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INTERNATIONAL COUNCIL OF MARINE INDUSTRY ASSOCIATIONS

Factsheet Restriction on Di-Isocyanate

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1. Introduction

Germany and EU:
The Federal Institute for Occupational Safety and Health in Germany (the German competent authority under EU regulation REACH; named BAuA) is pursuing the imposition of a restriction on the use and placing on the market of Di-Isocyanates. In particular, BAuA is exploring the "potential" need and feasibility of training measures under EU Regulation REACH (EC - 1907/2006)
Global:
Not only in Germany Governmental Authorities but Globally Governmental Authorities are taking actions to restrict and manage (risk managing) the use of Isocyanates and or Di Isocyanates (respiratory sensitizers). But we have seen that the Governmental Authorities in other parts of the World implemented or preparing legislations with the same goal but differences from the EU approach.

Health effects:
Di-Isocyanate can cause asthma, lung damage, and according to EPA – USA in severe cases, death.

The EU Legislation related to substances of concern like Isocyanate and Di-Isocyanate within chemicals and or chemical products, like PU Coatings is REACH (Regulation; EC - 1907/2006; Registration, Evaluation, Authorization and Restriction of Chemical Substances Regulation)

2. What is Isocyanate and Di-Isocyanate

DI-Isocyanates are compounds containing the isocyanate group. They react with compounds containing alcohol (hydroxyl) groups to produce polyurethane polymers, which are components of polyurethane foams, thermoplastic elastomers, spandex fibres, and polyurethane paints.

Isocyanates are the raw materials that make up all polyurethane products. Jobs that may involve exposure to isocyanates include painting, foam-blowing, and the manufacture of many Polyurethane products, such as chemicals, polyurethane foam, insulation materials, surface coatings, car seats, furniture, foam mattresses, under-carpet padding, packaging materials, shoes, laminated fabrics, polyurethane rubber, and adhesives, and during the thermal degradation of polyurethane products.

Di-Isocyanate are in fact the monomers
All di-isocyanates and some of their oligomers are respiratory and skin sensitizers.

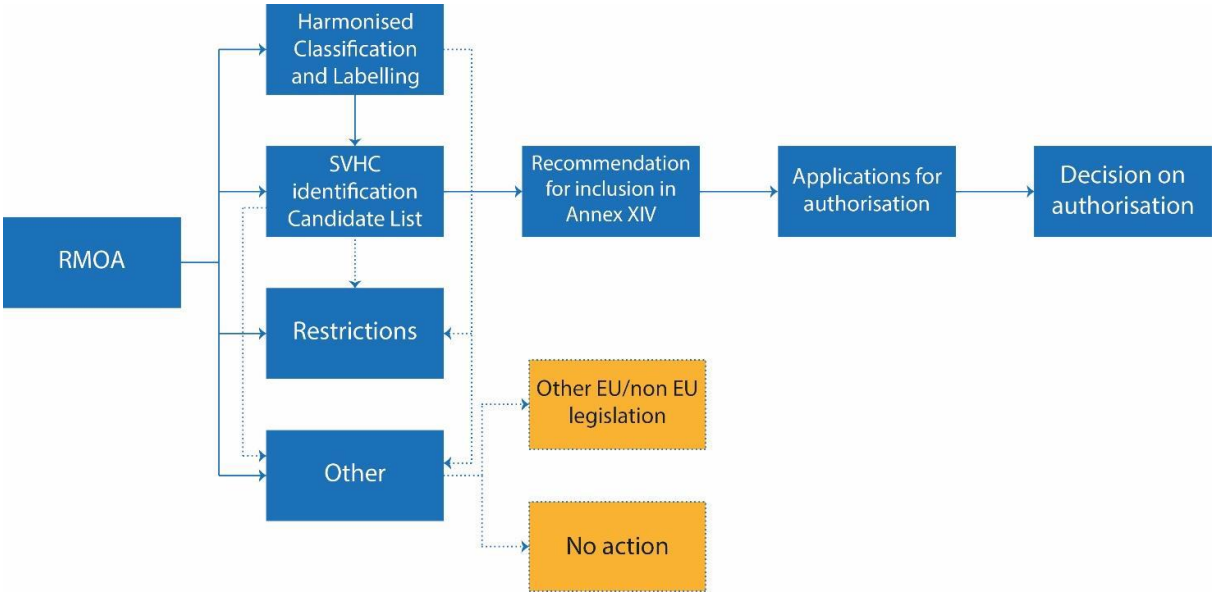
3. **Why restriction**

Health effects of isocyanate exposure include irritation of skin and mucous membranes, chest tightness, and difficult breathing. Isocyanates include compounds classified as potential human carcinogens and known to cause cancer in animals. The main effects of hazardous exposures are occupational asthma and other lung problems, as well as irritation of the eyes, nose, throat, and skin. Di Isocyanate can cause asthma, lung damage, and according to EPA – USA in severe cases, death.

