

Anhydrides Joint Industry Taskforce Public Consultation Report

Date: 16-2-2016

Table of Contents

1		Introduction						
2		Indu	Jstry	Consultation	4			
	2.	1	Use	of the substance	5			
	2.	2	Exp	osure, adverse health effects, and risk management measures	8			
	2.	3	Fec	asibility of exposure reduction	13			
	2.	4	Fec	sibility of substitution				
		2.4.	1	Other epoxy hardeners	15			
		2.4.	.2 Latent catalysts					
		2.4.	3	Resin Rich	15			
	2.	5	Soc	cio-economic impact	15			
		2.5.	1	Key strategic infrastructure	16			
		2.5.	2	Emergent Industries	17			
		2.5.	3	Environmental benefits	17			
		2.5.	4	Gross Domestic Product (GDP)	17			
		2.5.	5	Non-use scenario building	18			
		2.5.	6	Employment	21			
3		Eviden		ce review	22			
	3.	3.1 Lin		it values	22			
	3.	3.2 Tin		eline	24			
		3.2.1		Initial exposure	24			
		3.2.2		Sensitisation	24			
		3.2.3		Clinical symptoms	25			
		3.2.4		Irreversible effect	25			
		3.2.5		Occupational Health and Safety issue	25			
	3.	3.3 Red		commendation	26			
		3.3.1		Closed processes	26			
		3.3.2		Open process	27			
		3.3.3		Sensitised workers	27			
		3.3.4		Life cycle stages	27			
4		Anh	nydri	ides Joint Industry Taskforce Work-Program	28			
	4.	4.1 Exp		osure Inventory	28			
	4.	4.2 Inv		entory of respiratory sensitisation	28			
	4.	3	Rec	commendations	28			

5	С	Conclusion	28					
6	Disclaimer							
7	Re	eferences	30					
8	А	nnex I Process Descriptions	32					
8	8.1	Automatic Pressure Gelation	32					
8	3.2	Vacuum Casting	33					
8	3.3	Atmospheric Casting	33					
8	8.4	Vacuum Pressure Impregnation	33					
8	8.5	Filament Winding	35					
8	8.6	Pultrusion	36					
9	А	nnex II example Risk management measures questionnaire	37					
10		Annex III AJIT member companies	38					

1 Introduction

Hexahydrophthalic Anhydride (HHPA)¹ and Methylhexahydrophthalic Anhydride (MHHPA)² (hereinafter collectively referred to as Anhydrides) have been included in the draft prioritisation for authorisation by the European Chemicals Agency (ECHA) for their respiratory sensitising properties, which are regarded by authorities as constituting an equivalent level of concern to Carcinogenic, Mutagenic and Toxic to Reproduction (CMR) substances.

The Anhydrides Joint Industry Taskforce (AJIT) is a joint initiative of Producers/Importers, Formulators, and Downstream Users of the Anhydrides used as epoxy hardeners (member companies listed in annex III). The purpose of the AJIT is:

- To gather information on current exposure levels and risks associated with Anhydrides and propose protective measures.
- To evaluate socio-economic impacts of an authorisation.
- To inform authorities of possible risk management options for the use of Anhydrides

To achieve these aims the AJIT has requested the Consortium Manager, Polymer Comply Europe (PCE), to perform an industry consultation to:

- Ascertain the availability of exposure levels and medical data amongst AJIT members and other companies using Anhydrides.
- Determine the economic, social, and environmental benefits of Anhydrides for the European Union and what would happen if Anhydrides can no longer be used.

This report will be structured in three parts. Firstly, the results of the industry consultation will be presented. Secondly, the evidence provided by the European Authorities will be reviewed by industry experts. Lastly, the AJIT will present its intentions for future actions and the suggested approach for authorities.

2 Industry Consultation

The Anhydrides Joint Industry Taskforce initiated this industry consultation during the kick-off meeting of the Taskforce on 14 December. Industry experts were asked to work in a focus group exercise to identify key sectors, associated processes and to comment on whether these are open or closed systems. A number of processes were identified and sectors associated (see Table 1).

¹ Referring to the substances identifiable under CAS numbers: 85-42-7, 13149-00-3, and 14166-21-3

² Referring to the substances identifiable under CAS numbers: 25550-51-0, 19438-60-9, 48122-14-1, and 57110-29-9

Table 1 Result of Industry Mapping Focus Group.

Process	Sector	Closed	Closed with transport to curing oven	Open
Automatic Pressure Gelation and Vacuum Casting	High voltage switchgear ³ (>1 kV), Instrument transformers	Х		
Vacuum Pressure Impregnation	High Voltage Electric Rotating Machines ⁴ (>1 kV)		Х	
Filament winding	Material requiring high tensile strength			Х
Pultrusion Atmospheric Casting	High voltage Insulation High voltage Insulation		Х	Х

Subsequently, in cooperation with the AJIT Technical Committee (TC) the processes have been described in more detail to obtain a more complete picture on the possible critical exposure points in each process (see Annex I). These process descriptions were converted into a questionnaire asking respondents to identify which risk management measures were taken at each step (for example see annex II).

The risk management measures questionnaire was complemented with questions on:

- the use of the substance,
- exposure data,
- medical surveillance data,
- the possibility of reducing exposure,
- the feasibility of substitution,
- general socio-economic impact of the use of these substance, and
- what companies would do in the event of a non-use scenario

In total 17, mainly large, companies provided feedback to this questionnaire. These responses were obtained from within as well as outside of the Taskforce. The questionnaire was analysed in observance of the Cefic Statistics Service's Statistical Rules (1).

2.1 Use of the substance

An exact figure on the quantity of HHPA and MHHPA that is currently in use in the EU is unavailable. An estimate by industry experts indicates that around $10\ 000 - 12\ 000$ tons of HHPA and $5\ 000 - 6\ 000$ tons of MHHPA are used within the EU.

³ **Switchgear** is the combination of electrical disconnect switches, fuses or circuit breakers used to control, protect and isolate electrical equipment. High voltage switchgear is essential to the functioning of the power grid, as well most industries.

⁴ High voltage rotating machines are generators used in power generation as well as electric motors.

It is estimated that 74% of HHPA is used as a monomer in the manufacture of resins and between 3 – 8% is used as in chemical synthesis, and 23% is used as a hardener of epoxy resins. The latter use being identified by ECHA as being within the scope of the authorisation procedure. Therefore, the quantity of HHPA that is currently in the scope of authorisation is 2300 – 2760 ton.

The quantity of MHHPA that is in scope of authorisation is approximately 4500 – 5400 ton, as our estimates indicate that roughly 10% of this substance is used as a monomer in the manufacture of resins.

Only data collected from uses under the scope of authorisation will be considered below.

The structure of the life cycle of these products is relatively simple. The European market knows only one manufacturer of HPPA and MHHPA: Polynt and a small number of importers (e.g. the consortium members: Dixie Chemical (US) and Hitachi Chemical (JP)). These manufacturers/importers (M/I) supply formulators or end-users. Formulators supply end users, generally in the form of epoxy systems (a mixture or two component system of epoxy and anhydrides). The end user of these substances is generally operating in an industrial setting where the substances react as a monomer in a polymerisation reaction to form a thermoset. Indeed, AJIT member companies do not endorse the use of these chemicals outside of an industrial setting. Progression of these substances to professional or consumer life cycle stages should not be allowed.

