

EU REGULATIONS AND THEIR IMPACT ON THE MARKET POSITIONS OF A HUNGARIAN CHEMICAL PRODUCER SME

AGROTERM LTD

INTRODUCTION OF THE COMPANY

- × Foundation: 1991
- × Number of employees: 50
- × Ownership: privately owned by Hungarian individuals

ACTIVITIES

- × Pesticides

- × Other products:

 - + Potassium metabisulphite (E224)

 - + Potassium sulphite

 - + Dithiocarbamates (trade name: PERESTOP)

 - + Potassium/sodium/ammonium hydrogen sulphite

PESTICIDES – COPPER COMPOUNDS

- × Bordói Por[®] *(Bordeaux mixture)*
- × Bordóilé Neo SC[®] *(liquid bordeaux mixture)*
- × Bordóilé+Kén Neo SC[®] *(liquid bordeaux mixture+sulphur)*
- × Rézoxiklorid 50 WP *(copper oxychloride)*
- × MILTOX Special Extra WP *(mankozeb+COC)*
- × Rézkén 650 FW *(COC+Sulphur)*
- × Olajos Rézkén *(COC+Sulphur+oil)*

PESTICIDES II.

- × Lime sulphur+oil
- × IPAM 40 (metham ammonium)

REACH

**REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
OF 18 DECEMBER 2006 CONCERNING THE REGISTRATION, EVALUATION, AUTHORISATION
AND RESTRICTION OF CHEMICALS**

REACH – LANGUAGE BARRIERS

- × legal, technical English is hard to understand
- × legal uncertainties
- × REACH-IT, IUCLID (official form for submission) only available in English
- × guidance documents (hundreds of pages)– slow translation
- × work in SIEFs, all communication in English
- × specialised staff

SUGGESTIONS

- × better training for SMEs
- × provide documents in the language of the MS on time
- × legal help

REACH – IT TOOLS

- × IUCLID, REACH-IT
 - × difficult to use
 - × continuously changing
 - × requires IT expert (plugins, updates)

REACH – SAFETY DATA SHEETS

- very strict rules apply to the content, layout, language and the availability of the SDSs
- in practice – little has changed
- if not provided – change supplier?
- members of the supply chain are all liable for the existence and content of the SDSs
- exposure scenarios
- language – translation into different languages
- inspections

SUGGESTIONS

- × Software and database developed by ECHA
 - + linked to IUCLID, CHESAR and REACH-IT databases
 - + help to prepare SDS and ES in each EU language

REACH – COSTS OF REGISTRATION

- × SME: lack of capital, financial resources
- × reduced fee for REACH registrations
- × requirement: a **fair and transparent access** to data
- × **Letter of Acces**: fix price, different price for members and outsiders, not clear what is included in the price
- × costs and the number of members of the consortia are not predictable ⇒ additional future expenses
- × Σ : a **huge competitive disadvantage** for SMEs + substances may disappear

REACH - SUGGESTIONS

- × EU ownership of data
- × proportionate distribution of fees on the basis of the production volume
- × EU fund to provide resources for SMEs to pay for legal services and experts helping them to comply with the provisions of the regulation

SUGGESTIONS - SUMMARY

- × more useful support and a clearly stronger protection
- × detailed explanation of what *transparent, fair* and *non-discriminative* means
- × more involvement in SIEF-activities (ECHA)
- × payment of fees by installments
- × subsidies

ISSUES NOT MENTIONED

- × What if there is no lead-registrant?
- × SVHC substances
- × endocrine disruptors
- × Intermediate substances
- × nano materials

PESTICIDES

1107/2009/EC, 2009/128/EK, 91/414/EGK

REGISTRATION OF PESTICIDES

- × Pesticides – considered registered in REACH
- × Registration process – 2 basic steps – shared responsibility
 - × active ingredient – EU level
 - × formulation – Member State (national) level

AUTHORIZATION OF ACTIVE SUBSTANCES

- × Hazard based assessment
- × RMS
- × Annex I – positive list of AIs
- × validity for 10 years

AUTHORIZATION OF FORMULATIONS

- × national level
- × Annex III dossier
- × zonal authorisation
- × mutual recognition
- × 200-300.000 Euro / product + national costs

PROBLEMS

- × extremely complex , many uncertainties
- × products disappear (withdrawal or non-registration)
- × „double registration” (AIs & formulation)
- × national production decreases – import
- × LoA
- × CLP – only labels approved by the Authorities – modification of the registration

Thank you very much for your kind
attention!