

# WTO conformity of a REACH extension concerning authorisation of SVHC present in imported articles

Martin Führ / Julian Schenten (sofia)

# I. Subject matter

## ▶ **Current legal situation**

- REACH authorisation scheme (Art. 56 et seq.) only applies to SVHC used in EEA
- Use in third countries (e.g. incorporation of SVHC in product) not covered
- REACH treats European articles more strictly

## ▶ **Consequences**

- Competitive disadvantage for EU-producers
- (Potential) burden for human health and the environment

# I. Subject matter

- ▶ Possible solution: **extended authorisation**

*Modify Art. 56 REACH to the extent that Paragraph 1 also covers the import of an Annex XIV substance when incorporated into articles, where this substance is present in these articles, e.g. in a certain concentration.*

# I. Subject matter

- ▶ Aims of **WTO**:
  - Reduce restrictions to international trade
  - “primary purpose is to open trade for the benefit of all”
- ▶ **Potential area of conflict**
- ▶ **Starting point for legal analysis**

## II. Applicable law

- ▶ TBT [Technical Barriers to Trade]-Agreement
  - Authorisation scheme = „technical regulation“
  - Focus on Art. 2.1, 2.2 TBT
    - 2.1: National treatment and most-favoured nation treatment
    - 2.2: Prohibition of unnecessary obstacles to international trade




# III. TBT assessment (Art. 2.1)

- ▶ National treatment and most-favoured nation treatment
- ▶ Violation i.a. if
  - (1) Imported products from third countries are „like“ domestic (EEA) products or products from other third countries; **and**
  - (2) Products from third countries enjoy less favourable treatment than “like” domestic products or products imported from other third countries

## III. „likeness“ analysis (Art. 2.1)

- ▶ Pairing to be compared:
  - Domestic article without SVHC
  - Imported article with SVHC
  
- ▶ Appellate Body (AB):
  - Check competitive relationship
  - Risk is an important factor in determination (*EC-Asbestos*)

## III. „likeness“ analysis (Art. 2.1)

- ▶ Assessment criteria i.a.
  - Properties, nature and quality of the products 
  - End-uses 
  - Consumer tastes and habits 
  
- ▶ There are pairings conceivable, where articles can be deemed “like”



# III. Supplementary opinion

- ▶ If one assumes likeness: are imported products treated less favourably?
  - Text of regulation: **no de jure** discrimination
  - Also **no de facto** discrimination:
    - Regulatory aspects which might “detrimentally impact” non-EEA producers (e.g. necessity of establishment in the Community) solely based on legitimate distinction criteria

# III. Conclusion (Art. 2.1)

In any case:

An extended authorisation regime would not violate Art. 2.1 TBT

## IV. TBT Agreement Art. 2.2

- ▶ “Members shall ensure that technical regulations are not (...) creating unnecessary obstacles to international trade. For this purpose,
- ▶ **technical regulations shall not be more trade-restrictive than necessary**
- ▶ **to fulfil a legitimate objective. (...)**”

# IV. TBT Agreement Art. 2.2

- I. Is the extended authorisation trade restrictive?
  - Yes → non-compliance causes barrier to market access
- II. More trade-restrictive than necessary?
  1. Legitimate objective(s)? ✓
  2. Contribution to fulfil the objective(s)? **(appropriateness)**
  3. More trade-restrictive than necessary for the achieved degree of fulfilment?

## IV. Appropriateness (Art. 2.2)

- ▶ AB: “Degree of contribution toward the achievement of the legitimate objective”
- ▶ COM: Empirical data of „REACH Review“ confirm intended substitution effects → results transferable
- ▶ **Conclusion:**  
Extended authorisation requirement contributes to its objective

## IV. Necessity (Art. 2.2)

- ▶ „Relational analysis“ of
  1. actual trade restrictions ✓
  2. contribution to legitimate objective ✓
  3. the risks non-fulfilment would create
  4. availability of alternative measures

## IV. Necessity (Art. 2.2)

- ▶ Risks non-fulfilment would create
  - AB: „nature of the risks at issue and the gravity of the consequences that would arise from non-fulfilment of the legitimate objective”
  - Extended authorisation scheme aims to reduce and avoid the exposure of humans and the environment to SVHC listed in Annex XIV
  - Analyse risks of SVHC
  - Procedural and **substantive implications**

## IV. Risks non-fulfilment would create (2.2)

### ▶ **SVHC group I**

- CMRs, most PBTs, most 57(f) substances are based on GHS classification as “hazardous” substance
- ▶ **Science-based** proof of hazard potential
- ▶ Given exposure: Risk = often danger → **danger prevention**
- ▶ Consideration of **legitimate objectives**
- ▶ **Conclusion:** „Nature of the risks“ is significant; extended authorisation requirement of these SVHC categories is prima facie necessary



## IV. Risks non-fulfilment would create (2.2)

### ▶ SVHC group II

- vPvBs, cat. 2 reprotox. PBTs, some substances Art. 57(f)
- Science-based hazard potential with **uncertainty**
- Given exposure: Risk = precaution → **precautionary measure**
- Compliance? No indications in TBT (= no minimum level for risk)
- Interpretation of TBT Agreement in the light int'l env. law
- Strong emphasis on **precautionary principle** and, e.g., risks from P and B properties (POP Convention)
- Consider objective: **high level** of protection
- **Conclusion:**  
„Nature of the risks“ is significant; extended authorisation requirement of „precaution group“ is prima facie necessary