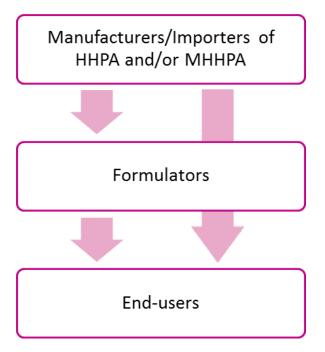


Figure 1 Industry description

The end users that have submitted questionnaires stated using the following processes:

- Vacuum Casting
- Automatic Pressure Gelation
- Vacuum Pressure Impregnation
- Atmospheric casting
- Pultrusion
- Filament winding
- Other uses

For Vacuum Casting, Automatic Pressure Gelation, and Vacuum Pressure Impregnation, sufficient responses were gathered to be displayed separately without risk of a breach of confidentiality. The other uses were merged into the category "Other" to allow us to display the information and perform further calculations. The total volume of end use of HHPA and MHHPA covered by our industry consultation is 712.2 and 1440.5 ton, respectively.

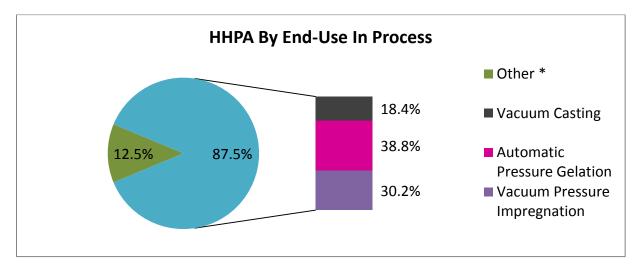


Figure 2 HHPA by end-use per process. Use as a monomer in the manufacture of resins and use as an intermediate in the chemical synthesis of another substance are excluded from this analysis. * Other use includes: Atmospheric casting, Pultrusion, Filament winding, and other uses

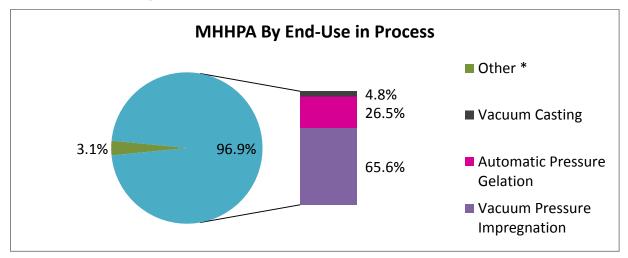


Figure 3 MHHPA by end-use per process. Use as a monomer in the manufacture of resins and use as an intermediate in the chemical synthesis of another substance are excluded from this analysis. * Other use includes: Atmospheric casting, Pultrusion, Filament winding, and other uses

The distribution of the use of these substances over the various processes can be seen in Figure 2 and Figure 3. As one can see, MHHPA is used relatively more in the Vacuum Pressure Impregnation than HHPA. As we have seen the Vacuum Casting and Automatic Pressure Gelation processes mainly produce Switch Gear, while Vacuum Pressure Impregnation is used for high voltage rotating machines. Therefore, MHHPA is used more in the production of high voltage rotating machines and HHPA is used more in the production of switchgear.

2.2 Exposure, adverse health effects, and risk management measures

The questionnaire required respondents to provide details on the number of employees exposed to HHPA and/or MHHPA. As many of the respondents use mixtures it is not possible to separate the number of exposed workers by anhydride. However it was possible to determine the number of exposed workers per process (see Table 2).

Table 2 Number of exposed workers per process. Use as a monomer in the manufacture of resins and use as an intermediate in the chemical synthesis of another substance are excluded from this analysis. * Other use includes: Atmospheric casting, Pultrusion, Filament winding, and other uses

Process	Number of Exposed workers
Other *	21
Vacuum Casting	12
Automatic Pressure Gelation	111
Vacuum Pressure Impregnation	140
Formulation	89
Total	372
Estimate for total EU market	1293

The total market estimate was calculated by multiplying the total number of exposed workers as declared in the questionnaire with the extrapolation factor.

$$estimated number of workers exposed in the EU$$
(1)
= Number of declared workers \cdot extrapolation factor

The extrapolation factor is calculated by dividing the abovementioned estimate of the total market size by the size of the market covered in this sample.

$$extrapolation \ factor = \frac{Estimated \ market \ size}{Market \ covered \ by \ sample} = \frac{2530 + 4950}{712.2 + 1440.5} = 3.47$$
(2)

In subsequent questions, companies were asked to provide measurement data on current exposures experienced in their plants. There were six plants in our sample that reported having taken measurements.

The first measurement was performed in a plant belonging in the other category performing a closed process. The concentration of HHPA and MHHPA were below the limit of detection (< 0.017 mg/m³).

Measurements of anhydrides from a plant performing Automatic Pressure Gelation are available. Here two personal measurements were taken, complemented by one stationary measurement (see Table 3). All measurements were below the limit of detection for this method.

Table 3 Measurements at an Automatic Pressure Gelation plant

Measurement	Concentration
Personal measurement machine 1	<0.0025 mg/m ³
Personal measurement machine 2	<0.0025 mg/m ³
Stationary measurement plant hall	<0.0025 mg/m ³

One plant operating the Vacuum Pressure Impregnation process had performed personal measurements on two workers for 430 minutes (one working day), complemented by a static measurement in the control cabinet (a separate cabinet used by workers to isolate themselves from the process as much as possible). The personal measurements included the critical step in the Vacuum Pressure Impregnation process of opening the Vacuum Pressure Impregnation vessel.

Table 4 Measurements in Vacuum Pressure Impregnation plant 1

Measurement	8-hour time weighted average
Person 1	0.0071 mg/m ³
Person 2	0.0030 mg/m ³
Control Cabinet	0.0019 mg/m ³

Another set of personal measurements was taken in a Vacuum Pressure Impregnation plant providing an indication of the average concentration observed in a shorter timeframe (40 min) inside as well as outside of a mask. The concentration within the mask is reduced to below the limit of detection 0.04 mg/m³.

Table 5 Measurements in Vacuum Pressure Impregnation plant 2

Measurements	Concentration
Person 1 (outside mask)	4.26 mg/m ³
Person 1 (inside mask)	<0.04 mg/m ³

The last set of measurements was obtained in a Vacuum Pressure Impregnation plant, as well. Here a number of static as well as personal measurements were taken during various points in time for 60 – 190 minute (see Table 6). From these measurements one can see that high exposure is contained to the Vacuum Pressure Impregnation hall, as the adjoining hall and the separate epoxy storage exhibit concentrations below the detection limit. Furthermore, the use of appropriate masks reduce worker exposure to levels below the detection limit of 0.04 mg/m³.

