Cii REACH OSH
Cross-Industry Initiative
for better regulation in chemicals management

POLICY RECOMMENDATIONS

Synergies between REACH and workplace legislation: Improved analysis of alternatives and substitution

November 2016

Executive Summary

Substitution is the replacement of a substance or material, a product or article, a process or technology, by an alternative which maintains the same function or use, while bringing one or more possible improvements. Analyses of alternatives (AoA) and substitution processes have been implemented for decades for a number of reasons, including the STOP principle[1] of workplace legislation and common industrial hygiene best practice.

In this paper, we wish to share success stories, as well as illustrate that substitution is not an easy process as it must integrate many different parameters. Sometimes suitable and/or sustainable alternatives cannot be identified. Examples are included in the Annex of this document. These examples show that substitution is not driven by REACH, workplace, or any other legislation alone, but is influenced by many other drivers, including market conditions, which are case-specific.

[1] STOP stands for: Substitution, Technical measures, Organisational measures, Personal protection measures. The sequence reflects the priority, with substitution being assigned the first priority in the hierarchy.

Informed substitution decisions entail a comprehensive comparison of substances, or technologies, to be substituted, against their potential alternatives, covering their whole life-cycle, in a holistic manner. Existing legislation is often considered to provide insufficient impetus for employers to document their efforts to search and develop alternatives.

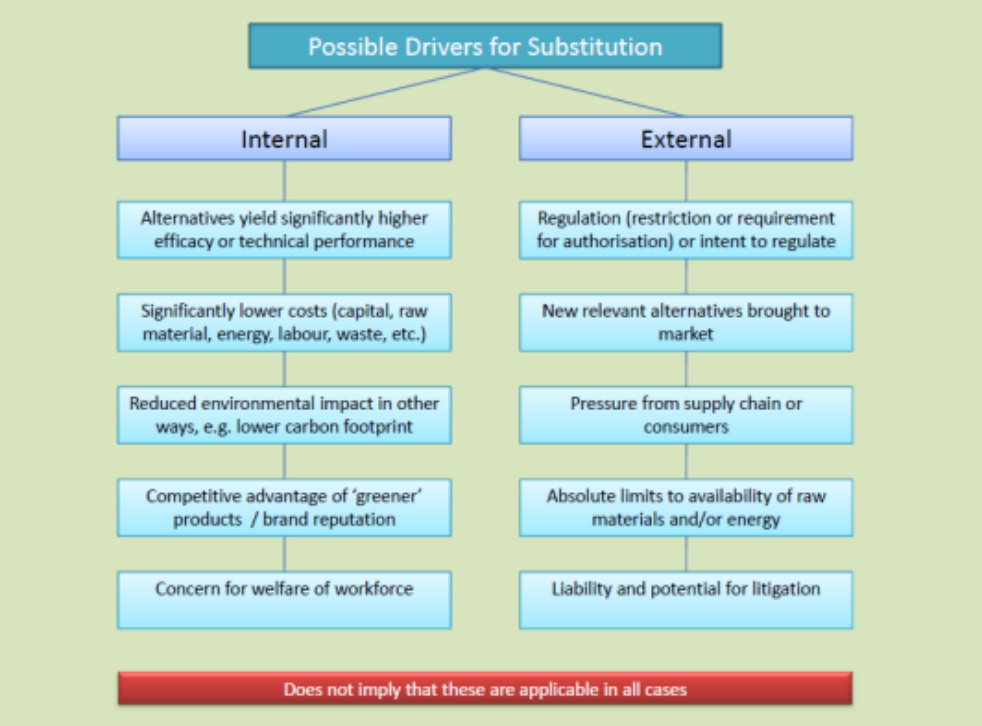
Only a synergistic implementation of REACH and workplace legislation will stimulate more effective AoA, and therefore more successful substitution. In practice, this is done with:

- Proper communication by suppliers and authorities, of quality REACH Registration datasets on substances to employers, so they can more robustly identify and manage (eliminate, reduce or control) the risks posed by certain substances, and search for alternatives;
- Support from authorities to employers about how to document AoA and their informed choices regarding the decision to substitute or not, and distinguish in this context what is confidential business information and what is not; and
- More systematic use of Risk Management Option Analyses (RMOAs) and their announcement on PACT to collect information on AoA from Industry, and use this information when choosing the most appropriate Risk Management Option (RMO) in the RMOA.

1. There are many drivers to Substitution, and the decision to substitute must be informed by an analysis of alternatives

Substitution is the replacement of a substance or material, a product or article, a process or technology, by an alternative which maintains the same functionality while bringing one or more possible improvements. The decision to substitute is informed by a comprehensive analysis of alternatives (AoA), to identify any solution(s) that is(/are) both technically and economically suitable for the specific use of the substance. The result of this analysis will be very much dependent on the use-specific context. Alternatives for some uses of a substance may be available, whereas for other uses no feasible alternative exists.

