Cii REACH OSH

Cross-Industry Initiative
for better regulation in chemicals management

POLICY RECOMMENDATIONS

CII background paper on Restrictions

November 2016

Executive summary:

- **The RMOA plays a pivotal role in selecting the most efficient regulatory risk management option, whether restriction or another risk management tool or a combination thereof. Because this step is so essential, we recommend that the RMOA process be standardised following defined and public quality criteria. These criteria should also define the circumstances under which a specific combination of RMOs may be justified.**

- **The early involvement of affected industry sectors will improve the validity, transparency and acceptability of regulatory decisions. While Restrictions and the required justifications are documented by the authorities, industry should be invited to contribute to the process at the earliest possible stage (continued co-operation following the RMOA is also essential).**

- **While situations where the risk is limited to the workplace should continue to be regulated via OSH Directives, Restrictions can be sensible complimentary measures under specific circumstances. However, the CII is opposed to the use of Restrictions to bypass or duplicate existing OSH procedures to determine exposure limits.**

- **Restrictions should be evaluated in cases where the application of OSH regulation leaves areas of remaining concerns. Especially in cases where Authorization is deemed too strong an intervention, or too unspecific for addressing the identified gaps in proper control for specific sectors/uses, targeted Restrictions should be preferably considered to complement OSH regulation.**

1. Introduction

This paper discusses Restrictions and explores how these can complement occupational safety and health (OSH) regulation for chemicals. The CII was encouraged by the EU-COM to provide its opinion on the suitability of Restrictions as risk management option (RMO) in the broader context of REACH and OSH interaction.

2. Restrictions – purpose and conditions

Restrictions have been a regulatory RMO in the EU since 1976 under Directive 76/769/EEC (Restrictions on the marketing and use of certain dangerous substances and preparations). Since June 2009, restrictions have been integrated in Title VIII of the REACH Regulation, replacing and repealing the old Directive. Existing and new Restrictions are listed in REACH Annex XVII.

Restrictions can either be proposed by Member States (MS), or by the EU-COM, tasking ECHA to develop restriction proposals. ECHA must also propose restrictions for substances subject to Authorisation after the sunset date, if the use in articles poses an unacceptable risk for human health or the environment (REACH Article 69(2)).

Provided the conditions for putting a restriction in place are met (e.g. demonstrated Community wide risk), restrictions can generally be an effective and flexible RMO to address specific concerns which are not sufficiently covered by other regulatory instruments. The "burden of proof" lies with the authorities (MS, COM, ECHA) who are proposing the Restriction. This is the main criticism some stakeholders have against this risk management option. However, because restrictions can cover situations outside the scope of Authorisation (e.g. substances present in articles), and can be much more targeted (i.e. covering specific substance uses/applications rather than all substance uses), this makes them a valid and useful tool to complement OSH and other regulations in certain cases.

3. Types of Restrictions

Since the scope of Restrictions is not limited to the use of chemical substances on their own or in mixtures, a broad range of Restriction approaches is theoretically possible. Based on traditional practice, and current developments, Restrictions can be categorised as follows:

- "Standard" Restrictions: traditionally, Restrictions were used to (1) prohibit the sales and marketing of specific substances or groups of substances to consumers or to (2) either completely ban the use of specific substances in specific applications, or limit the continued use defining conditions to be met.

  - A new variation of the standard restriction is currently being considered, i.e. to establish RAC-reference DNELs as "use condition".
- "Fast track" Restrictions based on art. 68 (2): another approach currently under discussion is the ban of individual substances and substance groups (substances classified as carcinogenic, mutagenic or toxic to reproduction 1A or 1B) in products for consumer use (e.g. carcinogens in textiles).

Since the last category (fast track Restrictions) is specifically related to consumer products, it is outside the defined scope of the CII. We will therefore not refer to it in the following discussion.

4. CII Position

Restrictions can be a useful RMO and could complement OSH in certain cases, provided the conditions listed in section 2 are fulfilled. Restrictions have the following advantages over other regulatory instruments:

- **Flexible**: Restrictions have a broad spectrum of potential control mechanisms, including the definition of substance concentration limits up to a total ban in selected applications. They also allow the definition of exceptions for defined uses. The requirements on substance identity are not as formalised as in the case of the authorisation.
- **Effective**: Restrictions usually provide a clearly defined scope which supports their implementation and enforcement. The consultation of the Forum for enforcement during a restriction-process further guarantees effective on-field enforcement.
- **Targeted**: Restrictions can address specific applications and are not limited to "substance uses" (i.e. they can include articles). This is specifically relevant if the health concern is focused on a specific use.
- **Proportionate**: Restriction can leave well-controlled applications and its users unaffected; these Downstream Users will not need to go through a bureaucratic Authorisation process (fees, extensive studies, administrative burden, etc.) without a corresponding health benefit.

We wish to reiterate that the decision to apply any regulatory instrument or combination of instruments must follow a thorough risk management option analysis (RMOA). The following generic examples reflect our position on the potential applicability of Restrictions for substances falling within the scope of the CII:

Case I: During the RMOA stage it becomes clear, that the substance is predominantly used in industrial settings. A portion of the volume, however, is used in consumer products, along with a potential risk of consumer exposure. Rather than including the substance on Annex XIV it would be sensible to regulate

the industrial uses via OSH, covering the remaining consumer uses of concern via a targeted Restriction.

Case II: The RMOA reveals the availability of feasible alternatives for the substance in a particular application or sector. Some actors in that sector have, however, not yet adopted the alternative without a sufficient justification. A targeted Restriction could be suitable to force substitution in such cases, without affecting those users, where despite intense R&D in this area, no alternative is available or expected to become available in the near future.