a. **When health effects, 3 options within EU:**

When health effects then according to EU legislations three options are possible, see the figure below:

i. Authorisation
ii. Restriction
iii. Or other EU - or Non - EU regulations



<u>Explanation:</u>

i. <u>Authorisation:</u>

Authorization procedure; Aims to assure that the risks (risk assessment) are properly controlled (time limit) and that these substances are replaced by suitable alternative. Phasing out as final result!

- Be aware that Authorisation is effectively a 'stay of execution' for a substance. It just extends the length of time before a substance is phased out but with one advance: <u>Chemical Industry has to deliver a replacement, with the demand of the EU ensuring the good functioning of the EU internal market!</u>

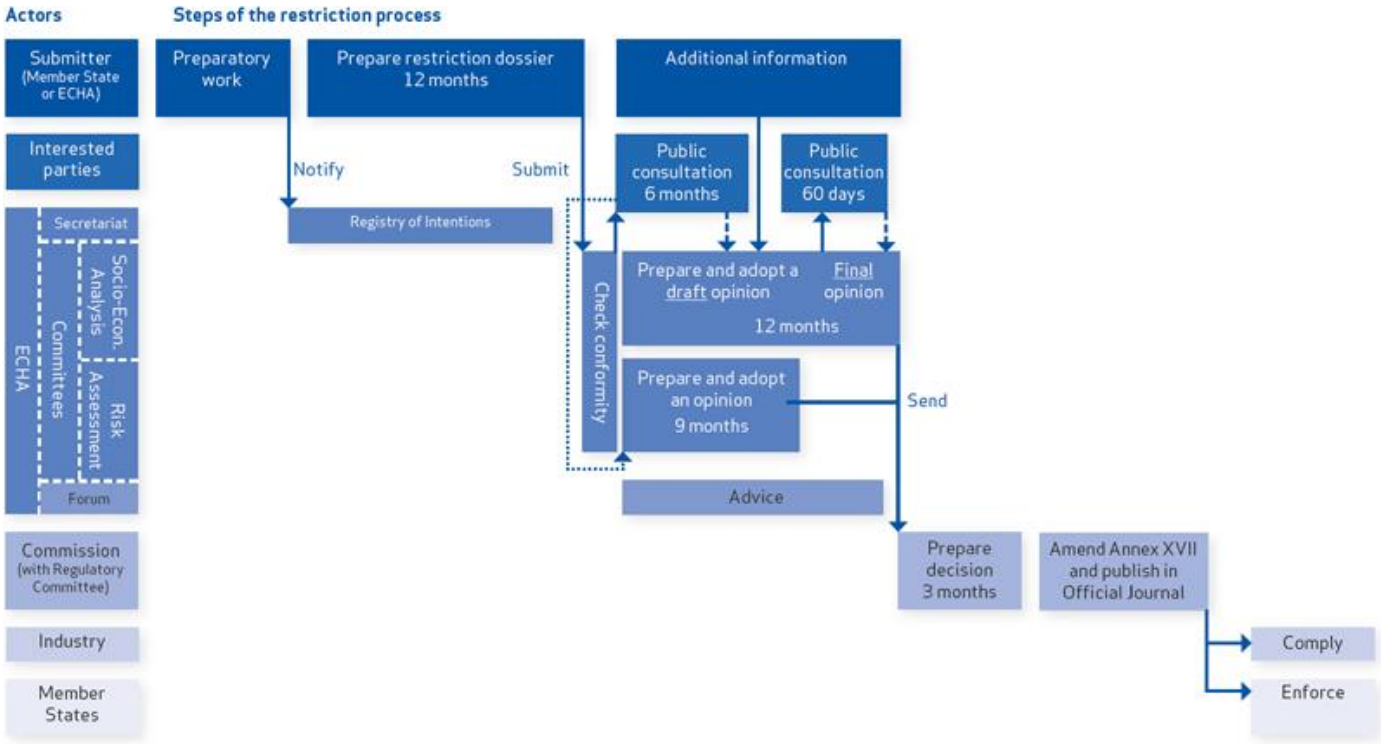
ii. Restriction:

The German approach is focused on Restriction. That is possible since the EU Regulation REACH foresees in special arrangements for MS's;

- Member States may carry out an RMOA (Risk Assessment) outside of the SVHC Roadmap implementation context (for example, as a result of a national programme/national priorities).

