Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Consumer Protection, Departement Chemicals

Chemical Regulation in Switzerland

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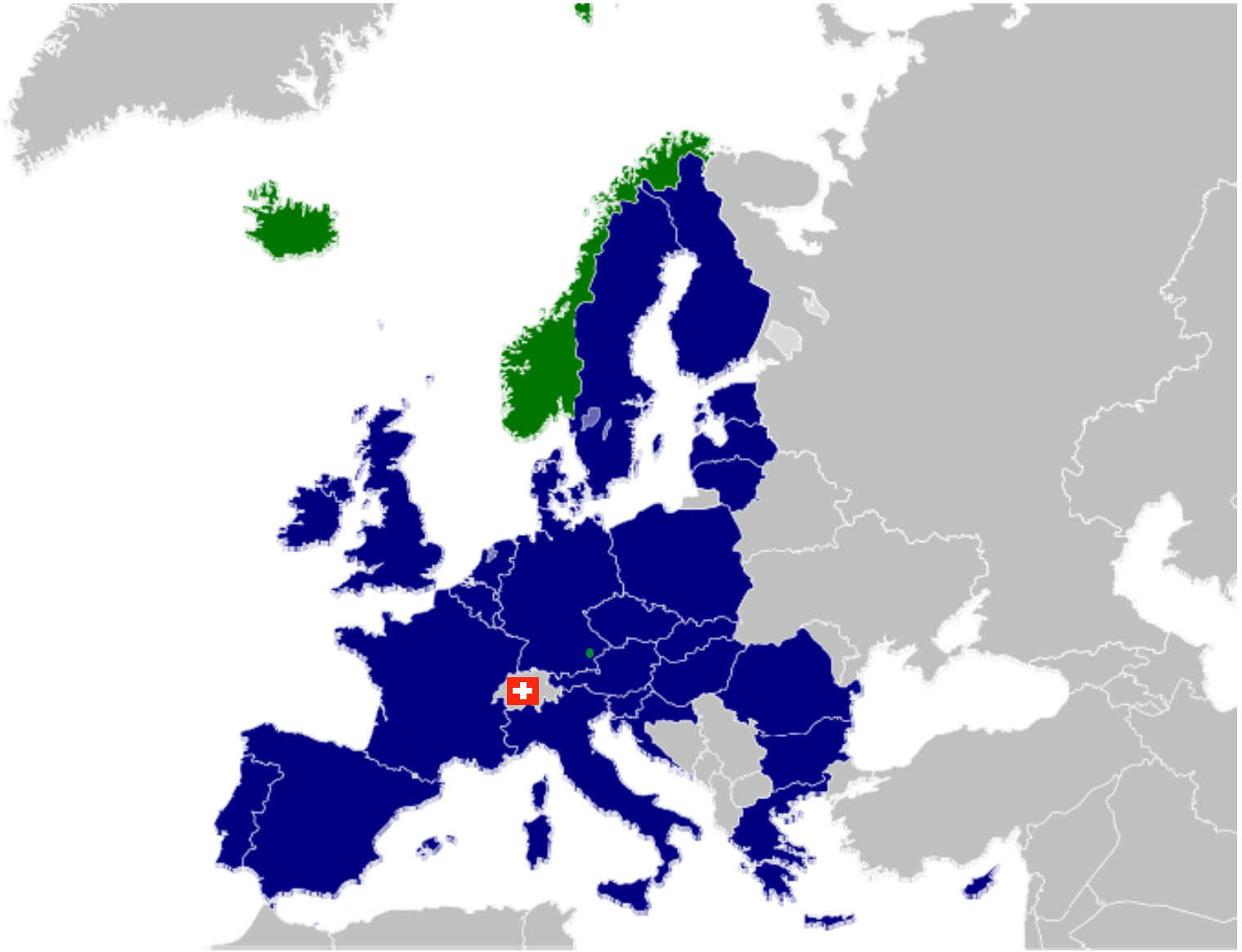
Content

- Switzerland as non EU Country
- Legislation on chemicals
- No data no market (registration)
- Regulatory risk reduction measures
- Enforcement



EU

EFTA_EEA

Switzerland

\+

EEA
European
Economic
Area

Switzerland (CH) as non EU Country

- CH is not EU Member State. Is EFTA member but not EFTA_EEA (Norway, Iceland, Liechtenstein)
  - No bilateral agreement with EU in chemicals area, but mutual recognition agreement in biocide products authorization.
- OECD member state
  - Participation in various programs on chemicals
- UN member state
  - Participation in chemicals programs (GHS)

Switzerland (CH) as non EU Country

- Trade on chemicals

  CH exports 61,5% / 39 Mrd CHF to EEA and imports 83,7% / 30 Mrd from EEA (value 2006)