The figure below, taken from "A Guide to Substitution: An Information Note from the UK Chemicals Stakeholder Forum" (August 2010), shows potential internal and external drivers for substitution[2]:



[2] A report commissioned by ECHA noted that besides REACH "the breadth of product safety regulations, occupational safety and health regulation and market pressures" were "important drivers of substitution". (Joel Tickner and Molly Jacobs, University of Massachusetts Lowell, Improving the Identification, Evaluation, Adoption and Development of Safer Alternatives: Needs and Opportunities to Enhance Substitution Efforts within the Context of REACH, August 2016, page ii). The report is hereinafter referred to as "ECHA commissioned report on substitution, 2016".

2. Substitution has been a requirement in workplace legislation for more than 25 years

We acknowledge that REACH, and its Authorisation process, have had a magnifying glass effect on substitution for the general public, the NGOs and authorities. Although the listing of a substance in the Candidate List and then its prioritisation in Annex XIV may send a signal to the value chain about the need to consider and engage in substitution, when one takes a closer look at the EU legislative framework and the reality of industrial practices, it is clear that the research and development of alternatives is not triggered by the REACH Regulation alone.

One such example is workplace legislation. Council Directive 89/391/EEC[3] on the introduction of measures to encourage improvements in the safety and health of workers at work, and its daughter directives 98/24/EC[4] (known as the Chemical Agents Directive (CAD)) and 2004/37/EC[5] (known as the Carcinogens and Mutagens Directive (CMD)) all incorporate substitution as a specific protection and prevention measure. Article 6 of the CAD recommends that "*substitution of a chemical agent be undertaken by preference*". According to Article 4 of the CMD, substitution is mandatory if technically feasible. Furthermore, Article 4(2) of the CMD sets an additional obligation for "*the employer to submit the findings of his investigations to the relevant authorities, upon request*".

Workplace legislation is one of the drivers of selective purchasing policies, as well as research and development (R&D) of alternatives to hazardous substances, as illustrated in the Annex of this document.

3. AoA and substitution are driven also by Innovation and Competition

Regulations are not the only forces which drive substitution. A report from CSES[6] dated June 2012 on the impact of the REACH Regulation on the innovativeness of the EU chemical industry, concludes that "*innovation is driven by many factors outside of REACH that have a greater impact than the regulation itself, in particular the state of markets and technology*". Whereas this quote reveals that substitution can drive innovation, it also stresses that innovation and competitiveness drive substitution.

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[3] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work – Official Journal of the European Community N° L183/1 – 26.06.1989.

[4] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work – Official Journal of the European Communities N° L131/11 – 5.05.1998.

[5] Directive 2004/37/EC of the European Parliament and of the Council on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, Official Journal of the European Union N° L158/50 30.04.2004.

[6] ' Interim Evaluation: Impact of the REACH Regulation on the innovativeness of the EU chemical industry', Centre for Strategy and Evaluation Services, report June 2012.

Substitution is a complex process in which different drivers are usually combined. The objective of replacing a given substance or technology may be related to the protection of the workers' health, the reduction of the costs linked to the prevention of health and environmental risks[7], or the desire to reduce the use of natural resources or the cost of raw materials used in an industrial process[8], etc. The search for and development of alternatives will be influenced by numerous drivers including company values, public expectations, market and customers demand, economic and cost factors, risk of supply disruption, competitive edge, innovation and technical factors. Hazard is hence not the only factor driving substitution; this is commonly reflected in Product Stewardship Policies or Sustainable Development policies incorporated into the Corporate Governance of many companies.

Substitution can also result from individual or collective voluntary initiatives by industry when there is overall a good business case for doing so. Published examples of substitution are however not that numerous, mainly because AoA and substitution is a component of companies' innovation and R&D strategy, and intellectual property. Although much more than what is in the public sphere is happening within companies in terms of substitution, such information is not easily shared as it often constitutes Confidential Business Information (CBI).[9]

4. The effectiveness of Authorisation regarding substitution has not been demonstrated

REACH Authorisation is a too recent regulatory tool to draw conclusions on how effectively it contributes to substitution. Recent figures[10] show that of the 14 substances on the Authorisation list (Annex XIV) that have passed their sunset date and are, therefore, banned in the EU (except for any authorised uses), seven of these have had no Authorisation applications. It is not clear to date whether these substances will continue to be produced in the EU for export, or are imported into the EU through articles, or whether their use has actually been substituted or whether the use has simply been given up without a replacement.

Before allocating the merits of use abandonments (in the EU!) or substitution to Authorisation, an in-depth evaluation of the substitution trends for those substances for which applications have been received (and for those for which none have been received), and of the business decisions to either abandon a substance or substitute, should be performed. Particularly, we recommend assessing whether the substance

[7] The costs associated with the use of hazardous chemicals materials is also one of the drivers to find suitable substitutes to these substances.