Table 6 Measurements in Vacuum Pressure Impregnation plant 3

Measurement location Concentration								
Stationary measurement next to opening of Vacuum Pressure	1.70 mg/m ³							
Impregnation vessel								
Stationary measurement of transport from Vacuum Pressure	2.29 mg/m ³							
Impregnation vessel to curing oven								
Stationary measurement next to curing oven	1.75 mg/m3							
Employee measured outside of mask	3.67 – 3.81							
n								
Employee measured inside of mask	<0.04 mg/m ³							
Stationary measurement epoxy storage	<0.04 mg/m ³							
Stationary measurement adjoining hall behind separation door	<0.04 mg/m3							

There are a number of reasons for the lack of exposure measurements so far. The main one is that there is **no commonly accepted standardised method**. This is the reason that there are several different limits of detection in the above reported measurements.

The lack of a commonly accepted standardised method is also one of the problems which the Anhydrides Joint Industry Taskforce, together with the Zentralverband Elektrotechnik- und Elektronikindustrie e.V. (ZVEI) and other stakeholders, is trying to overcome. In fact, many respondents indicated a willingness to perform measurements in the event a commonly accepted standardised method with suitable detection limit was available.

Companies were asked to report if any adverse health effect occurred during the last 10 years that can be linked to the use of anhydrides. In our sample companies reported 12 cases:

- 1 case of mucosal irritation
- 1 case without providing description of type of effect
- 1 case of skin contact issues (possible skin sensitisation)
- 5 cases of probable respiratory sensitisation
- 4 cases of with allergic reactions (probable respiratory sensitisation)

All but one of the incidences of sensitisation occurred during the Vacuum Pressure Impregnation process. The absence of sensitisation occurring during closed processes indicates that the closing of processes is a strong deterrent to sensitisation and hints that there are concentrations at which no sensitisation occurs.

Furthermore, it can be noted that with 12 cases in the past 10 years on a population of 372 workers in our sample, this would translate into an incidence of 3.2 per 1000 person working years which compares favourably with the figure of 8 per 1000 person working years mentioned in the annex XV dossier for HHPA, thus showing that the risk management measures taken are reducing the occurrence of sensitisation and that further reductions appear possible with increasing awareness and training/enforcement. This is illustrated by the fact that all companies that reported possible sensitisation in the last 10 years, stated to have taken further measures to prevent this in the future. Measures taken include:

- Regular health monitoring
- Restriction of access to trained personnel
- Use of gloves, masks, and protective clothing with a higher protection factor
- More stringent use of gloves, masks, and protective clothes
- Relocation of washing area
- Time delayed opening of impregnation chamber

In all cases affected employees were reallocated to other jobs within the company.

Companies were asked to provide details on which risk management measures they take at different stages in their production process. Enough data was collected from Vacuum Pressure Impregnation and Automatic Pressure Gelation. The data for Automatic Pressure Gelation was supplemented by data from Vacuum Casting as the process steps are similar and their inclusion increases the statistical value.

Data from eleven plants were obtained that perform either Automatic Pressure Gelation or Vacuum Casting. The process steps are described below:

- 1. Raw material handling
- 2. Raw material feeding to mixing unit
- 3. Raw material mixing
- 4. Mixture feeding into mould
- 5. Curing in mould
- 6. Opening of mould
- 7. Transport of freshly cured material
- 8. Curing of product in oven, if necessary.

The most critical steps in this process are the handling of raw material. In process step 1 seven respondents report having a closed process. In the four other plants workers are required to wear gloves when performing this activity, as do workers in six of the seven plants reporting to have a closed process. Two of the plants using an open process require their workers to wear an appropriate mask for the task (which as we have seen above can significantly reduce exposure); however two do not require a mask during this critical step.

The feeding of HHPA and MHHPA to the mixing unit is performed in all but one plant in a closed process. This one plant requires gloves to be used, but no mask to be worn.

All companies report mixing the raw materials in a closed process.

The feeding of the mixture into the mould is performed at ten of the reporting plants in a closed system. The plant not using a closed system uses local exhaust ventilation and gloves. During Vacuum Casting and Automatic Pressure Gelation the products are cured in a mould, this curing process is by its very nature a closed process whereby HHPA and MHHPA react with epoxy to form a thermosetting polymer. after this process, all HHPA and MHHPA have reacted and no free Anhydrides are available for exposure.

Vacuum Pressure Impregnation can be described as a seven step process:

- 1. Raw material handling
- 2. Raw material feeding to mixing unit
- 3. Raw material mixing
- 4. Mixture feeding into impregnation chamber
- 5. Draining the resin
- 6. Opening of pressure chamber and transport to curing oven
- 7. Curing of product in oven

The most critical steps are: the handling of raw material, the opening of the pressure chamber, and transport to the curing oven. Data for eight plants are available. All of these plants report using local exhaust ventilation, generally as a system that keeps the Vacuum Pressure Impregnation hall under reduced pressure as this provides the highest degree of efficiency as well as avoiding contamination of other areas of the plant.

Four of the plants report having a closed system for raw material handling. While all plants report using gloves and masks. In industry, over the past decades, it has become standard to use often full masks in compliance with EN 12941 (see Figure 5) or in some cases a half mask with appropriate filters (see Figure 4) and goggles. Combined with appropriate clothing and gloves (EN 374; Nitrile) a typical worker will enter a Vacuum Pressure Impregnation hall as described in Figure 6.



Figure 4 Full Mask in compliance with EN 12941. Source: Health and Safety Authority (2)



Figure 5 Half Mask with appropriate filters. Applicable standards: EN 140 and EN 14387; EN 405; EN 1827. Source: Health and Safety Authority (2)



Figure 6 Worker in the Vacuum Pressure Impregnation Hall.

This initial investigation into currently available data shows that within the electrical industry there are in essence two processes for which enough data are available: the closed process of Automatic Pressure Gelation/Vacuum Casting and the open process of Vacuum Pressure Impregnation. The closed process seems to generate minimal exposure (<0.0025 mg/m³; below detection limit) and an open process which causes relatively high exposure, but one in which exposure can be contained by using strict personal protective equipment.

2.3 Feasibility of exposure reduction

The questionnaire contained a section asking respondents if it would be technically possible to reduce exposure to a level of 0.005 mg/m³, 0.0005 mg/m³, and 0.0001

mg/m³. For each level it was asked what kind of costs would be associated with such an exposure reduction⁵ and how it would be achieved.

All respondents indicated either to not know if they would be able to reach the lowest two levels (0.0005 mg/m³ and 0.0001 mg/m³) or that such concentrations are impossible to measure and that improvements in the limit of detection of analytical methods to such levels is either impossible or highly unlikely. Therefore, two respondents indicated that to comply with such limit values, the processes would need to be completely automated and separated from workers. This complete separation would carry with it costs that no company could possibly bear.

Due to the fact that few companies had measurements, few companies were able to comment on whether or not they would be capable of reaching the limit of 0.005 mg/m³. However, as seen in the section on exposure, it is possible for companies operating in the fields of Automatic Pressure Gelation and Vacuum Casting to achieve this level. Respondents without measurements offered the following technical solutions:

- Implementing a closed system for storing, loading, mixing, and feeding the raw material
- Installing extra ventilation
- Design and development of specific containers to store liquid losses in a closed tank

The respondents offering these solutions indicated that the cost of such measures were very high.