  - Technical barrier to trade with EEA should be avoided (law)

- Health and Environment protection :

  - Population expects a level of protection similar to EU
  - Industry expects less charges as in the EU

Switzerland (CH) as non EU Country

- Consequence

Chemical Regulation in Switzerland should be largely harmonised with the EU legislation (REACH, CLP, BPR)

For political reasons, the chemical regulation should be independent of the EU legislation [static reference]

Swiss Legislation on chemicals

- On scope: Industrial chemicals and biocide products

Adotped by Parliament

Laws

Modification takes several years



Adopted by Federal Council or Department

Ordinances (applicable)

Modification takes Monthes (3 - 12)

Legislation on chemicals - Development

- 1976
  Legislation on poison substances

- 2005
  Legislation on chemicals, harmonised with EU Directives

- 2007 (EU REACH) and 2010 (EU CLP)
  Successive adaptations of the Swiss ordinances

Legislation on chemicals – actual acts

- Main ordinances

  on chemicals (ChemO)

  https://www.admin.ch/opc/en/classified-compilation/20141117/index.html

  on chemical risk reduction (ORRChem)

  https://www.admin.ch/opc/en/classified-compilation/20021520/index.html

  on biocidal products (OPB)

  https://www.admin.ch/opc/en/classified-compilation/20021524/index.html

Legislation on chemicals – Harmonisation with EU

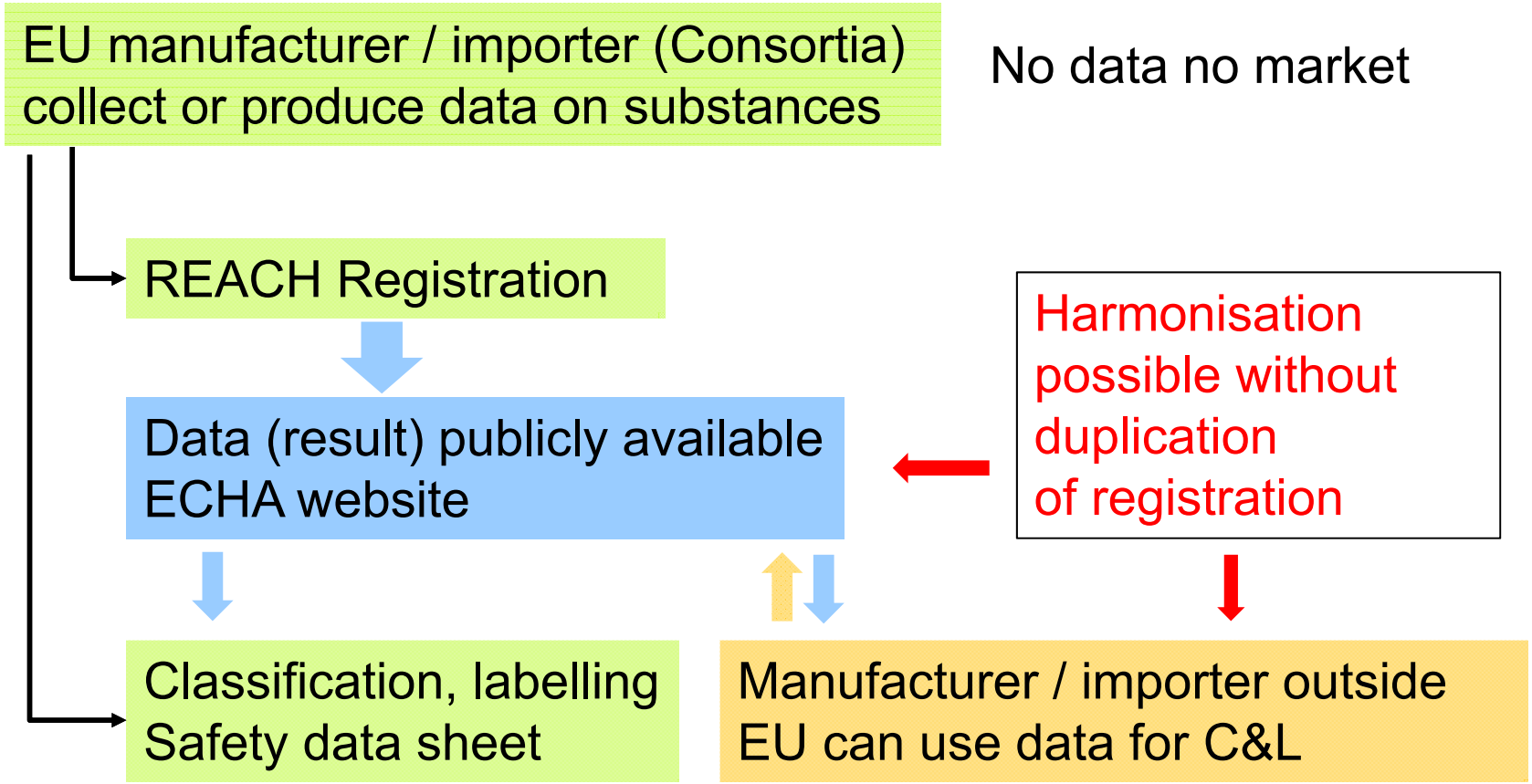
How to harmonise different legislations ?