[8] For example the attempts to substitute cobalt diacetate as a catalyst for the manufacture of PET precursor.

[9] Some examples are made available publicly, for example in the case story database of the website www.subsport.eu.

[10] Chemical Watch, 'ECHA tracks Annex XIV substances attracting no applications', 14 January 2016. Source reference: Authorisation statistics (ECHA website): http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/received-applications

was already being substituted regardless of REACH Authorisation. In such a case, the substitution should not be claimed to be a result of REACH Authorisation. It could however be interesting to study whether in such cases where alternatives were already identified, REACH Authorisation has influenced the speed of substitution on the market.

5. 'Regrettable' substitution may be the result of regulatory pressure

Candidate Listing (and further Annex XIV listing) generates market uncertainties that put pressure on companies who aim to remove the listed substances from their portfolios, inventories and supply chain as quickly as possible. Although such reactive behaviour may seem honourable and wise, in practice, decisions taken under such pressure may precipitate 'regrettable substitution'. Regrettable substitution is not only the substitution of a substance or a technology by an alternative which may actually pose similar or worse risks, but also the substitution by alternatives which are unsustainable from an energy consumption, sourcing, or resource efficiency standpoint for instance, and which shift or transfer the risk elsewhere.
Such regrettable substitutions do not bring an overall added-value for human health and the environment when the substance was initially used safely. They may actually trigger additional or worse problems than those originally posed by the targeted substance or technology. For a substitution to be successful, it must be the result of an informed, well-thought and documented AoA exercise including: a comprehensive comparison of substances or technologies to be substituted against their potential alternatives, on an equal footing, covering their entire life-cycle, in a holistic manner.[11]

6. Candidate Listing and REACH Authorisation may discourage innovation to be conducted in the EU

Many substances that could be considered for inclusion in the Candidate List and REACH Authorisation are key enablers of innovation (for example for green technologies). Candidate Listing or inclusion on Annex XIV of such substances would discourage any research in their innovative use and in particular the introduction of innovative uses into the market to rather occur outside the European Union than within.

[11] The ECHA commissioned report on substitution, 2016 also noted (on page 15) that the current practice of analysis of alternatives under REACH needs to be improved towards a "broader comparative assessment than simply the comparison of GHS hazard classifications". It also highlighted that data gaps for potential alternatives need to be taken into account, to "prevent unintended consequences associated with the adoption of product designs or the substitution of specific chemicals, materials or technological processes about which there is little information".

Where the sunset date or review periods seek to encourage innovation in looking for the alternative, it meets the reality that innovation is a stepwise exploratory process and can rarely be subjected to specific timelines.[12] The uncertainty and the administrative burden of (repeated) applications for authorisation encourage the shifting of the continued use of the substance and the search for an alternative to outside the EU.

7. Inability or difficulty to substitute

Some uses of substances cannot – despite decade-long research and proper AoA – be substituted. Either because there are generic or niche uses for which there are currently no existing substitutes (e.g. alumino silicate RCFs[13] or bio-essential uses such as borates, cobalt) or because the different intrinsic parameters that are critical to substitution are simply not met.

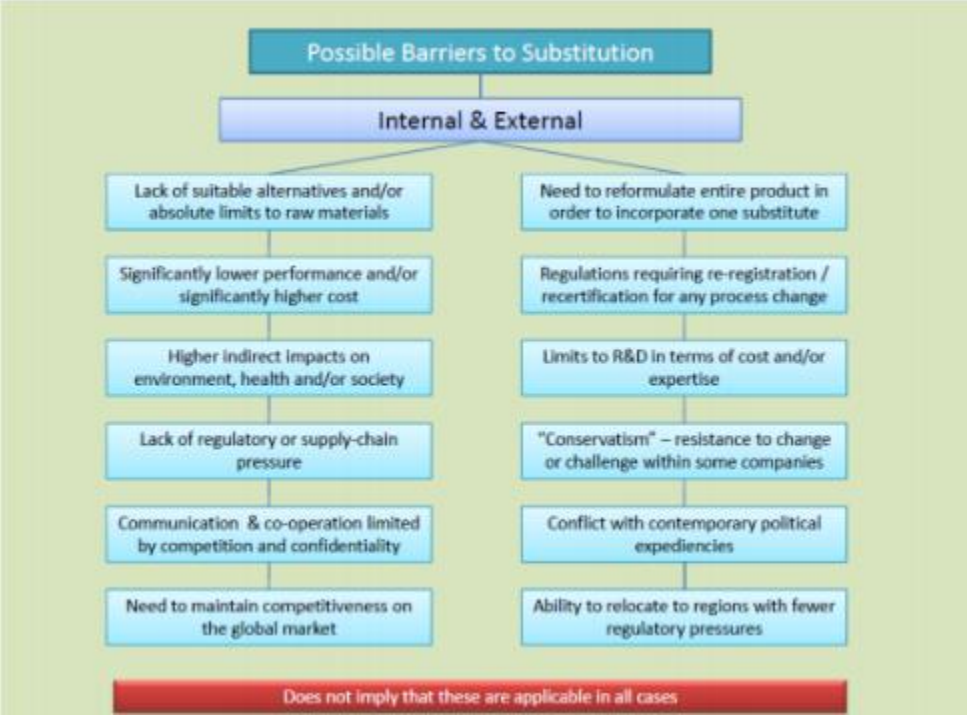
The reasons for this inability to substitute could be that potential alternatives are no less toxic and exhibit another toxicity of equivalent concern; do not meet the technical performances that are required; are not economically feasible for the employer or user; cannot be sourced in sufficient quantities or from a sufficient number of suppliers; or skilled workers, profession of the entrepreneur, local operating permits and others which are necessary to implement the alternative are not available. In other cases, there is simply not enough data on the alternatives for companies to be able to draw conclusions on whether they would really be less hazardous, and whether their hazards can be well-managed or bring other (sustainability) improvements.

