

IMPACT OF NEW EU REGULATIONS ON NATIONAL PPPs MARKET

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NEW EU REGULATIONS

- REGULATION 1272/2008 - CLP -
(REPLACING 67/548/EU DIRECTIVE)
- REGULATION 1107/2009
(REPLACING 91/414/EU DIRECTIVE)

**BOTH OF THEM IMPACTING ON AUTHORIZED
PLANT PROTECTION PRODUCTS**

THE NEW CLP REGULATION

THE NEW CLP REGULATION (CLASSIFICATION, LABELLING AND PACKAGING), INCLUDING ITS ADAPTATIONS TO TECHNICAL PROGRESS (ATPs), HAS CARRIED OUT SIGNIFICANT IMPLICATIONS ALSO FOR SUBSTANCES NOT DIRECTLY INVOLVED IN REACH PROCEDURES, SUCH AS PESTICIDES.

THE CONSEQUENCES PROVIDED FOR SUBSTANCES AND MIXTURES, REGARDLESS OF THE INTENDED USE, HAVE BEEN STAGGERED IN TIME:

- **NEW C&L OF SUBSTANCES** ACCORDING TO CLP BY 1 DEC.2010, WITH SIMULTANEOUS DISPOSAL OF STOCKS.
- **NEW C&L OF ATPs SUBSTANCES** ENTRIES.
- **SUBSEQUENT REVIEW** OF SUBSTANCES MSDS.
- **NEW C&L OF MIXTURES** CONTAINING ATPs SUBSTANCES, BY 1 DEC. 2010, WITH SIMULTANEOUS DISPOSAL OF STOCKS.
- **SUBSEQUENT REVIEW** OF MIXTURES MSDS.
- **REGISTRATION** OF DANGEROUS MIXTURES INTO NATIONAL DATABASES, ACCORDING TO CLP ART. 45
- **NEW C&L** OF MIXTURES ACCORDING TO CLP CRITERIA BY JUNE 2015, FOLLOWED BY A **NEW MSDSs REVISION** AND A **NEW REGISTRATION** IN THE NATIONAL DATABASES ACCORDING TO CLP ART. 45

SUBSTANCES WITH NEW CLASSIFICATION

(ATP)

- **GLUPHOSYNATE AMMONIUM: T (CAT 2-3) R 60-20/21/22-48/20/22-63**
- **DIMOXYSTROBIN: X_N, N (CAT 3) R 20-40-63-50/53 M=10**
- **SULPHUR : X_I, R 38**
- **IMIDACLOPRID : X_N, N R 22-50/53**
- **MCPA : X_N, N R 22-38-41-50/53**
- **MCPA SALTS: X_N, N R 20/21/22-50/53**
- **MANCOZEB: X_N, N (CAT 3) R 43-63-50**
- **CHLOROTALONIL : T⁺, N : R 26-37-40-41-43-50/53**
- **FOLPET: X_N, N R 20-36-40-43-50 + SCLs***
- **ESFENVALERATE : NEW SCLs***
- **SEVERAL PYRETROIDS : NEW SCLs***

* SPECIFIC CONCENTRATION LIMITS

CO-FORMULATING AGENTS WITH NEW CLASSIFICATION (ATP)

- **N-METHYL-2-PYRROLIDON:**
T (CAT 2) R 61-36/37/38

R 61 SCL* 5%

R 36/37/38 SCL* 10%

- **3-HEXYLHEPTAMETHYLTRISILOXANE:**
XN, N: R 20-53

IMMEDIATE CONSEQUENCES :

NEW CLASSIFICATION OF

SUBSTANCES AS INTRODUCED BY

ATPs

AT NATIONAL LEVEL, 1ST ATP TO THE NEW CLP SEEMS TO HAVE AFFECTED ONLY LIMITED NUMBER OF AUTHORIZED ACTIVE INGREDIENTS ALTHOUGH IMPACTING A LARGE NUMBER OF MIXTURES (> 400), INCREASING IF WE ALSO CONSIDER CO-FORMULATING AGENTS.

DELAYED CONSEQUENCES:

CLP APPLICATION TO MIXTURES

- **IRRITATING CUT-OFF VALUES LOWERED TO 10% INSTEAD OF CURRENT 20%**
- **REPROTOXICITY: CUT OFF VALUES → →**
 - LOWERED TO 3% INSTEAD OF CURRENT 5% (CAT 2 EX CAT 3).**
 - LOWERED TO 0.3% INSTEAD OF CURRENT 0.5% (CAT 1 A-B, EX CAT 1-2)**

EFFECTS :

MORE MIXTURES CLASSIFIED AS IRRITATING AND REPROTOXIC

COST

UPDATING LABELS FOR AFFECTED SUBSTANCES

ESTIMATED ON THE BASIS OF 600 CHANGES TO EXISTING CLASSIFICATIONS FOR SUBSTANCES.