In the field of Vacuum Pressure Impregnation respondents indicated that the level of exposure in the Vacuum Pressure Impregnation hall cannot be brought down to 0.005 mg/m³. However, it is might be possible to achieve this with personal protective equipment. In fact, there is a possibility that this level is already achieved inside of the mask; a measurement taken in the mask reported above states a concentration below the limit of detection (<0.040 mg/m³). This limit of detection was state of the art of analytical methods at the time of the measurement. This test will be repeated with a new testing method to be recommended by the Anhydrides Joint Industry Taskforce.

Solutions offered by respondents operating in this sector include:

- Installation of additional local exhaust ventilation
- Strict personal protective equipment
 - masks supplied with air from outside of the Vacuum Pressure Impregnation hall,
 - o closed protective clothing,
 - o full respiratory protection,

Respondents indicated the cost of such measures would be very high.

⁵ Measured on a Likert scale (low – medium – high – very high – impossible)

2.4 Feasibility of substitution

Eight of the responding companies reported to have attempted to use an alternative substance or process. Substitutes that have been attempted:

- Other epoxy hardeners
- Latent catalysts

2.4.1 Other epoxy hardeners

A number of companies report having experimented with the use of other epoxy hardeners. Commonly observed problems with other epoxy hardeners are (3):

- Other hardeners do not provide the required process capability
- They do not lead to the required combination of mechanical, thermal, and electrical resistance
- The use of other hardeners does not create products with the required durability for outdoor use.

2.4.2 Latent catalysts

Acid anhydrides such as HHPA and MHHPA are sometimes referred to as latent hardeners. Their low reactivity with epoxy allows them to be mixed without immediately forming a thermoset, i.e. the mixture has a long pot life. When the mixture is heated to temperatures above 160 °C the polymerisation is initiated and a thermoset is formed.

When epoxy alone is heated a similar polymerisation occurs, albeit at a much slower pace and with a brittle product as the end result. Latent catalysts increase the rate of polymerisation and thus the speed of this process (4). A number of these have been tried by respondents to this questionnaire in their production processes. The main reasons for failure were lacking electrical performance⁶ of the final product and process stability.

2.4.3 Resin Rich

One old/historic alternative process has been identified for Vacuum Pressure Impregnation: the "Resin Rich" approach. This approach is however not economically viable as production cost would increase while extra EU competition inhibits the possibility to pass cost increases on to customers. The technology also produces an inferior product in terms of energy efficiency which will be hard to market.

2.5 Socio-economic impact

Companies were asked to provide qualitative comments on the use of their final products in key strategic infrastructure⁷ and emergent industries⁸, as well as the

⁶ The lower electrical isolation the cured product offered resulted in lower energy efficiency of the final product.

⁷ Key strategic infrastructure is infrastructure vital to the functioning of society. For example roads, electrical power distribution, digital infrastructure, etc.

environmental benefit of such use. Subsequently companies were asked to how much turnover they would lose in the event of discontinued use of HHPA and MHHPA. The companies were then asked what they would do if they would no longer be able to use HHPA and MHHPA and how many of their employees would have to be dismissed as a result.

2.5.1 Key strategic infrastructure

All but one company reported producing essential equipment for the electric power grid. Companies performing Vacuum Pressure Impregnation reported producing the generators required for producing the power of the European society. The switchgear and transformers required for the efficient distribution of this power are produced by companies engaging in Automatic Pressure Gelation and/or Vacuum Casting.

The electric motors ensuring: the functioning of the pulp and paper industry, the production of oil and gas (e.g. compressor drives), and the European water supply (e.g. pump drives) are produced by respondents of the questionnaire.

If these parts were created without HHPA or MHHPA the generation, distribution, and use of electricity will be performed with far lower efficiency, thus increasing supply costs and drastically increasing the ecological footprint of the EU (3).

As explained above, HHPA and MHHPA are not present in the products⁹ they are used to produce and downstream users of these products will not accept inferior products. The logical conclusion is that production will shift to extra-EU countries where the use of HHPA and MHHPA is still possible. As one reporting company declared: "this will result in the loss of the technological leadership of Europe concerning electrical equipment, massively impact the renewal of energy generation plants, and the extension of power distribution".

The discontinued use of HHPA and MHHPA is thus an impediment to the creation of a European smart electricity grid, as envisioned in the European Commission's Single Energy Market (5).

A number of reporting companies produce input for the generation of renewable energy sector. Reporting companies produce the generators and switchgear that function in hydropower plants as well as wind turbines.

Sustainability goals such as the switch from a fossil fuel and/or nuclear based society to one relying on renewable energy such as promoted by Germany in its *energiewende* will require the use of HHPA and MHHPA.

⁸ Emergent industries are defined here as new desirable industries. For example: 3d-printing, Electric Cars, Nanotechnology, etc.

 $^{^{9}}$ Measurements taken by a consortium member report concentrations of 0.03 – 0.04 %

2.5.2 Emergent Industries

Many reporting companies stated that the use of HHPA and MHHPA are essential to certain emergent industries. The most notable were:

- Renewable energy (wind and solar industries)
- Smart grids
- Electric Cars

As stated above generators are manufactured using HHPA and/or MHHPA. However, one respondent reported that HHPA and MHHPA are also required for the production of photovoltaic cells used in the solar energy industry, an infant industry that the European Commission itself has sought to protect from unfair competition (6).

The possible discontinued use of HHPA and MHHPA would hamper the European Union's ambitions to establish a single energy market. One objective formulated Regulation on the Connecting Europe Facility (7): "Increase competitiveness by promoting the further integration of the internal energy market and the interoperability of electricity and gas networks across borders." will certainly become more difficult to realise.

2.5.3 Environmental benefits

The environmental benefit of HHPA and MHHPA is mostly the result of two properties of the finished products they help to manufacture: efficient electrical insulation and durability.

Within electric motors/generators the more efficient the electrical insulation is the greater the electric field strength that can be obtained thus the greater the efficiency of energy use/production. This efficiency reduces power consumption and thus CO₂ production. Furthermore, high durability means that motors/generators produced with HHPA and MHHPA last for longer periods of time compared to motors/generators produced with inferior methods, thus meaning that less of them have to be build.

When it comes to switchgear that is produced with HHPA and MHHPA this electrical insulation has a similar effect. Again due to epoxy systems hardened with HHPA and MHHPA offering greater insulation, less power is lost during the transmission from power stations to end users (household and industrial consumers). Their durability ensures functioning over the course of several decades, without the need for replacements.

2.5.4 Gross Domestic Product (GDP)

Companies were asked to report the turnover they "would lose by discontinued use of HHPA and MHHPA". This information will form the basis for our simulation of what would happen to the European GDP in the event HHPA and MHHPA become unavailable.