There may be other cases, where alternatives may be technically feasible, however the market has a preference for the article produced by using the substance for which an alternative is sought. If the article does not contain the substance (as it was consumed in the production process), European producers who employ the technically feasible alternative will compete with those who outside the EU produce the article that meets market preferences. This can thus lead to a distortion of competition between EU and non-EU manufacturers.

[12] This is also acknowledged in the ECHA commissioned report on substitution, 2016 (page 22): "Developing alternatives once a chemical is on the authorisation list however is often too late for enterprises to start innovation research".

[13] "Overview on Alternatives for Alumino-silicate Wools/Refractory Ceramic Fibres (ASW/RCF) products" from BiPRO, October 2015.

The figure below taken from "A Guide to Substitution: An Information Note from the UK Chemicals Stakeholder Forum" (August 2010), shows other possible barriers to substitution:



8. Synergies between REACH and workplace legislation regarding analysis of alternatives and substitution

> "*REACH is concerned with authorising substances of very high concern for continued use under certain strict conditions with the specific aim of enabling substitution. This applies to the workplace, where such chemicals are also covered by occupational health and safety (OSH) legislation. These pieces of legislation should work together 'without prejudice' and in a complementary way, covering all essential aspects of workplace chemical safety.*" ECHA REACH Article 117/REACH Review Report, 26 May 2016

The data generated under REACH for Registration and which are being transmitted along the value chain in particular via the Safety Data Sheets (SDS) (including results of the Chemical Safety Assessment such as exposure scenarios and information on exposure control) should enable employers to better understand the potential hazardous properties of the substances that are used at the workplace, enabling them to revisit/review the way in which they have assessed and managed the risks at

the workplace, and to consider possible alternatives that could be implemented instead[14].

The reappraisal of the situation at the workplace based on new data generated under REACH or old data more widely disseminated in the value chain could further facilitate employers' efforts to identify suitable alternatives and eventually engage in substitution processes.[15] This positive benefit is linked to the obligation to generate and share data along the supply chain under REACH; it is not the result of the SVHC or the Authorisation process as such.

Under workplace legislation, it is the employer's responsibility to identify hazardous substances which should be replaced and to investigate replacement options (i.e. perform an AoA), and to document the findings of their investigations. It is subsequently workplace legislation authorities' right to request these findings and agree/challenge the (non-)substitutability claim made by each employer. REACH can bring value in the context of AoA under workplace legislation, if the tools specifically developed are made available to/promoted with the workplace legislation community too. Tools include e.g. ECHA Guidance on Authorisation Applications, and substitution support website and tools developed by ECHA, RAC and SEAC's learning lessons and recommendations inspired by the Authorisation applications received, etc.

9. PACT listing and RMOAs: the most efficient tools to promote the documentation of analyses of alternatives

A Risk Management Option Analysis, or RMOA, assesses the need for risk management, and can act as a bridging tool between workplace legislation and REACH, and any other possible option to manage an identified risk. In an RMOA, substitution should be compared next to any other RMO considered as potentially applicable. Substitution may, or may not, appear to be the most efficient option, depending on the specific case. It would appear to be the preferred RMO when viable alternatives do exist. The likely feasibility of substitution however, can only be informed by the output of an AoA. Whichever the best option identified by an RMOA, it should ensure that the risk is managed, and where necessary and feasible, promote the development and implementation of alternatives (which is the goal of both workplace legislation and REACH).