Di-Isocyanate Restriction:

For Di-Isocyanate restriction the leading principle has to be establish a legal EU-wide framework that would be instrumental in unifying handling standards in the EU and thereby increase occupational safety throughout the industrial sectors handling (di)isocyanates!



iii. Other

Other is meant to use existing EU legislations and or non EU Regulations (like ISO Guidelines, Standards or legislations/regulations from Countries outside EU).

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4. What will be the impact for our Industry

The Super Yacht – and Boating Industry operates International and need International regulations. The issue is that the German restriction proposals of (Di-) Isocyanate are purely focused on implementation within the EU regulations and not taking in account the existing International rules and or other National and EU Legislations.

When approved by the EU it will have direct affects our Industries and the position and competition of EU Yards and Boat builders and SY - Applicators Globally. Application process will be much more expensive compared to the SY and Boating Industry outside the EU!

Di-Isocyanate is used in the 2 pack PU Coatings effecting 90 - 95% of the Top Coats within the Super Yacht and Boating Industry!

The restriction route to risk managing isocyanates (respiratory sensitizers that cause asthma and even more) is according to BAuA seen to be in the best interest of the Chemical Industry, as the alternative (Authorisation) would be costly and would increase the pressure to replace this technology altogether.

Note: Authorisation would be not of interest for the Chemical Industry but it is in the best interest of the Downstream users (like Yards, Applicators, Paint Suppliers/Manufacturers etc.). When Authorisation the Chemical Industry would have the responsibility to deliver good replacements which ensures good functioning of the EU Internal Market!

The intention of BAuA is to have the dossier ready for submitting to ECHA later this year (probably October 2016), and it will cover the general restriction (supporting only industrial and professional uses), along with the need for training and a certification scheme for users, depending on the level of hazard associated with the products they use, and the application process employed.

<u>Financial impact on downstream users:</u>
In fact Paint or Foam Supplier are only allowed to deliver their products to certified companies (downstream users). Everybody related to the process of using (DI)-Isocyanate containing products must be certified, this includes according to the German proposals the staff for internal logistics but also persons who have access to areas where the processes will be handled must be certified.

The costs per person for a training and exams to be certified, based on the original German proposals more or less € 2,500.- . The German proposals include a repeat system of every 4 years!

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Example

For example a SY Applicator with a staff of 50 the German proposal will increase their costs every 4 years with € 125,000.- and the costs of traveling and missing the person for work, which means at least for the whole staff 100 days plus traveling & hotel costs. Roughly it will cost the applicator with 50 staff € 300,000 - € 400,000. The same for the Yards (even when they appoint subcontractors)! Also the paint manufacturers and suppliers will be effected by the rule (including the logistics). What the effect will be on the product prices is unknown.

a. Economical value of the Recreational Boating Industry

At a minimum, the consolidated figures shows the global boating industry consists of:
• 100,000 direct companies (primarily small to medium-sized businesses),
• 1 million direct employees,
• 25 million recreational boats, and
• 25,000 marinas
• More than €40 billion in manufacturing turnover

These numbers don't capture the extensive indirect economic contributions that come from a highly varied supply chain and array of services related to recreational boating, including marina-based restaurants, shops, marine tourism, repair and maintenance, fuel and provisioning, surveyors, insurance, boating publications, boat shows, fishing, boat charters and excursions, sailing schools, regattas, harbour festivals and so on.

b. Superyachts:

- In total, 413 yachts 30+ metres and above were under construction last year.
  - Economical value of a Super Yacht larger than 30 metres are roughly between 0.70 and 1.00 million per meter.
- If also taking account of smaller yachts between 24m and 30m in the SY annual order book round-up, then 734 superyachts were on order.
  - Economical value of a 24 – 30 m. Super Yacht will be roughly 0.40 to 0.60 million per meter.

Note: 80 percent of the Super Yachts Yards are built/constructed in Europe!

5. **Global overview measures taken by Authorities**

a. **Germany;** The German proposal to the EU:
The German Governmental Authorities, Federal Institute for Occupational Safety and Health; the BAuA are preparing a dossier/proposal to the EU under EU Regulation REACH for a restriction approach for the use isocyanate-based products, more specific to Di-Isocyanates (a monomer). This will potential affects our Industry due in the Super Yacht and Yacht and Boatbuilding sector for 90 – 95% top coats are the 2 pack polyurethane (PU Coatings).