RELABELLING COSTS € 570 (MAX) PER SUBSTANCE .

ESTIMATED 10 SUPPLIERS PER SUBSTANCE.

UP TO

€3.400.000

UPDATING LABELS FOR PREPARATIONS CONTAINING AFFECTED SUBSTANCES

ESTIMATED 25% OF SUBSTANCES USED IN PREPARATIONS.

FOR EACH SUBSTANCE, 100 PREPARATIONS REQUIRE RELABELLING.

RELABELLING COSTS € 570 (MAX).

UP TO

€8.500.000

RELABELLING COSTS FOR PESTICIDE LABELS

ESTIMATED THAT 10% OF SUBSTANCES IN ATP ARE ACTIVE PESTICIDE SUBSTANCES, AND THAT THESE ARE USED IN 10X NUMBER OF PRODUCTS, OF WHICH 10% HAVE A BOOKLET STYLE LABEL.

COST OF UPDATING BOOKLET-STYLE LABEL IS ESTIMATED AT € 4000 (MAX) PER SUBSTANCE.

UP TO

€340.000

UPDATING SAFETY DATA SHEETS FOR SUBSTANCES

ESTIMATED 10 SUPPLIERS PER SUBSTANCE.

COST ESTIMATES TO €360 (MAX) TO UPDATE SDS PER SUBSTANCE PER SUPPLIER.

UP TO

€2.200.000

UPDATING SAFETY DATA SHEETS FOR PREPARATIONS

ESTIMATED 25% OF 600 SUBSTANCES USED IN PREPARATIONS, AND 100 PREPARATIONS PER SUBSTANCE. COST ESTIMATES TO €360 (MAX) TO UPDATE SDS PER SUBSTANCE PER SUPPLIER.

UP TO

€5.500.000

REGULATION 1107/2009

FOR THE SPECIFIC CATEGORY OF PLANT PROTECTION PRODUCTS,
THE RULES SETTLED BY THE NEW REGULATION 1107/2009 WHICH REPLACES
DIRECTIVE 91/414/EU ,ADDS NEW CUT-OFF CRITERIA RELATED TO CLASSIFICATION.
THIS REGULATION PROVIDES THAT AN ACTIVE SUBSTANCE IS APPROVED FOR
USE AS PLANT PROTECTION PRODUCTS ONLY IF:

- IT IS NOT CLASSIFIED AS C (CARCINOGEN) 1A AND 1B (EX 1 & 2), UNLESS HUMAN EXPOSURE IS NEGLIGIBLE
- IT IS NOT CLASSIFIED AS M (MUTAGEN) 1A AND 1B (EX 1 & 2)
- IT IS NOT CLASSIFIED AS R (TOXIC FOR REPRODUCTION) 1A AND 1B (EX 1 & 2), UNLESS HUMAN EXPOSURE IS NEGLIGIBLE
- DOES NOT HAVE AN ADVERSE EFFECT ON THE ENDOCRINE SYSTEM, UNLESS EXPOSURE IS NEGLIGIBLE (WAITING FOR A CLEARER DEFINITION WITHIN 2013)

THE NEW CRITERIA FOR CLASSIFICATION SET BY THE CLP PROVIDE A SERIES OF OUTCOME ON THE NUMBER AND QUALITY OF SUBSTANCES APPROVED IN THE LIGHT OF THE NEW REGULATION.

UK IMPACT STUDY (PSD)

- 286 SUBSTANCES EVALUATED
- 19 SUBSTANCES (15%) FALLING INTO NEW REGULATION CUT-OFF CRITERIA
- SOME UNCERTANTIES DERIVING FROM NOT YET CLEAR DEFINITION OF EDs

REMOVAL FROM THE MARKET: DIFFERENT CONCLUSIONS

	PSD – EU	PSD – UK	ECPA
INSECTICIDES	6-10 %	5-10 %	8-20 %
FUNGICIDES	8-32 %	7-35 %	12-34 %
HERBICIDES	4-10 %	5-12 %	10-23 %

CANDIDATE TO SUBSTITUTION: UK APPROACH

- **INSECTICIDES** **38%***
- **FUNGICIDES** **20%***
- **HERBICIDES** **24%***

(*) OUT OF 100%

SWEDEN IMPACT STUDY (KEMI)

- 271 SUBSTANCES EVALUATED
- 23 SUBSTANCES (11%) FALLING INTO NEW REGULATION CUT-OFF CRITERIA.