[14] REACH Annex II "*the information provided by the Safety Data Sheets shall also meet the requirements set out in Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. In particular, the SDS shall enable the employer to determine whether any hazardous chemical agents are present in the workplace, and to assess any risk to the health and safety of workers arising from their use.*"

[15] See also the findings of the ECHA commissioned report on substitution, 2016, page iii: "[…] REACH has made possible an abundance of data that could be extremely valuable in enhancing support for the initial identification of potential alternatives".

The Public Activities Coordination Tool or PACT lists the substances for which an RMOA is either under development or has been completed. Experience with the use of PACT demonstrates that it functions as:

- a call for information[16]: triggering the compilation and documentation of information on available alternatives, on limiting or feasibility conditions for their implementation, and other AoA-relevant information; as well as
- an awareness raising campaign: which alerts on potential risks associated with the uses of a substance, and suggests to move to an existing and performing alternative, where market drivers alone have failed to achieve this.

Before PACT existed, Candidate Listing was used to trigger this. But then substances had effectively entered the path towards the Authorisation process, which is only one of many possible RMOs, and not always the more efficient one. With the SVHC Roadmap, the performance of RMOAs and the use of PACT, a more efficient way exists now to call for information and influence market behaviour, without jeopardising the competitiveness of EU Industry.

Announcements on PACT further contribute to three goals of the better regulation agenda:

- They provide the proper impetus for employers to document their efforts to search and develop alternatives (as this information can now be collected in a more systematic manner): better implementation of existing legislation without duplicating legislation.
- They stimulate manufacturers and users to provide information to the authorities performing the RMOA: increasing stakeholders' involvement and consultation.
- They enable authorities to more efficiently assess various RMO possibilities, including those having substitution as main goal, using the available AoA-related information to more accurately predict the actual (non-)feasibility of substitution: early identification of the best (regulatory) and most proportionate choice of action[17].

[16] If an RMOA guidance is developed for authorities, relevant recommendations could be included to ensure a systematic and consistent documentation and consideration of AoAs in any RMOA.

[17] If in an RMOA, the substitution of a substance in a use seems unfeasible despite demonstrated R&D, this information should allow to predict that the regulatory pressure created by Candidate Listing and Authorisation would have a negative impact on the continued activity of the sector in the EU, without effectively influencing the replacement of a given substance, for which no feasible alternatives seem to be available. Again, if the risk is limited to the workplace, actions under the workplace legislation may enable to control the risk posed by the substances while maintaining an obligation on Industry to search for and develop feasible alternatives.

10. AoA information: modalities of submission to authorities performing RMOAs

Often, the time needed to generate, gather, and compile documented information on AoA efforts is longer than the time made available to provide such information to authorities. Authorities conducting RMOAs could consider the possibility to provide extended deadlines to allow a meaningful (and iterative/refined) submission of information. Alternatively, upcoming RMOAs could be announced earlier. If it was ensured that any RMOA will take into account existing AoAs, then the value chain would have the required confidence that it is worth preparing the documentation of the AoA as soon as the RMOA is announced.

There is also no specific format foreseen to report AoA information. This may result both in under- or over-information situations. A minimum format could be developed to streamline and harmonise the structure and content of AoA information that can be provided by stakeholders.[18] Such a format could be developed and used in order to satisfy both RMOA and workplace legislation needs.

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Annexes:

- *Annex 1: Examples of analysis of alternatives and substitution efforts*
- *without REACH Authorisation pressure*
- *Annex 2: 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).

[18] The ECHA commissioned report on substitution, 2016 called for the development of "more detailed guidance or guidelines, instructions or other suitable material for authorities and industry to complete analyses of alternatives in applications for authorisations and restrictions proposals outlining minimum components and quality criteria" (see page v). In the conclusions of the same report (page 34) it is also suggested that it is possible to use "discretionary powers to facilitate and encourage early marketplace actions to identify, develop and adopt safer substitutes (even before regulation)". Following this logic, the more detailed guidance would also be applicable prior to the Candidate Listing, i.e. in RMOAs and the preparations for RMOAs from the side of industry.

Annex 1: Examples of analysis of alternatives and substitution efforts without REACH Authorisation pressure

Employers in the EU have actively engaged in the assessment of the risks present at their workplace, and have focussed on eliminating or reducing the risk by looking for suitable alternatives. The examples that we have selected illustrate both successful and on-going analysis of alternative (AoA) processes. They demonstrate that the output of an AoA often requires to be complemented with additional considerations, before the decision to substitute or not, can actually be made.

1. Alumino-silicate (ASW/RCF), an example of progressive substitution

RCFs, more accurately described as Alumino-Silicate Wool (ASW), are part of the Insulating Refractory Products or High Temperature Insulation Wools (HTIW) with classification temperatures above 1000°C (EU Standard EN 1094-1). HTIW products consist of fibres and are particularly suitable for use as insulation in high temperature industrial processes. ASW/RCF products are used at temperatures between 800°C and 1300°C, where other forms of synthetic mineral and glass wools with classification temperatures below 1000°C would melt or show severe degradation.