The restriction route to risk managing isocyanates (respiratory sensitizers that cause asthma) is according to BAuA seen to be in the best interest of the Chemical Industry, as the alternative (authorisation) would be costly and would increase the pressure to replace this technology altogether (which is not feasible according to most of the Chemical Industry, not enough replacements available).

The intention of BAuA is to have the dossier ready for submitting to ECHA later this year (probably October 2016), and it will cover the general restriction (supporting only industrial and professional uses), along with the need for training and a certification scheme for users, depending on the level of hazard associated with the products they use, and the application process employed.

Although the in our sector finished (once mixed) 2-pack isocyanate coatings are believed to be below the exemption threshold with regard to the free isocyanate level provisionally set by the BAuA (0.1%), and could therefore be exempt, the hardener component alone will be not exempted.

Also, as many 2-packs are spray applied in our sector (like in other Industries especially for the vehicle refinish and aerospace sectors), we are expecting to fall into scope with regard to the requirement for restriction by use of training and certification of the applicators and the use of PPE at the facilities where the paints and or isolation foams are applied.

Conclusions:
According to the German proposals Paint Suppliers are only allowed to deliver Di-Isocyanate containing paint products to certified companies, applicators and or yards. Even the company responsible for transport and logistics should according to the German proposals be certified. And be aware the German proposals affects also the Pain t Manufacturers due they are Down Stream users as well!

b. USA

EPA – USA announced on January 8th, 2015 that it is taking action to protect consumers from new uses and imports of harmful (di) isocyanates in polyurethane.

The EPA's proposed action, a Significant New Use Rule (SNUR) under the Toxic Substances Control Act (TSCA), would require manufacturers (including importers) to notify the EPA at least 90 days before starting or resuming new uses of isocyanates in polyurethane based consumer products. The EPA would then have the opportunity to evaluate the intended use of and if necessary, to take action to prohibit or limit all products containing over one tenth of one percent of the chemical including imported products that make their way into the United States.

According to the US EPA, isocyanates are currently widely used in the production of polyurethanes such as coatings, elastomers, adhesives, and sealants and can be found in consumer products used in and around homes or schools. Isocyanates are well known dermal and inhalation sensitizers in the workplace and can cause asthma, lung damage, and in severe cases, death.

The proposed decision would give EPA the opportunity to evaluate the use of, and if necessary, to take action to prohibit or limit all products containing over 0.1 percent of the chemical including imported products that make their way into the United States.

c. Australia,

Australia but also Ireland, and the United Kingdom have set long-term occupational exposure limits (8 h time-weighted average) of 20 µg/m3 [total isocyanate (NCO) group] and short-term limits (15 min) of 70 µg/m3 for workplace air. Whereby Australia wants to follow the US road to the restriction of use, to stay in compliance with EPA - USA

d. Other Countries:

In addition, Finland has set a short term limit (15 min) of 35 µg/m3 and Sweden has set long-term occupational exposure limits (8 h time-weighted average) of 5 ppb1) [total isocyanate (NCO) group] and short-term limits (15 min) of 10 ppb for workplace air. These limits are for total isocyanate, i.e. monomeric and all polymeric (also called oligomeric, poly isocyanates, oligo-isocyanates or prepolymeric) isocyanates.

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Are there regulations and/or legislations available which potential reduce the restriction rules while health and safety is ensured

Australia:

Australia (Safe Work Australia) has published guidelines; “Guide to handle Isocyanates” . This Guide provides information on how to manage health and safety risks associated with the manufacture, storage, handling, generation1 and use of isocyanates in the workplace.

- Safe Work Australia is an Australian Government statutory agency established in 2009. Safe Work Australia consists of representatives of the Commonwealth, state and territory governments, the Australian Council of Trade Unions, the Australian Chamber of Commerce and Industry and the Australian Industry Group.

EU:

Directive 89/391/EEC - OSH "Framework Directive"

The introduction of measures to encourage improvements in the safety and health of workers at work, "a so called Framework Directive"

Objective

The aim of this Directive is to introduce measures to encourage improvements in the safety and health of workers at work. It applies to all sectors of activity, both public and private, except for specific public service activities, such as the armed forces, the police or certain civil protection services.

It is of fundamental importance as it the basic safety and health legal act which lays down general principles concerning the prevention and protection of workers against occupational accidents and diseases. It contains principles concerning the prevention of risks, the protection of safety and health, the assessment of risks, the elimination of risks and accident factors, the informing, consultation and balanced participation and training of workers and their representatives.