The data collected from end users can be seen in Table 7 separated by processes. The use of HHPA and MHHPA in the Vacuum Pressure Impregnation process is associated with the greatest revenue; this is due to complexity and thus high added value of high voltage rotating machines. The second largest process by market value is Automatic Pressure Gelation, which is mainly used in the production of switchgear. A total market estimate is obtained as followed:

$Total market estimate = Declared revenue \cdot extrapolation factor$ (3)

A conservative figure of 6.6 billion euro of economic activity is added to the European economy by the use of HHPA and MHHPA.

Table 7 Revenue per process. Use as a monomer in the manufacture of resins and use as an intermediate in the chemical synthesis of another substance are excluded from this analysis. * Other use includes: Atmospheric casting, Pultrusion, Filament winding, and other uses

Process	Reported Revenue per Process	Total Market Estimate	
Other *	€ 9,083,773	€ 31,563,745	
Vacuum Casting	€ 8,600,000	€ 29,882,759	
Automatic Pressure Gelation	€ 122,275,382	€ 424,875,093	
Vacuum Pressure Impregnation	€ 1,756,146,789	€ 6,102,152,500	
Total	€ 1,896,105,505	€ 6,588,474,097	

2.5.5 Non-use scenario building

A non-use scenario building exercise was performed by asking companies to predict what they would do in the event HHPA and MHHPA would become unavailable. Respondents were given 5 possible options:

- Alternative Process, making a switch to an alternative without epoxy
- Close down, stopping completely all activities related to anhydrides
- Becoming a **Distributor**, importing the products that the company previously produced to sell to an existing customer base
- **Relocation** of production to a non-EU country
- Substitution, switching to another substance to produce the same products

When a respondent indicated multiple scenarios these were given a weighted score, unless subsequent answers to scenario specific questions warranted the elimination of a scenario¹⁰. The results can be seen in Figure 7.

¹⁰ E.g. When a respondent indicated to relocate and to act as a distributor, but only to import from the non-EU subsidiary this was interpreted as relocation only.

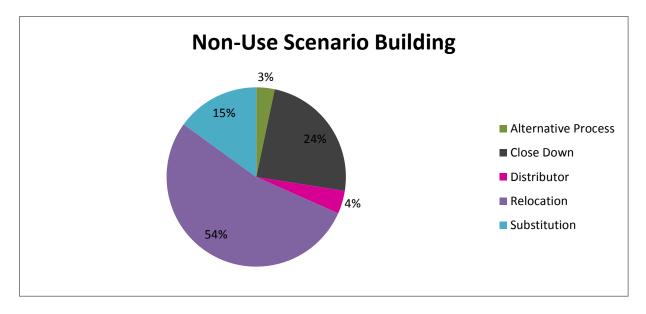


Figure 7 The results of non-use scenario building.

Each respondent was asked to provide qualitative comments on the selected scenario. The results of which will be discussed below

2.5.5.1 Alternative Process

Switching to an alternative process was only opted for as a possible scenario by companies also selecting other scenarios. Companies selecting this option indicate that the cost of production using this alternative process would require significant investments and have far higher operating costs (60 – 100% greater than at present). The respondents furthermore indicate that, as the final products of extra-EU competitors do not contain HHPA or MHHPA, they would not able to transfer this increase in production costs on to their customers in the form of higher prices. Therefore, they expect their customers to start importing the products from outside of the EU making the alternative production process an unattractive option.

2.5.5.2 Close Down

The companies that indicated to have to close down completely their operations related to HHPA and/or MHHPA were generally smaller than companies indicating to be able to shift production to non-EU countries.

None of the respondents indicated that they would be able to recuperate investments by selling of production equipment and most have outstanding obligations that would have to be honoured in the event of a cessation of production (e.g. supply contracts, loans, warranty).

One of the respondents indicated that there might be a possibility to shift only part of the production process abroad, thereby maintaining part of its turnover. All other companies indicated that in the event of a close down they would lose all turnover.

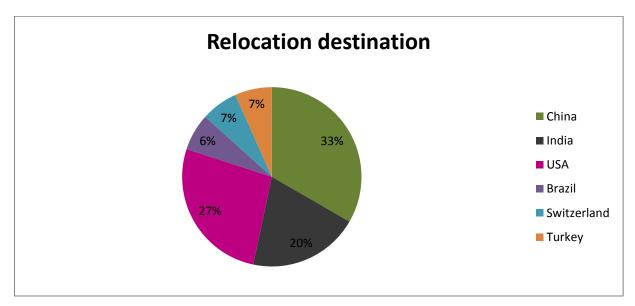
2.5.5.3 Distributor

One respondent reported that it might switch to the role of becoming a distributor. It indicated not to be able to recuperate investments by selling of equipment. It stated

that the impact on the profit margin would be high and indicated to have to lay off employees. Lastly it commented that if HHPA and MHHPA become unavailable, it would have a detrimental effect on the innovative capacity of Europe, know-how will be lost, and the competitiveness of the EU over non-EU countries will deteriorate.

2.5.5.4 Relocation

The by far most probable scenario for most companies is to relocate the production process. Companies were asked where they would shift their production to; the results can be reviewed in Figure 8. Most companies indicate that they already have production facilities in these countries and that the shift of production can be done reasonably rapidly (range: 6 months – 5 years). This does not necessarily mean that their markets will change as without HHPA or MHHPA in the final product, these can be imported to EU countries. Such a shift would deteriorate the EU's balance of trade.





No company reported being able to recuperate any EU investments by selling production equipment in the event HHPA and MHHPA are no longer available and the vast majority of companies report that relocation would impact other operations not linked to the use of HHPA and/or MHHPA.

All companies indicate that their company would be severely disadvantaged in relation to non-EU competitors. Often cited reasons are:

- Loss of customers
- Loss of (worldwide) market share
- Higher transport cost
- Longer transport time

One of the most critical problems most companies face is the loss of the "Made in Europe" advantage. The technology for producing products with HHPA and/or MHHPA is relatively widely known and is already in use by extra-EU competition. However, some reporting companies state explicitly to be manufacturing in Europe

due to the fact that European products are perceived, often rightly, as qualitatively superior to extra-EU alternatives. Furthermore, manufacturing in the EU means that production occurs geographically close to customers, allowing for quick and customer orientated services to be delivered along with the product (e.g. spare parts, technical know-how). All of this would be lost if HHPA and MHHPA would no longer be available in the EU.

2.5.5.5 Substitution

Of the few companies that report substitution as an option one was using another epoxy hardener; the other reporting companies did not know exactly what substance would be used to substitute HHPA and/or MHHPA. Two companies stated the substitute would have to be developed, which would lead to an uncertified product combined with huge R&D expenditure.

2.5.6 Employment

To ascertain the effect on employment of discontinued use of HHPA and MHHPA respondents were asked to provide information on the total number of employees currently employed at the company and the number that would have to be dismissed in the event HHPA and MHHPA would no longer be available; the figures are shown in Table 8 and Table 9, respectively. Total market estimates are obtained by multiplication by the extrapolation factor (eq. 2).

Table 8 Employment associated with the use of HHPA and MHHPA per process. Use as a monomer in the manufacture of resins and use as an intermediate in the chemical synthesis of another substance are excluded from this analysis * Other use includes: Atmospheric casting, Pultrusion, Filament winding, and other uses.

