH, Annex II has been updated to be in line with GHS requirements after the entry into force of the CLP Regulation
 - “ Registration number
 - “ Inversing chapter 2 and 3
 - “ Mandatory use of sub-chapters

sheets



- “ What is the real problem?
 - “ The safety data sheets or
 - “ The exposure scenarios?

h CSR/ES roadmap



3. Further development of IT tools and standardisation for generating, processing and exchanging CSR and ES information

3.1 Further development of IUCLID and Chesar

3.2

3.3 Develop the phrase library (ESCom) and the electronic exchange format (ESComXML), and set up a transparent and sufficiently resourced mechanism for standardisation

4.1 CSR/ES roadmap



4. Support understanding and processing exposure scenario information at formulators' level

4.1 Intensify cooperation of co-registrants to harmonise advice on safe use for their substance

4.2 Agree on harmonised template for ES for communication to aid information retrieval

4.3 Support for formulators to understand their options when receiving an extended SDS

4.4 Further develop methodology for converting substance information into communication on safe use of mixtures

4.5 Explain and exemplify DU CSR in practice

4.6

5.1.2.3 on CSR/ES roadmap



5. Support understanding and processing exposure scenario information at end-users' level

5.1 Analyse the information needs of different recipients and improve the presentation of information on safe use of mixtures in the SDS

5.2 Spread information to increase awareness in the end-user sectors



- “ **The existing problems with safety data sheets are known and discussed how to improve**
- “ **The exposure scenarios are adding a layer of difficulty**
 - “ **The CSR/ES roadmap has been created to find solutions**
- “ **The CLP classification for mixtures will create additional problems**
- “ **ECHA, Commission, Member States and industry associations are aware of the problems and are trying to find solutions**
- “ **But how to reach the unreachable?**



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