On the basis of this "Framework Directive" a series of individual directives were adopted. The Framework Directive with its general principles continues to apply in full to all the areas covered by the individual directives, but where individual directives contain more stringent and/or specific provisions, these special provisions of individual directives prevail.

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Contents

The **general principles of prevention** listed in the directive (89/391/EEC – OSH) are the following:

- avoiding risks
- evaluating the risks
- combating the risks at source
- adapting the work to the individual
- adapting to technical progress
- replacing the dangerous by the non- or the less dangerous
- developing a coherent overall prevention policy
- prioritizing collective protective measures (over individual protective measures)
- giving appropriate instructions to the workers

Due 89/391 is a Framework Directive, see overview below for Daughter Directives (in red applicable for Di-Isocyanate and important for our Industry)

- Directive 1989/654/EEC on minimum safety and health requirements for the workplace: The object of this Directive is to introduce minimum measures designed to improve the working environment, in order to guarantee a better standard of safety and health protection (first individual Directive);
- Directive 2009/104/EC concerning the minimum safety and health requirements for the use of work equipment by workers at work which repealed Directive 89/655/EEC (second individual Directive) ;
- Directive 1989/656/EEC on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace: This Directive lays down minimum requirements for the assessment, selection and correct use of personal protective equipment PPE (third individual Directive);
- Directive 1990/269/EEC on minimum safety and health requirements for the manual handling of loads involving risk: This Directive shall ensure that workers are protected against the risks involved in the manual handling of heavy loads especially contribute to the prevention of musculoskeletal disorders Risk factors for musculoskeletal disorders in manual handling of loads (forth individual Directive);
- Directive 1990/270/EEC on minimum safety and health requirements for work with display screen equipment: The aim of this Directive is to implement specific minimum measures to ensure the safety and health of workers using display screen equipment Musculoskeletal disorders in visual display unit (VDU) tasks (fifth individual Directive);
- Directive 2004/37/EC on the protection of workers from risks related to the exposure to carcinogens and mutagens: This Directive sets out the minimum requirements for protecting workers who have been exposed to carcinogens and mutagens Carcinogenic, mutagenic, reprotoxic (CMR) substances (sixth individual Directive);
- Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work: This Directive is designed to establish specific minimum requirements designed to guarantee a better standard of safety and health for

workers exposed to biological agents at work Biological agents (seventh individual Directive);

- Directive 1992/57/EEC on the implementation of minimum safety and health requirements at temporary and mobile work sites: This Directive aims at promoting better working conditions in the construction sector (building and civil engineering) Health in the Construction Industry (eighth individual Directive);
- Directive 1992/58/EEC on the provision of health and safety signs at work introduces an harmonized system of safety signs that shall help to reduce the risk of accidents at work and occupational diseases (ninth individual Directive)
- Directive 1992/85/EEC on the protection of pregnant women, women who have recently given birth and women who are breastfeeding establishes guidelines for assessing the risks related to specific tasks, movements and postures (e.g. heavy lifting, handling loads, night work), related to the exposure to chemical, physical and biological agents, and to physical and mental stress which are considered to be particularly dangerous for pregnant or breastfeeding women and their child New and expectant mothers (tenth individual Directive);
- Directive 1992/91/EEC concerning the minimum requirements for improving the safety and health protection of workers in the mineral- extracting industries through drilling: The object of this Directive is to improve the safety and health conditions of workers in the extractive industries concerned with exploration for and exploitation of minerals by means of boreholes (onshore and offshore), with a higher than average risk (eleventh individual Directive);
- Directive 1992/104/EEC on minimum safety and health protection of workers in the surface and underground extractive industries: This Directive aims primarily to improve the safety and health protection of workers in the surface and underground extractive industries which is considered to be a sector of elevated risk for the workers' health (twelfth individual Directive);
- Directive 1993/103/EC concerning the minimum safety and health requirements working on board of fishing vessels: The Directive sets out minimum practical measures with a view to encouraging an improvement in the health and safety of workers on board fishing vessels (thirteenth individual Directive) Accident prevention in fisheries;
- Directive 1998/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work: The aim of this Directive is to lay down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents Dangerous substances (chemical and biological) (fourteenth individual Directive);
- Directive 1999/92/EC on the protection of the health and safety of workers from the risks from explosive atmosphere: This directive establishes and harmonize minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres Prevention of fires and explosions (fifteenth individual Directive);