Process	Sample Associated Employment	Total Market Associated Employment
Other *	38	133
Vacuum Casting	582	2022
Automatic Pressure Gelation	2059	7153
Vacuum Pressure Impregnation	17989	62507
Formulation	875	3041
Total	21543	74856

The discrepancy between the number of workers exposed (Table 2) and the employment associated with the use of HHPA and MHHPA can be explained by dependency of support functions (administration, sales, purchasing, etc.) as well as the use of HHPA and MHHPA being a critical step in a long production line/value chain. The latter is especially true for the production of high voltage rotating machines, where the production of the rotating device prior to impregnation requires large amounts of labour.

Table 9 Loss of employment that would result from discontinued use of HHPA and MHHPA per process. Use as a monomer in the manufacture of resins and use as an intermediate in the chemical synthesis of another substance are excluded from this analysis. * Other use includes: Atmospheric casting, Pultrusion, Filament winding, and other uses.

Process	Sample Job Loss	Total Market Job Loss	
Other *	17	58	
Vacuum Casting	50	172	
Automatic Pressure Gelation	520	1806	
Vacuum Pressure Impregnation	11593	40283	
Formulation	185	644	
Total	12364	42962	

The fact that "only" 57.4% of the employment associated with HHPA and MHHPA will be lost is probably due to the fact that large companies are overrepresented in our sample. As can be seen in the non-use scenarios, the likelihood of a SME closing down is greater than for large companies. Furthermore, large companies have more scope to provide jobs on other production lines for affected workers.

3 Evidence review

Respiratory sensitisation caused by low molecular weight substances occurs due to conjugation of these substances with proteins present in the human body. These protein-substance conjugates are recognised as foreign by the immune system leading to an immune response. There is some debate within the scientific community as to whether this is a threshold phenomenon and if such a threshold exists what would be the method of quantification for setting such a threshold (8). The available limit values will be discussed in part 3.1. There is also some significant delay between sensitisation, the onset of clinical symptoms, and the moment at which such symptoms become irreversible; this timeline will be discussed in section 3.2. In conclusion the AJIT will make a recommendation on how to protect the health of workers within industry without having to eliminate HHPA and MHHPA from the EU (section 3.3).

3.1 Limit values

A number of limit values will be discussed below. Some of these limit values will prove difficult if not impossible to measure, as seen above the currently available methods have detection limits varying between $40 - 2.5 \,\mu\text{g/m}^3$. Any limit value set below this level of detection will not be enforceable without advances in analytical methodology.

One of the implicit limit values was touched upon above, as a review by the World Health Organisation reveals that sensitisation occurs above 10 μ g/m³, implicitly stating concentrations below 10 μ g/m³ are safe. The source cited (9) does indeed show that when there is no intermittent peak exposure above 10 μ g/m³ no

sensitisation occurs¹¹. This indicates that there are levels of exposure whereby no sensitisation occurs.

An explicit value of 5 μ g/m³ is advised by the American Conference of Governmental Industrial Hygienists (ACGIH), a professional association of industrial hygienists and practitioners of related professions (10). This limit has been adopted in the form of an OEL by the Belgian competent authority and has probably inspired the competent authorities in Ireland and Spain. In the determination of this limit the same source is used as the one in the WHO report. The basis of evidence is the same however the ACGIH recommends an additional safety margin of 50% thus establishing the 5 μ g/m³.

The limit values proposed in the Annex XV dossier, apart from being impractical due to not being able to measure such a level¹², are also founded on relatively questionable scientific data. The values were derived by the Health Council of the Netherlands by fitting a dose response curve over data obtained by Rosqvist et al. who performed a cross-sectional study in a plant producing electrical capacitors (11), which is a commonly accepted method. However the evidence presented by Rosqvist explicitly states: "Determinations of HHPA in air were stated 5 years before the investigation, and the air levels at the time of the study were approximately 50% of those 5 years earlier" and "The median employment time was 4 (range 0 - 29) years". Combined with the fact that sensitisation is an irreversible effect, it is highly likely that while the authors used current air concentrations in their regression model the incidence of sensitisation occurred many years before while workers were exposed to much higher concentrations of HHPA, thereby overestimating sensitisation that occurs when exposed to the reported exposure. Thus although the method of derivation used by the Health Council is sound, the data on which it is based is questionable. Derivations based on such frail data should not be the basis for policy and should perhaps even be scrapped from the annex XV dossier.

¹¹ As measured by specific Immunoglobulin (Ig) E and G blood levels. Immunoglobulins are more commonly referred to as antibodies and involved in the specific immune system.

 $^{^{12}}$ Levels proposed include 0.07 μ g/m³ and 0.007 μ g/m³ leading to an additional risk of sensitization of 1% and 0.1% over the general population, respectively.

3.2 Timeline

The progression from initial exposure to irreversible severe organ damage is graphically depicted in Figure 9 and will be detailed below.

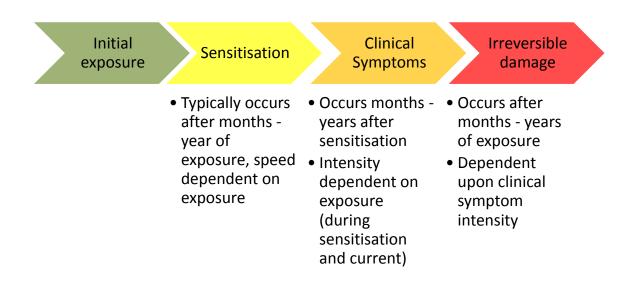


Figure 9 Respiratory Sensitisation, from exposure to irreversible damage

3.2.1 Initial exposure

The only place where it is possible to be exposed is in a controlled industrial setting, as HHPA and MHHPA is not present in products moving into the professional and consumer life cycle stages.

3.2.2 Sensitisation

Due to exposure protein-anhydride conjugates are formed which can be recognised by the host as foreign. When recognised as foreign the host develops a specific immunity. Typically either Ig-E and/or Ig-G are formed by the immune system at this stage which bind the protein-anhydride conjugates. These protein-anhydride-Ig complexes initiate a local immune response that can lead to the development of clinical symptoms. An individual is considered sensitised at the moment he has developed specific immunity and is thus capable of producing Ig-E and/or Ig-G which specifically bind the protein-anhydride conjugates. The detection of these antibodies is often used to prove sensitisation has occurred even though clinical symptoms may not be evident.

Sensitisation is a process that is considered to be a dose dependent phenomenon (8, 11, 12). It typically takes months to years to elicit the effects of sensitisation depending on the level of exposure (dose) and often personal predisposition to become sensitised. There is also consensus amongst scientists that the dose with which one is sensitised influences the exposure level at which clinical symptoms can

be elicited, higher doses during the induction of sensitisation require lower exposure concentrations for sensitisation to be elicited (13).