## IV. Interim result (necessity)

- ▶ Extended authorisation requirement serves a legitimate objective in terms of 2.2 TBT
- ▶ Regulation is appropriate to contribute to its objectives
- ▶ Risks non-fulfilment would create are not acceptable (for all SVHC categories)

## IV. Necessity - alternatives (Art. 2.2)

- ▶ Possible alternative measures
  - *Is there an (1) equally effective but (2) less intrusive alternative measure available?*
  - **Restriction (Art. 69 II REACH)**
  - *“After the [sunset date for Annex XIV substances] the Agency shall consider whether the use of that substance in articles poses a risk to human health or the environment that is not adequately controlled. If the Agency considers that the risk is not adequately controlled, it shall prepare a dossier which conforms to the requirements of Annex XV.”*
- Effects both domestic and imported articles

# IV. Necessity - alternatives (Art. 2.2)

	<b>Art. 69 II Restriction</b>	<b>Ext. Authorisation requirement</b>
<b>Burden of proof</b>	ECHA has to prove that use of the substance in article poses an unacceptable risk that needs to be addressed Union wide	Companies must demonstrate that risks arising from use of the substance in article are adequately controlled
<b>Risk substantiation</b>	Description of risks addressed in Annex XV Dossier is based on all substance related hazards and risks in CSR	Authorisation application addresses only the risks due to the substance hazard listed in Annex XIV
<b>Time factor</b>	Applies only after "sunset date" stipulated in Annex XIV + changes to Annex XVII entry into force	Applies with effect of "sunset date" stipulated in Annex XIV
<b>Exceptions to the regulation</b>	Annex XVII entry allows exceptions for certain applications	Annex XIV entry allows exceptions for certain applications
<b>Specific design of the measure</b>	Restriction may be designed as a partial ban, effective e.g. only regarding a threshold value of a substance in articles	Exceptions defined in Annex XIV may be linked to certain conditions, e.g. thresholds. However, a more specific design of the general authorisation requirement is not possible
<b>Scope</b>	Scenarios where a restricted substance is only used during the production of articles, but is not present in the product itself, fall outside the scope	Scenarios where the SVHC is only used during the production of articles, but is not present in the product itself, fall outside the scope
<b>costs and benefits</b>	<p>One legislative act regulates all prohibitions and exceptions                      -&gt; This is beneficial for administration                      -&gt; Can however also prove to be a disadvantage, because in <i>situations with a partial restriction</i> an adequate official response to a specific product risk, which was not known when adopting the restriction, is not impossible</p>	<p>Each (group) application for a substance use must be examined separately                      --&gt; This disadvantageously affects administration because "costs" are increasing                      --&gt; However, there is the advantage that an adequate (single case) decision can be taken</p>

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<b>costs and benefits</b>	One legislative act regulates all prohibitions and exceptions -> This is beneficial for administration -> This can however prove to be a disadvantage, because in <i>situations with a partial restriction</i> an adequate official response to a specific product risk, which was not known when adopting the restriction, is not impossible	-	+	Each (group) application for a substance use must be examined separately --> This disadvantageously affects administration because "costs" are increasing --> However, there is the advantage that an adequate (single case) decision can be taken

- ▶ The authorisation requirement's is clearly preferable to effectively reduce emissions of SVHC

## IV. Necessity - alternatives (Art. 2.2)

- ▶ Restriction + authorisation requirement both intend adequate “risk” control, however **risks are not identical**
  - Restriction refers to unacceptable risk that regulatory bodies are aware of and able to substantiate
  - Authorisation is triggered by hazard potential (with reversed burden of proof), including situations of uncertain hazard/risk (→ SVHC “precaution group” II)
  - **Input** (sovereign risk knowledge) and **output** (quality of adequately controlled risks) **are different!**
- ▶ Restriction is no equally effective measure

## IV. Necessity - alternatives (Art. 2.2)

- ▶ Single restrictions that are specifically tailored might be **less intrusive** than a specific authorisation requirement
- ▶ **Not relevant** for TBT analysis since restriction is no equally effective measure
- ▶ **Conclusion:**  
Restriction is no alternative within the meaning of 2.2 TBT  
Extended authorisation is not more trade-restrictive than necessary

## IV. Final Conclusion (Art. 2.2 TBT)

- ▶ The relational analysis shows that the extended authorisation requirement does not constitute an unnecessary obstacle to trade
- ▶ Extended authorisation requirement does not violate Art. 2.2 TBT



# Contact

[fuehr@sofia-darmstadt.de](mailto:fuehr@sofia-darmstadt.de)

[schenten@sofia-darmstadt.de](mailto:schenten@sofia-darmstadt.de)

[www.sofia-darmstadt.de](http://www.sofia-darmstadt.de)

[www.sofia-research.com](http://www.sofia-research.com)

[www.elni.org](http://www.elni.org)