- Directive 2002/44/EC on the protection of the health and safety of workers from the risks arising from the exposure to mechanical vibration: This Directive aims to improve the protection of workers against the risks arising from exposure to mechanical vibration by laying down minimum requirements with regard to the protection of health and safety vibration Vibration, Risk factors for musculoskeletal disorders development: hand-arm tasks, repetitive work (sixteenth individual Directive);
- Directive 2003/10/EC on the protection of the health and safety of workers from the risks arising from the exposure to noise. This Directive lays down minimum requirements for the protection of workers against the risks resulting from exposure to noise, and notably risks to hearing Noise (seventeenth individual Directive);
- Directive 2006/25/EC on the protection of the health and safety of workers from the risks arising from the exposure to artificial optical radiation: This Directive lays down minimum harmonized requirements for the protection of workers against the risks arising from exposure to artificial optical radiation Introduction to UVR at work (e.g. UVA, laser, etc.), (nineteenth individual Directive);
- Directive 2013/35/EU on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) [24]: This Directive is the 20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC and repeals Directive 2004/40/EC on electromagnetic fields which used to be the eighteenth individual Directive. It establishes minimum requirements concerning the protection of workers from the risks arising from exposure to electromagnetic fields and waves Electromagnetic fields.

e. <u>ISO</u>

ISO 17735:2009 ·
Workplace atmospheres -- Determination of total isocyanate groups in air using 1-(9-anthracenylmethyl) piperazine (MAP) reagent and liquid chromatography

ISO 17736:2010 ·
Workplace air quality -- Determination of isocyanate in air using a double-filter sampling device and analysis by high pressure liquid chromatography

These International Standards gives general guidance for the sampling and analysis of airborne organic isocyanate (NCO) compounds in workplace air;

- This International Standard is appropriate for a wide range of organic compounds containing isocyanate functional groups, including isocyanate monomers and pre-polymers. Polymeric di-isocyanates are widely used in the polyurethanes, paints and coatings, and adhesives industries.
- This International Standard is appropriate for measuring any product containing free isocyanate groups. It was developed primarily for the commonly used MDI, HDI, and TDI, and their oligomers and polymers.

6. Proposals:

The International Super Yacht and Boating Industry are facing restriction on use of Isocyanates and Di-Isocyanates, which are used in the 2 pack PU Coatings and PU - Foams. 90 - 95% of the top coats used in Paint Products in the Super Yacht - and Boating Industry are 2 pack PU Coatings.

Although the goal for restriction on use is Globally the same, there are differences to achieve it, whereby the EU have the most complicated approach due the complexity of the EU legislations (REACH). The German proposals potential affect our Industry, special who are based in the EU!

EU:

Lobby to the National Governmental Authorities within the EU and to the relevant EC officers and when needed to the EU Parliament to review the German proposal to practical acceptable regulations related to the Restriction of use of Di-Isocyanate's.

ICOMIA position:

- Using existing EU legislations, in this case the EU Framework Directive Framework Directive 89/391 and integrate the specialities of use and restriction of use of Di-Isocyanate;
  - **Using the relevant and following Daughter Directives of Framework Directive 89/391; see below:**
- Directive 1989/654/EEC on minimum safety and health requirements for the workplace
- Directive 2009/104/EC concerning the minimum safety and health requirements for the use of work equipment by workers at work which repealed Directive 89/655/EEC
- Directive 1989/656/EEC on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace
- Directive 1998/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work
- Directive 1999/92/EC on the protection of the health and safety of workers from the risks from explosive atmosphere
  - Refer within the EU legislations to a set of International Guidelines or International Standard how to use and safe handling of (Di) Isocyanate containing products/coatings
  - Integrate into guidelines the requirements of the existing EU, Australian and upcoming USA rules and the specialities of the Coating Industry combined with Sector related items
  - Dissemination and conformation of a training package in the framework of the planned restriction within the proposed approach;
    - A training system that is completely driven by industry. (This can be an industry associations or even a purposely founded "training unit") . The trainers will take care of the actual trainings and will issues a "certificate" (only when needed within current EU legislations).

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USA - Canada:

- Using Industry experiences and results for an Industry based lobby to Governmental Authorities and EPA in USA.
    - Integrate the existing Australian regulations and approach

Lobbying in coordination with Super Yacht - and Boating Industry and CePe :

- CePe (Marine Group) and or other Associations within CEFIC
- IPPIC.
- EBI
- CESA and Sea Europe
- SYBAss
- In the USA and Canada with NMMA and CNMA.