The CII objects to the suggestion that RAC reference DNELs could serve as "use conditions" in Restrictions. OSH Directives were established to define all important aspects of workplace risk management and are viewed as the correct legal route to establish specific occupational exposure limits (OEL). The introduction of "binding" derived no effect levels (DNEL) as an alternative to OELs via Restrictions undermines existing legal systems and is clearly at odds with REACH Article 1(4)[1]. ECHA has no legal mandate to derive workplace limits.[2]

A recent explanatory memorandum of the Commission acknowledged[3]: "REACH, on the other hand, is not intended to set occupational exposure limit values […]. The Commission services, Member States, and the social partners have all expressed their view that occupational health and safety directives are the appropriate EU legislative framework to establish harmonised limit values for the protection of workers."

The discussion above leads us to formulate the following recommendations:

1. The RMOA plays a pivotal role in selecting the most efficient regulatory risk management option, whether restriction or another risk management tool or a combination thereof. Because this step is so essential, we recommend that the RMOA process be standardised following defined and public quality criteria. These criteria should also define the circumstances under which a specific combination of RMOs may be justified.
2. The early involvement of affected industry sectors will improve the validity, transparency and acceptability of regulatory decisions. While Restrictions and the required justifications are documented by the authorities, industry should be

[1] According to Article 1(4) of REACH, the Regulation applies without prejudice to workplace legislation. While there may be overlaps and areas where OSH and REACH may complement each other and lead to synergies, REACH does not provide the RAC-Committee with the mandate to establish exposure limit values, which would potentially be contradicting OELs that have been (or can be) established as explicitly mandated by EU legislation.

[2] Furthermore, resources which are financed to a great extent through enterprises' fees and are dedicated for the implementation of tasks foreseen by the REACH Regulation, should not be used to fulfil the work, which should be actually performed by other competent bodies.

[3] European Commission: Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC, COM(2016) 248 final 13.05.2016

invited to contribute to the process at the earliest possible stage (continued co-operation following the RMOA is also essential).

3. While situations where the risk is limited to the workplace should continue to be regulated via OSH Directives, Restrictions can be sensible complimentary measures under specific circumstances. However, the CII is opposed to the use of Restrictions to bypass or duplicate existing OSH procedures to determine exposure limits.
4. Restrictions should be evaluated in cases where the application of OSH regulation leaves areas of remaining concerns. Especially in cases where Authorization is deemed too strong an intervention, or too unspecific for addressing the identified gaps in proper control for specific sectors/uses, targeted Restrictions should be preferably considered to complement OSH regulation.

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Annex:

- *Annex 1: List of signatory organisations*

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About the CII

The Cross-Industry Initiative (CII) was set up between December 2014 and March 2015 as a loose coalition aimed at streamlining chemicals management. It currently comprises over 50 organisations: sectoral associations at EU and national level, as well as companies. Please find more information on our website (www.cii-reach-osh.eu) or contact us by email (info@cii-reach-osh.eu).

Annex 1: List of signatory organisations

European and global associations and platforms

ACEA – European Automobile Manufacturers' Association
AmCham EU
BeST – Beryllium Science and Technology Association
BSEF – The International Bromine Council
Cadmium Consortium
CAEF – European Foundry Association
CDI – Cobalt Development Institute
CECOF - The European Committee of Industrial Furnace and Heating Equipment Associations
CEMBUREAU – The European Cement Association
CerameUnie – The European Ceramic Industry Association
CETS – European Committee for Surface Treatment
ChemLeg PharmaNet
CIRFS – European Man-made Fibres Association
CPME – Committee of PET Manufacturers in Europe
EAA – European Aluminum Association
EBA – European Borates Association
ECFIA – Representing the High Temperature Insulation Wool Industry
ECGA – European Carbon and Graphite Association
ECMA – European Catalyst Manufacturers Association
EDMA – European Diagnostic Manufacturers Association
EPMF – European Precious Metals Federation
ETRMA – European Tyre & Rubber Manufacturers' Association
Eucomed
Euroalliages – Association of European Ferro-alloy Producers
EUROBAT
EUROFER
Eurometaux
Euromines
FEPA – Federation of European Producers of Abrasives products
Frit consortium
Glass Alliance Europe
I2a – International Antimony Association
ICdA – International Cadmium Association
IIMA – International Iron Metallics Association
IMAT – Innovative Materials for Sustainable High-Tech Electronics, Photonics and Related Industries
Ipconsortium
Lead REACH Consortium
Nickel Institute
PRE – The European Refractories Producers Federation
RECHARGE – European Association for Advanced Rechargeable Batteries
UEAPME – European Association of Craft, Small and Medium-Sized Enterprises
UNIFE – The European Rail Industry

National associations

A3M – Alliance des Minerais, Minéraux et Métaux (French Ores, Minerals and Metals Association)
ASSOGALVANICA – Associazione Italiana Industrie Galvaniche (Italian Plating Industry Association)
BCF – British Coatings Federation
BVKI – Bundesverband Keramische Industrie e.V. (German Association of the Ceramic Industry)
ION – Dutch Association Industrial Surface Technology
NFA – Non-Ferrous Alliance
SEA – Surface Engineering Association
VDA – Verband der Automobilindustrie (German Automotive Industry Association)
VDFFI – Verband der Deutschen Feuerfest-Industrie e.V. (German Association of the Refractory Industry)
VDS – Verband Deutscher Schleifmittelwerke e.V. (German Abrasives Association)
WKÖ – Wirtschaftskammer Österreich (Austrian Federal Economic Chamber)
WVMetalle – Wirtschaftsvereinigung Metalle (German Metals Trade Association)
ZVO – Zentralverband Oberflächentechnik e.V. (Central Association of Surface Technology)

Corporations

Colorobbia
Ferro