- Introduce same requirements concerning
  - Classification, labelling, safety data sheet
- Introduce same risk management measures
  - Official classification, restrictions, authorisations

Then

- Consider available information on substances to update the legislation [autonomous follow-up]

How to harmonise with Registration



How to harmonise Risk Reduction Measures

EU Authorities
evaluate danger and risk
of certain substances

- Official C&L (annex VI CLP) → Apply as such
- Restrictions
  Annex XVII REACH
- Subst. very high concern
  Autorisation list (annex XIV)

→ National CH legislations and socio-economic aspects should be evaluated to decide how to apply EU decisions

Harmonisation possible without duplication of (all) evaluations

Comparaison CH – EU legislations

EU	CH	Remarks
CLP (GHS) Classifcation, labelling, packaging	Same requirements ChemO	To avoid technical barriers
CLP Official classification	Same requirements ChemO	To avoid technical barriers
REACH Registration	Notification of new substances ChemO	Dossier as defined by REACH annexes
REACH Restrictions	Similar requirements ORRChem	Decision case by case concerning substances
REACH Authorisations	Similar requirements ChemO, ORRChem	Decision case by case concerning substances

CH Notification compared to EU registration

- CH notification of new substances is consequence of previous EU system [established in the law]
- Notification dossier same as registration dossier

- Notification requirements should be revised to cover only (EEA) non registered substances
  - Avoid duplication
  - Ensure «no data no market» principle

Obligations Manufacturer / Importeur

EU	Switzerland CH
Registration substances > 1 T/year	Only new substances > 1 T/year Export not taken into consideration
Classification and labelling	Same requirements
Safety data sheet Exposure scenario	Same requirements
	Communication to product register

Evaluation of substances

EU:

- Evaluation of some registred substances [selection criteria] ► CoRAP

CH:

- Limited evaluation of new substances
- Cooperation with one EU Authority with CoRAP

Regulatory Risk Management Measures

- Measures decided by authorities to ensure a high level of protection of health and environment
  - Official classification & labelling of substances
  - Restrictions
  - Substances of very high concern [SVHC] and Authorisation list

Autonomous follow-up

EU Authority proposal to regulate a substances

Publicly available on ECHA website
> Supporting dossier
> Public consultation

Decision Commission

CH Authorities evaluate publicly available data and Commission decision

CH Decision
6 to 18 month later

Autonomous follow-up

- Classification and Labelling (update without evaluation)
- Restrictions
  - update after evaluation of other national legislations. Decision may be different as in EU.
- SVHC and authorisation list
  - update after evaluation of other national legislations and socio-economic situation. Decision may be different as in EU.

CH own risk reduction measures

- CH can regulate substances which are not or otherwise regulated in EU

Examples:

Phosphate in cleaning products

Lead in paints

Are more severly restricted in CH

CH own rules for handling of dangerous products

- Concern: acute and chronic toxic and corrosive products
  - These product should not be offered to private user in self service
  - Supplier (non self service) should inform private users on precautions required and correct disposal

Enforcement

- Enforcement is important to improve correct application of the legislation



  - Product's labels not correct (~ 50%)
  - Safety data sheets not complete
  - ……..

Enforcement organisation

- Each «Canton» (26 Cantons) has its own enforcement team
- Coordination by Ministry of Health. Limited cooperation with EU programs
- Measures in case of non compliance
  - Correction of label or safety data sheet
  - Retrieval of the product from the market

Organisation of the Swiss Competent Authority







Enforcement - Inspectors
26 cantons

NOTIFICATION AUTHORITY

MANUFACTURER

Situation for CH Industry

- Advantages
  - No registration of all substances and intermediates
  - Pre-marketing concept (export is not considered)
  - Socio-economic aspects better taken into consideration
- Disadvantages
  - CH decisions (eg classification) not recognized in EU
  - Authorisation procedure too costly for small CH market
  - Stricter enforcement

Conclusion

- Chemicals legislation in Switzerland is independent but largely harmonised with EU legislation
- Manufacturer / importer should use publicly available data (based on REACH registration) to fulfil their obligations
- Authorities evaluate publicly available data / information to update regulatory risk management measures
  - Similar level of protection with limited resources

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