Albert Willemsen; ICOMIA Environment Consultant; updated 31 August 2016.

Annex 1; Training options according to German proposals

The different options of dissemination and conformation of training packages in the framework of the planned restriction. In a general summary these are the following three options:

1. A system that is completely driven by industry. (This can be an industry associations or even a purposely founded "training unit" – in the rest of this summary to be called "initiators" for short).
   In this case trainers are selected by the initiators. This can also happen indirectly via training institutes taking a kind of "licence" to this system and training the trainers or even the employees. Materials are prepared and offered by the initiators. The trainers will take care of the actual trainings and will issues a "certificate".
   In the discussions so far the attractiveness of this option as far as industry does all the work themselves has been rated low, because of the long term efforts it will mean for the initiators.

2. A system that creates an initial package of information that is used for an EU-Wide accreditation. In this case, national training institutes or individuals can ask for an accreditation and disseminate the training content in their country.

3. A system similar to EU 843/2006 (Art 5).
   In this case, as defined in this directive, the individual Member states (MS) can determine content and certification process. (be aware that in Germany this is even going one step further: The individual federal states define this).
   In our discussion, the attractiveness of such an approach has suffered from the risk that one may end up with widely varying conditions among different MS.

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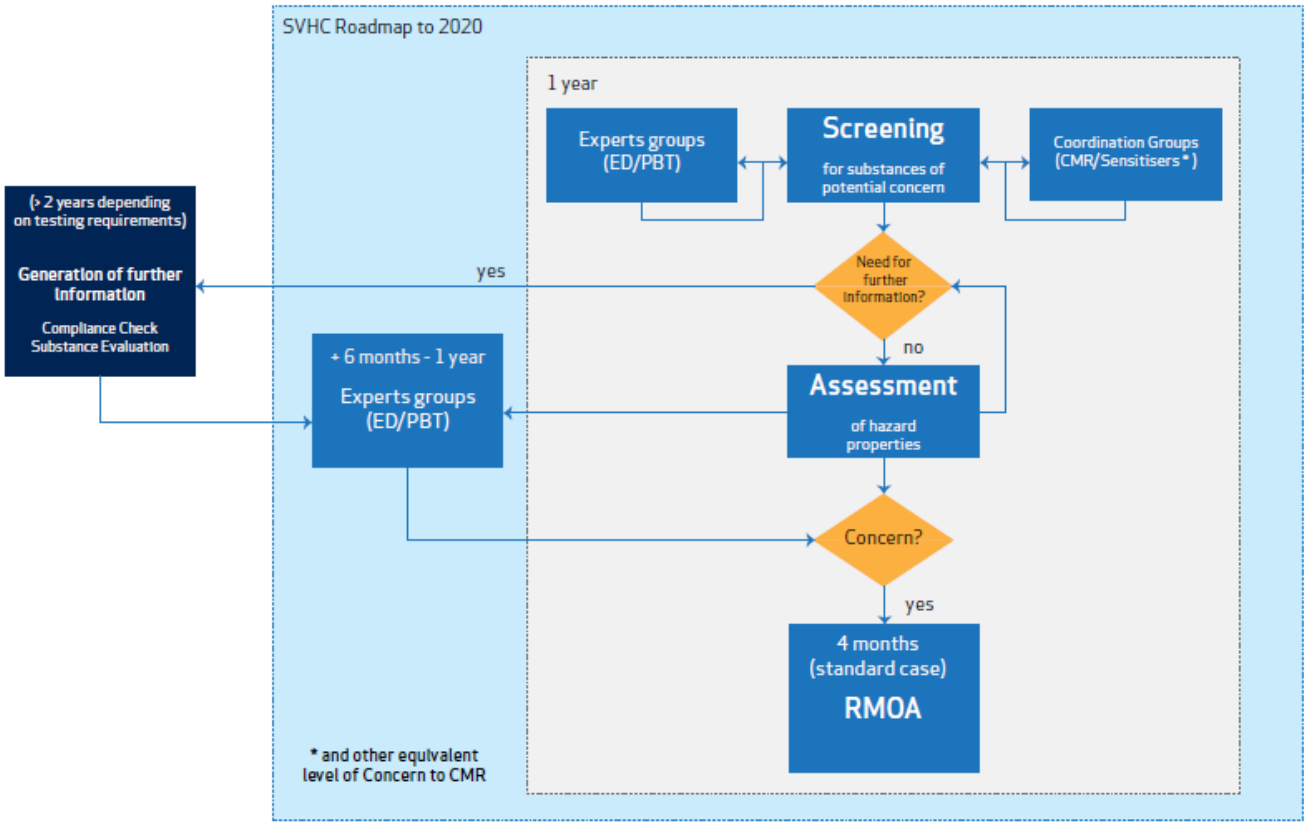
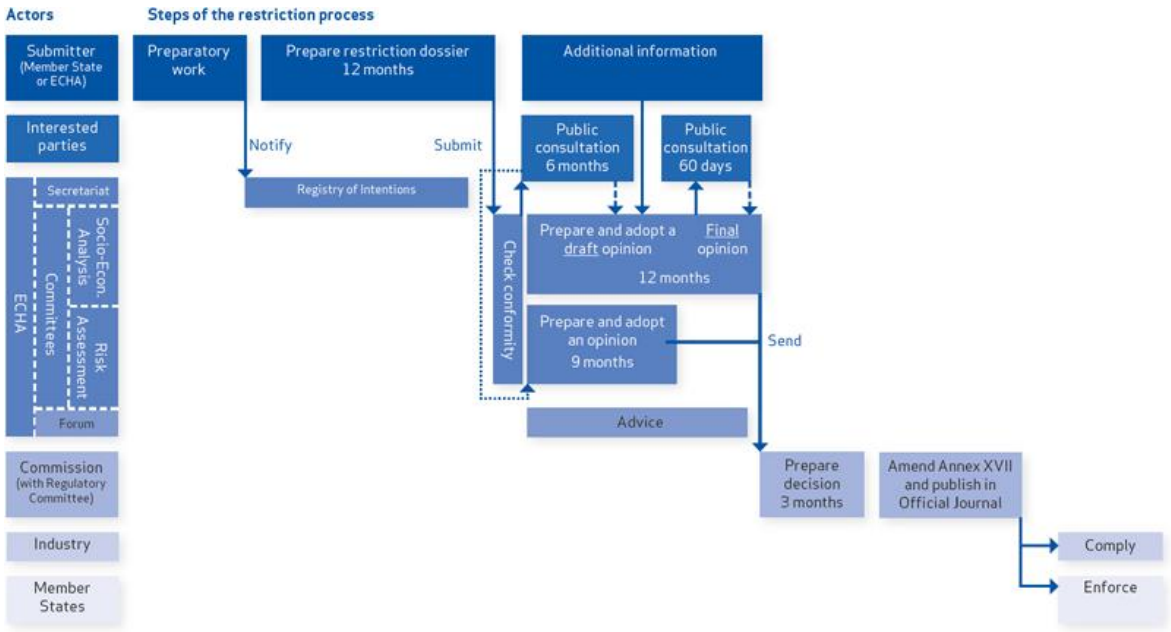
Annex 2; Certification options