3.2.3 Clinical symptoms

Clinical symptoms resulting from sensitisation occur months to years after the induction of sensitisation has occurred. Their frequency and intensity often depend on the current exposure and as explained above on the exposure during sensitisation. Symptoms include:

- Symptoms of the eyes:
 - o Lacrimation, itching, scratching, smarting or burning
- Symptoms of the nose
 - Blocked, runny, itchy, or attacks of sneezing or bleeding
- Symptoms of the lower airways
 - o Dyspnea, wheezing, chest tightness or dry cough

When these symptoms are a result of respiratory sensitisation they can be referred to as Occupational Asthma. In the early stages of occupational asthma the symptoms are not permanent and usually disappear in weekends and/or during holidays (11). Therefore the British Thoracic Society Standards of Care Subcommittee Guidelines on Occupational Asthma and the Irish Health Safety and Environmental Agency have developed guidance in identifying and dealing with occupational asthma (14, 15). One of the aims of these guidelines is to prevent the progression of clinical symptoms into an irreversible effect.

3.2.4 Irreversible effect

If workers with clinical symptoms are not stopped from working with the substances to which they are in effect allergic the symptoms caused by the immune reaction can cause permanent damage to the workers organs, particularly the lungs. This is an undisputed fact; the best way to avoid this effect is the subject of debate.

3.2.5 Occupational Health and Safety issue

Under REACH substances are to be included in Annex XIV if they are:

- Carcinogenic, Mutagenic, and/or toxic to Reproduction (CMR);
- Persistent Bioaccumulative and Toxic (PBT); or
- very Persistent and very Bioaccumulative (vPvB); or
- when the substances give rise to an equivalent level of concern.

The precise definition for equivalent level of concern in the legal text (art 57(f)):

"substances (...) for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to" CMR, PBT or vPvB substances.

The annex XV dossier elaborates further based on the guidance for the identification of Substances of Very High Concern (SVHC) that at the time was most recent:

"The concerns for substances which exhibit carcinogenicity, mutagenicity and reproductive toxicity arise from a number of factors – **the seriousness of the effects**,

the often **irreversible nature of the effects**, the consequences for society and the **difficulty in performing concentration-based risk assessments** - should be taken into account when considering whether a substance shows an equivalent level of concern to CMR (cat 1 or 2) substances."

The members of the AJIT admit that it is difficult to perform a concentration-based risk assessment, but will perform one as part of its upcoming work program (see below).

Furthermore, the AJIT members agree that the seriousness of the effects that occur when individuals with clinical symptoms are exposed for prolonged periods and develop irreversible damage is great and should be avoided. However, the annex XV dossier does not state this to be the critical effect, but rather the induction of sensitisation in workers. Although sensitisation is indeed regarded as an irreversible effect it, in itself, does not constitute a seriously detrimental effect on the functioning of an individual. AJIT member companies are confident that the progression from the induction of sensitisation to irreversible clinical symptoms, and perhaps even the induction of sensitisation itself, can be avoided through strong exposure reduction measures complemented by strict health monitoring such as advocated by the Health and Safety Authority and the British Thoracic Society. Therefore the risk associated with the use of HHPA and MHHPA, should be dealt with as an Occupational Health and Safety issue.

3.3 Recommendation

The AJIT has developed specific recommendations in order to eliminate/minimize the health risks associated with the use of HHPA and MHHPA in its member company processes.

3.3.1 Closed processes

When operating in closed condition, such as during Automatic Pressure Gelation and Vacuum Casting, workplace exposure measurements should be taken by a harmonised method¹³. Such exposure measurements should be repeated periodically and should be accompanied with frequent workplace health monitoring in the form of a questionnaire¹⁴ with subsequent follow up investigations if sensitisation is suspected.

¹³ The AJIT will recommend a method in the first half of this year which will be performed in all AJIT member companies.

¹⁴ Such as those advocated by the British Thoracic Society (<u>example</u>; <u>guidance</u>)

3.3.2 Open process

When operating in open processes and where there is considerable difficulty to contain the process (i.e. turn it into a closed process) such as Vacuum Pressure Impregnation the following should be used:

- Overalls protective clothing
- Nitrile Gloves compliant with EN 374
- Full Mask in compliance with EN 12941 (see Figure 4)
- And an reduced pressure work hall to avoid contamination to other sections of the plant

This should be accompanied with exposure measurements within the masks and frequent workplace health monitoring in the form of a questionnaire with subsequent follow up investigations if sensitisation is suspected.

3.3.3 Sensitised workers

When an individual is diagnosed as having acquired immunity to protein-anhydride conjugates he or she should be prevented from working in areas containing any anhydrides. As responsible corporate citizens the AJIT member companies vow to:

 To find another job within the company for the affected worker(s), following a recommendation of company doctor offering retraining as necessary

3.3.4 Life cycle stages

The AJIT does not endorse the use of HHPA or MHHPA in professional or consumer life cycle stages and would like to see this restricted.

The AJIT is open to working in cooperation with European Authorities in order to incorporate these recommendations into Community legislation, thereby exempting these uses from authorisation (REACH art. 58.2). Indeed the REACH guidance on the identification of SVHC quoted in the annex XV dossier states that: if serious effects can be adequately addressed by a normal risk assessment, then "the substance could probably be managed through other REACH procedures, primarily registration." To this end the AJIT is working together with the lead registrant to update the registration dossier and exposure scenarios. Furthermore, the quoted guidance states that "If an Authority has suspicion or concerns that such a substance poses an unacceptable risk, it could be very willing to help shape such a restriction in close cooperation with European Authorities.

4 Anhydrides Joint Industry Taskforce Work-Program

The AJIT will perform a number of actions in the coming year to gather data on the risks associated with the use of HHPA and MHHPA.

4.1 Exposure Inventory

By end-February the AJIT will promote the best available method for measuring HHPA and MHHPA that will be selected by the ZVEI working group. The AJIT member companies are committed to performing these measurements within their plants in the first semester of this year. These measurements will be aggregated and anonymised by the project manager of the AJIT to be incorporated into an exposure report.

4.2 Inventory of respiratory sensitisation

In the first semester of this year the AJIT will hire an independent consultant to review currently available medical records in certain member companies to ascertain the incidence of sensitisation. This information will be coupled to the measured exposure levels obtained at the plant level in the exposure inventory and incorporated in the exposure report.

4.3 Recommendations

Based on the information obtained from the exposure report the AJIT will specify detailed instructions on the use of HHPA and MHHPA in the member companies processes that will eliminate/minimise the risk of respiratory sensitisation.

These recommendations will in any case be communicated to the lead registrant and the other suppliers of HHPA and MHHPA for inclusion in the registration dossier and exposure scenarios, to be annexed to the Safety Data Sheet for communication to downstream users. This should significantly reduce the exposure/incidence of sensitisation throughout the EU.

In the event European Authorities are willing to cooperate in translating these recommendations into other Community regulations the Anhydrides Joint Industry Taskforce will be eager to oblige.

5 Conclusion

As the risks associated with the use of HHPA and MHHPA is strictly confined to an industrial setting the AJIT strongly believes that it would be more efficient, appropriate, and expedient to address the risk arising from the use of HHPA and MHHPA with risk management options other than authorisation.