In 1988, IARC classified RCF as a possibly carcinogenic (IARC 2b); this classification was confirmed by IARC in 2002 in Monograph VOLUME 81 MAN-MADE VITREOUS FIBRES. However, in 1997, RCF was classified in the EU as carcinogen 2 (Directive 97/69/EC adapting Council Directive 67/548/EEC[19]). This classification triggered the implementation of the substitution principle under the CMD, where the manufacturers and users of ASW/RCF products have had the responsibility to substitute ASW/RCF where technically possible and, where this was not possible, to limit exposure to the extent possible.

As a matter of fact, based on the RCC animal test in the mid-1980's, and the discussions on a possible classification, manufacturers of ASW/RCF had already been working on developing alternatives even before the actual classification of ASW/RCF (1997).

During the 1980's, the manufacturers committed substantial R&D to developing alternatives to ASW/RCF that would exhibit a lower hazard classification: AES Wool (Alkaline Earth Silicate) displays lower bio-persistence allowing inhaled fibrous dust to be cleared quickly from the lungs; a second alternative is PCW (PolyCrystalline Wool). These fibres are made by a different manufacturing process allowing the content of respirable fibres to be reduced to a very low level.

[19] Now category 1B under CLP. Some RCF have consequently been included on the REACH candidate list.

Following the initial R&D work, the manufacturers have progressively developed these alternatives to become industrial products during the period from mid-1980's to today. This process has been supported by ECFIA, the European industry association for high temperature insulation wool, which has placed strong emphasis on substitution where feasible.

The substitution of ASW/RCF is challenging as ASW/RCF products (mainly articles) are used in a large number of different industrial processes where very high temperatures must be contained by insulation. The thermal, chemical and physical process conditions in each industry are very different, especially aggressive atmospheres which may react with and erode the insulation materials. Nevertheless, significant progress has been made and recent studies of the HTIW industry prepared by AMEC consultants showed that ASW/RCF sales in EU had declined from €150m to €56m between 1994 and 2013 (historical values converted to Euros)[20]. Sales of the alternative materials AES and PCW have at the same time risen to a combined total of €113m.

Another study from BIPRO 'Overview on Alternatives for Alumino-silicate Wools/Refractory Ceramic Fibres (ASW/RCF) products' concluded "*However, since the requirements of each individual application vary, the replacement of ASW/RCF in the process has to be evaluated and decided on a case-by-case basis, and cannot be generalized throughout an industry or technology. […] Because of chemical and physical limitations, a break-through in finding new substitutes to ASW/RCF cannot be expected in the foreseeable future*."

This record of progressive substitution is interesting for the following reasons:

a) Around <u>60% of the substitution of ASW/RCF products has already taken place and for the remaining uses there are significant technical impediments or economic difficulties to substitute</u>.
b) The ASW/RCF user industry has recognised its substitution obligations and has worked with the manufacturers to implement significant changes across many industries in the value chain.
c) The R&D which led the current alternatives took place in the 1980's and substitution has been the consequence of a progressive development, not a sudden change.

Both reports, Amec and BiPRO, support the findings reported in the "Sustainable Industrial Policy –on Eco-design Directive – Energy-Using Products Group Analysis – Lot 4: Industrial and Laboratory Furnaces and Ovens" initiated by the European Commission, DG Enterprise

[20] AMEC Report on The Socio-economic importance of aluminosilicate wools (ASW/RCF) in the context of EU regulations, update of key socio-economic data, April 2015.

"Alumino-silicate RCF products, better described as alumino-silicate wools, are one of the most energy efficient insulation materials available with, in many applications, no alternatives that have the same performance. AES HTIW cannot be used in some types of furnace and polycrystalline HTIW is so much more expensive that its use would cause the user's business to be uncompetitive with non-EU competitors who would not need to comply with REACH Authorisation obligations. If alumino-silicate wool (ASW/RCF) could not be used, EU energy consumption would increase very significantly. The toxicity classification of RCF is outside the scope of this study but as its classification could directly impact on the energy consumed by EU furnaces it is recommended that the available toxicity evidence is re-evaluated." It should be noted that no human disease associated with ASW/RCF exposure has been reported after more than 60 years of industrial use and 30 years of epidemiological research.