Option	*Advantage*	*Disadvantage*
"Industry owned" system	Under industries own control (Idea of product stewardship)	Needs long term commitment of resources
	Maximum in unified approach possible	Needs to organise resources in all MS (be it under own control or via other institutes)
	Minimum bureaucracy	Long term costs considerable (maintenance, renewal)
	Possibility to transfer activity to selected national institutes of good reputation	Totally outside of MS control, may create difficulties to match with existing national systems like in DK and SE
	Implementation according to own priorities	There may be legal questions about industry (not an authority) issuing "certificates"
	Initial implementation costs moderate	There may be legal questions about transferability of certificates from one MS to another
	Maximised knowledge on safe handling available in industry	
Via Accreditation Authority	EU-Accreditation system was implemented for such cases	Bureaucratic to set up and maintain
	EU-Wide unified approach possible	Considerable up-front costs for implementation
	National training institutes may take an accreditation and disseminate the system	Considerable up-front costs for individual accreditation
	Only serious trainers will apply (cost barrier)	Unknown costs for long term continuation (needs renewal after a number of years)
		Risk that certain countries with few companies may not be economically interesting for trainers
Member State System similar to "F Gases System" (EG 842/2006) and Asbestos	Puts the implementation burden on MS	Needs specific action of MS to implement
	MS likely to take whatever unified material is offered	Some MS may try to opt-out
	May still include well known national training institutes as disseminators	Risk of MS differentiation and significant differences in final requirements
	Implementation costs moderate	Potential discussion on comparability of trainings and certificates in different MS
	Similar systems up and working (e.g. for asbestos)	Needs discussion with individual MS to get implementation in the way one wants. Needs considerable resources from initiators to make sure implementation covers original objectives

Annex 3; The Restriction route under REACH



Overview Roadmap and related activities under REACH



Steps of Restriction Process