AMONG THESE*:

- CMR (7)
- ED (11)
- PBT / vPvB (4)

* POSSIBLE COUPLED PROPERTIES

ITALIAN IMPACT STUDY (ISS)

235 ACTIVE INGREDIENTS CURRENTLY MARKETED IN ITALY HAVE BEEN CONSIDERED FOR EVALUATION OF THE POTENTIAL EFFECTS DERIVING FROM NEW REGULATION CUT-OFF CRITERIA.

- **WORKING APPROACH HAS BEEN DEFINED TAKING INTO ACCOUNT DIFFERENT HARMONIZED OR PUBLISHED CLASSIFICATION (EU, WHO, EPA, IARC, PAN, FOOTPRINT)**
- **THE STRICTEST DEFINITION OF ENDOCRINE DISRUPTOR PROVIDED BY SEVERAL NATIONAL EU AUTHORITIES (KEMI, PSD, GERMAN FMFACP) HAS BEEN CONSIDERED**

ITALIAN IMPACT STUDY (ISS)

235 SUBSTANCES EVALUATED*

- 12 CMR
- 24 ED
- 9 PBT
- 2 vPvB

*

POSSIBLE COUPLED PROPERTIES

CANDIDATE TO SUBSTITUTION: ITALIAN (ISS) APPROACH

- 26 CS/ POP
- 93 CS/ PBT
- 36 GW
- 29 EFFECTS ON BEES
- 7 ADI
- 13 ARFD

* POSSIBLE COUPLED PROPERTIES

RESULTS

DIRECT IMPACT ON **12** SUBSTANCES CURRENTLY CLASSIFIED AS **CMR CAT 1B**, ACCORDING TO THE NEW CLP CRITERIA AND DEFINITIONS.

TAKING INTO ACCOUNT OTHER PROPERTIES AS DEFINED FOR A POSSIBLE CUT-OFF APPROACH:

24/235 SHOWED ENDOCRINE DISRUPTION PROPERTIES

9/235 HAVE BEEN FOUND POSSIBLE PERSISTENT/BIOACCUMULATING/TOXIC (PBT)

2/235 HAVE BEEN FOUND VERY PERSISTENT /VERY BIOACCUMULATING (vPvB).

AS FAR AS THE POSSIBILITY OF A COMPARATIVE ASSESSMENT,

26 SUBSTANCES MET AT LEAST 1/3 POP (PERSISTENT ORGANIC POLLUTANT) CRITERIA

93 SHOWED AT LEAST 1/3 PBT CRITERIA.

36 HAVE BEEN FOUND POSSIBLE GROUND WATER CONTAMINANT **AND**

29 SHOWED POSSIBLE EFFECTS ON BEES.

7 SUBSTANCES WERE POSSIBLY SUBSTITUTED FOR THEIR ACCEPTABLE DAILY INTAKE VALUE (ADI) **AND 13** FOR THEIR ACUTE REFERENCE DOSE (ARfD).

OBVIOUSLY, MORE THAN ONE OF THIS NEGATIVE EFFECTS COULD BE COUPLED FOR EACH SINGLE SUBSTANCE.

POSSIBLE REMOVAL FROM
THE MARKET ACCORDING TO
ISS APPROACH:

- **HERBICIDES 10%**
- **FUNGICIDES: 10%**
- **INSECTICIDES: 5%**

CANDIDATE TO SUBSTITUTION ACCORDING TO ISS APPROACH:

- **HERBICIDES 8%**
- **FUNGICIDES: 15%**
- **INSECTICIDES: 25%**

CONCLUSIONS

THE NEW PROCEDURES PROVIDED BY NEW REGULATION ARE LIKELY TO RESULT IN PHASING OUT OF SOME SUBSTANCES AFTER THEIR ANNEX I REGISTRATION HAS EXPIRED.

HOWEVER, EVEN IF THIS HAPPENS, THERE IS THE POSSIBILITY OF A FURTHER FIVE YEARS EXTENSION SUBJECT TO DEROGATION.

THIS WILL SIGNIFICATIVELY HELP TO REDUCE THE SHORT-TERM IMPACT AND WILL ALLOW TIME FOR ALTERNATIVE SUBSTANCES .

CONCERNING THE FUTURE AVAILABILITY OF ALTERNATIVES ,THE RELUCTANCE OF SOME MANUFACTURERS TO REGISTER NEW OR ALTERNATIVE SUBSTANCES, EITHER FOR COST OR BECAUSE OF NATIONAL/REGIONAL MARKETING STRATEGIES SHOULD BE CONSIDERED.

WHEN SUBSTANCES ARE WITHDRAWN UNDER THE NEW REGULATION, COST OF THE DATA PACKAGE NECESSARY FOR REGISTRATION, AS WELL AS THE REGISTRATION ITSELF COULD LEAD TO THE CHOICE OF NEW OR ALTERNATIVE PRODUCTS , EVENT THAT MAY BE PARTICULARLY LIMITED IN SOME COUNTRIES.