2. *Lead stabilizers, an example of successful substitution*

In 2000, the stabiliser producers committed to replace lead-based stabilisers by the end of 2015 in the EU-15, with an interim target of a 50% reduction by 2010. The commitment was extended to the EU-28 in 2014. This substitution programme was initiated in the framework of the Voluntary Commitment of the European PVC industry, Vinyl 2010*, a 10-year programme to move the PVC industry towards sustainability by minimizing the environmental impact of production and promoting responsible use of additives. Since 2000, the progressive substitution of lead-based stabilisers is monitored by sales statistics provided by the members of the European Stabiliser Producers Association (ESPA). At the same time there is a corresponding growth in calcium based stabilisers, used as an alternative to lead-based stabilisers (see graph). The stabilisers industry, by engaging itself in this substitution process, devoted considerable time and resources to the research and development of alternative stabilisers to the widely used lead-based systems.

The substitution plan required many efforts from the stabilisers manufacturers and from the downstream customer sectors to ensure completion. By the end of 2015, the members of the European Stabiliser Producers Association (ESPA), representing more than 95% of the stabiliser industry across Europe, completed the replacement of lead-based (Pb) stabilisers in all their formulations sold in the EU-28 market.

More information can be found on the ESPA website (www.stabilisers.eu) and from the VinylPlus Progress Report 2015 (http://www.vinylplus.eu/).

3. The replacement of thiourea-based accelerators, the most recent successful example that confirms the rubber industry approach towards substitution

A project called SAFERUBBER which was financed by the 7th Framework Programme lasted 3 years (2010-2013) and was successfully completed. The project was already conceived in 2008. Its objective was to find a safer alternative to replace the use of thiourea-based accelerators, primarily ethylene thiourea (ETU), in the vulcanisation process. The substance involved was a hazardous substance used to manufacture certain rubber products. Users of this chemical were mainly SMEs.

Some important elements to be highlighted and that were crucial to succeed in the project are:

- Cooperation – The project was run by a consortium of 12 partners including chemical producers, compounders, manufacturers and research centres;
- Funding – without EU funds it would not have been possible for SMEs to achieve the results;
- 3 years project (including minimum 1-2 years to prepare the project). To be noted that, since the project aimed at identifying and/or developing a new molecule, there was no certainty of the results at the beginning of the project. If the final validation test would not have been successful, the project could have failed to lead to substitution;
- Voluntary industry action: This particular substance was classified for reproductive toxicity and the exposure was limited to manufacturing (exposure to workers), since the substance reacts during vulcanization. There was no REACH legislative pressure to replace this substance. Industry, in line with its continuous effort toward sustainable safer solutions, voluntarily decided to discuss and initiate the collective project. Only in 2013 was ETU identified as SVHC and was it included in the Candidate List (the substance was pre-screened for SVHC status in July 2012, four years after the project was started).

In short, this example illustrates that:

i) SMEs could never have initiated such replacement project alone without involving experts along the entire supply chain;
ii) Economic and research support was needed;
iii) Time is very important and the time needed can only be estimated for the best case scenario;
iv) Industry has been active in finding safer alternatives before REACH;
v) The success of a research for substitutes cannot be guaranteed upfront;
vi) Public funding support to SMEs, and not regulatory pressure on them, turned out to enable the substitution process.

The rubber and tyre sectors have faced similar trends to replace substances posing exposure and health risks to the workers for decades now. Some of these trends include

the replacement of antioxidants containing 2-naphthylamine by antioxidants which do not contain this compound; the replacement of benzene containing raw materials by low-benzene or benzene-free raw materials (only traces of benzene are detected in the raw materials used nowadays); the replacement of accelerator chemicals used in the vulcanisation of rubber and which would generate volatile nitrosamines by accelerators which did not produce such compounds. More globally, processes and technology have evolved to reduce or eliminate solvent consumption, in order to reduce the potential of cumulative exposure to hazardous substances for workers.
Also the development and implementation of low PAH oils involving the petroleum industry, polymer producers and the tire sector was a significant industry effort over a period of 15 years.

4. Co and Ni compounds in hydrotreating catalysts manufacturing, an illustration of AoA conducted by employers outside the REACH Authorisation process[21]

A vast majority of petroleum refineries use alumina supported Co/Ni-Mo/W catalysts in their hydrotreating units. Catalysts manufacturers are required under the existing workplace legislation to look for suitable substitutes to Ni and Co compounds in this use.

There is extensive literature on alternatives to using Co and Ni in hydrotreating catalysts. Several compositions were reported to have high activities in various hydrotreating reactions. However, in reality, the options are limited as potential alternatives are either extremely expensive, and/or are not available in sufficient amounts for commercial use, or are known to be toxic. Most noble metal compositions proposed in the literature are several orders of magnitude more expensive than normal hydrotreating catalysts and, in addition, would not be available in sufficient quantity on the world market. Other compositions that are acceptable from the cost point of view do not show sufficient catalytic activity. A series of tests was conducted to assess the activity of the identified potential alternatives. Tests demonstrated clearly that all catalysts tested had much lower catalytic activities than the commercial catalysts.

The technical and economic consequences of using such low active catalysts in existing refinery unit were also analysed. To achieve the same product quality and cycle length a catalyst with half the activity of a reference catalysts requires a 50% reduction in space velocity, which is infeasible for virtually every refinery. The refiner can significantly increase reactor temperature or invest in additional reactors (thus using more energy). Either way, the additional refining costs will increase the fuel price paid

[21] Albemarle published in 2013 in a scientific journal (see footnote 19) an article in which they described the work conducted to identify potential alternatives and assess by testing in particular, their suitability in terms of technical performance efficiency, commercial availability, costs, toxicity, etc.

by the consumers at the pump, and have major negative impact on the competitiveness of many European refineries, which are already confronted with a fierce competition from third countries. Besides the negative economic impacts, the use of less-well performing catalysts would considerably increase use of energy and thus be contrary to environmental objectives.

This example is interesting in that it illustrates and demonstrates that:

a) Employers take their substitution obligation under the workplace legislation seriously and research has been undertaken for years to find technically feasible alternatives.
b) However, success of substitution depends on many different parameters: toxicity exhibited by the alternatives, commercial availability of the substitutes, ability to deliver the same technical performances, need to keep the industrial process energy efficient (protection of the environment); costs of the alternatives, etc. As catalysts are mixtures, the change of one substance in the composition might also have an impact on the behaviour of the other substances and the mixtures as such.
c) Analysis of alternatives requires specific *in situ* testing: several series of catalysts with different metal loadings to be tested were prepared for each metal or metals combination. The samples were then submitted to activity testing under different conditions corresponding to actual use. This is required to reflect case-specific applicable conditions.
d) In this case, theoretically potential alternatives revealed not to be technically and economically suitable. This illustrates the fact that the information which is available in the literature does not always guarantee an effective substitution, which ultimately constitutes a case-specific decision.

5. Cobalt diacetate as a catalyst for the manufacture of PET precursor, an example of years of research for alternatives, yet no performing substitute identified

The MC Oxidation Process for producing purified terephthalic acid (PTA) from para-xylene (PX) was invented in the mid-1950s. This oxidation process uses a catalyst mixture of cobalt diacetate + manganese diacetate + bromine in acetic acid solvent.

Shortly after the initial discovery, researchers at Amoco (now BP), ICI and elsewhere began looking to improve upon this oxidation process due to the high costs of cobalt diacetate and acetic acid and due to the corrosive nature of bromine[22].

[22] Methodology and scope of metal/bromide autoxidation of hydrocarbons, W. Partenheimer, Amoco Chemical Company Annuitant, 352 Pearson Circle, Naperville, IL 60563, USA, Catalysis Today 23

Over the past 50 years, thousands of man-hours of research have been conducted costing millions of dollars by numerous industrial PTA producers and academic institutions looking for alternatives to the MC Oxidation Process using Co-Mn-Br catalyst in acetic acid solvent for PTA production.

However, despite decades of research which continue to the present, no suitable alternative to cobalt diacetate as an oxidation catalyst has been found which achieves the same high level of efficiency in the conversion of PX to PTA. To date, all alternative PTA production processes not utilising cobalt diacetate suffer from significantly poorer yields of PTA from PX, resulting in severely increased PTA production costs which would make them non-competitive in the marketplace. In addition, the use of an alternative, probably less efficient, catalyst can be expected to produce higher levels of greenhouse gas and waste water emissions than the current PTA process utilising cobalt diacetate-based catalyst systems, thereby driving a negative environmental and economic impact. More precisely, an alternate catalyst system would cause an increase in global warming potential due to more acetic acid burn. The potential of higher process emissions of unwanted compounds and higher generation of impurities would require additional processing steps resulting in a less energy efficient process than the successfully optimised process that industry is currently using.[23]

This example is interesting in illustrating that:

a) The driver for searching and analysing alternatives were the costs of the raw materials – regulatory pressure was not needed; and
b) Despite decades of very significant research and investment, the decision to substitute has not been taken due to a lack of technical performance of the available alternatives.

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(1995) 69-158, and New Oxidation Process for production of terephthalic acid, YATARO ICHIKAWA et al, INDUSTRIAL AND ENGINEERING CHEMISTRY, p38 – 42, VOL.62 NO.4 APRIL 1970.

[23] CPME, December 2014: IFEU PTA datasets, in 'An Eco-Profile and Environmental Product Declaration of the PET manufacturers in Europe- Purified Terephtalic Acid (PTA) ' https://www.ifeu.de/oekobilanzen/pic/PTA%20Eco-profile%20final%20report%20V15_Cover%20%20original.jpg

Annex 2: 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
EPMF – European Precious Metals Federation
ETRMA – European Tyre & Rubber Manufacturers' Association
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
MedTech Europe
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