Authorisation and its associated uncertainty would impose a disproportionate burden upon industry and would likely result in the closure of SMEs and delocalisation of large companies. This would be a grave loss for the EU in terms of innovative capacity and technological leadership in a high value added sector of industry. Registrants can adjust their registration dossiers to advise against the use of HHPA and MHHPA in the professional and consumer life cycle stage as well as tighten the safety requirements to be communicated down the supply chain via Safety Data Sheets and Exposure Scenarios. This would lead to the quickest gains in worker safety.

Alternatively a restriction under REACH specifying reasonable maximum exposure thresholds in combination with specific risk management measures per process and strict mandatory health monitoring. This can be formulated and imposed quite rapidly and would provide adequate protection of the health of employees working with these substances. Such an approach will lead to much more rapid gains in worker safety and would be binding community legislation.

Furthermore, measures through EU directives on safety and health at work (e.g. OEL) could be considered. This would offer an alternative to authorisation to cover the risks associated with the use of HHPA and MHHPA.

6 Disclaimer

This work is based on the input provided by respondents to the industry consultation. Information presented in this document is to the best knowledge of the Anhydrides Joint Industry Taskforce correct and valid for industry.

The Anhydrides Joint Industry Taskforce and its project manager Polymer Comply Europe do not accept any liability resulting from any of this data being proven incorrect.

7 References

1. Service CS. Handling Confidential statistics in compliance with competition laws. 2013.

2. HSE. Respiratory protective equipment at work. A practical guide2013.

3. ZVEI. Position Paper: Anhydrides MHHPA and HHPA under the REACH Regulation. 2014.

4. Naumann S, Buchmeiser MR. Latent and Delayed Action Polymerization Systems. Macromolecular Rapid Communications. 2014;35(7):682-701.

5. EC. COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS. Progress towards completing the Internal Energy Market 2014.

6. COUNCIL IMPLEMENTING REGULATION (EU) No 1238/2013. imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of crystalline silicon photovoltaic modules and key components (ie cells) originating in or consigned from the People's Republic of China2013.

7. REGULATION (EU) No 1316/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. establishing the Connecting Europe Facility, amending Regulation (EU) No 913/2010 and repealing Regulations (EC) No 680/2007 and (EC) No 67/20102013.

8. Cochrane SA, Arts JH, Ehnes C, Hindle S, Hollnagel HM, Poole A, et al. Thresholds in chemical respiratory sensitisation. Toxicology. 2015;333:179-94.

9. Welinder HE, Jonsson BA, Nielsen JE, Ottosson HE, Gustavsson CA. Exposureresponse relationships in the formation of specific antibodies to hexahydrophthalic anhydride in exposed workers. Scand J Work Environ Health. 1994;20(6):459-65.

10. ACGIH. Hexanydrophthalic Anhydride, All Isomers. 2015.

11. Rosqvist S, Nielsen J, Welinder H, Rylander L, Lindh CH, Jonsson BA. Exposureresponse relationships for hexahydrophthalic and methylhexahydrophthalic anhydrides with total plasma protein adducts as biomarkers. Scand J Work Environ Health. 2003;29(4):297-303.

12. Nielsen J, Welinder H, Jonsson B, Axmon A, Rylander L, Skerfving S. Exposure to hexahydrophthalic and methylhexahydrophthalic anhydrides--dose-response for sensitization and airway effects. Scand J Work Environ Health. 2001;27(5):327-34.

13. Pauluhn J. State of Science for Respiratory Sensitization. Dose-Response Models for the OEL-Derivation of Chemicals. Alexandria, VA, USA: ILSI/HESI-Workshop on Assessment of Respiratory Sensitization 28-29 May; 2014.

14. Fishwick D, Barber CM, Bradshaw LM, Ayres JG, Barraclough R, Burge S, et al. Standards of care for occupational asthma: an update. Thorax. 2011.

HSA. Guidelines on Occupational Asthma. Dublin: Health and Safety Authority;
2008.

16. Bardtenschlager R, editor Fully automatic process control for vacuum resin casting systems. Electrical Insulation Conference and Electrical Manufacturing & Coil Winding Conference, 2001 Proceedings; 2001 2001.

17. Pandita SD, Irfan MS, Machavaram VR, Shotton-Gale N, Mahendran RS, Wait CF, et al. Clean wet-filament winding – Part 1: design concept and simulations. Journal of Composite Materials. 2012.

8 Annex I Process Descriptions

Below you will find a description of the processes used in industry, which accompanied the questionnaire.

8.1 Automatic Pressure Gelation

The process of Automatic Pressure Gelation involves the injection under high pressure of an epoxy/hardener mixture into a mould. Most often this is a 2 part mould clamped under high pressure. This mould is then heated to accelerate polymerisation. See Figure 10.

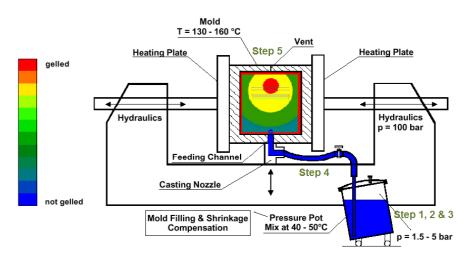


Figure 10 Automatic Pressure Gelation. Source: AJIT

The epoxy and hardener can also be mixed in a continuous system which is displayed in Figure 11.

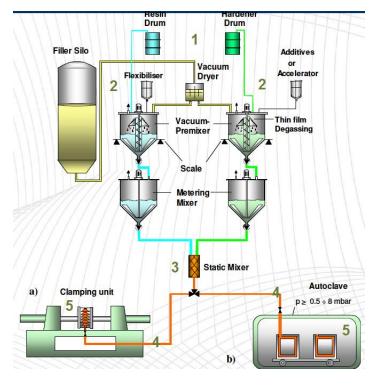


Figure 11 Continuous processing. Source: AJIT

8.2 Vacuum Casting

A Vacuum Casting process employs a continuous mixing system under vacuum as described in Figure 12. Epoxy and hardener are mixed in predefined proportions under vacuum and injected into moulds in a vacuum chamber.

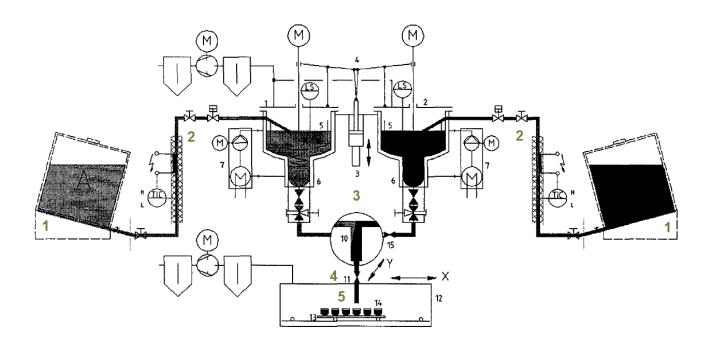


Figure 12 Continuous vacuum preparation and casting system. (1) Vacuum metering mixer, resin component; (2) Vacuum metering mixer, hardener component; (3) Pneumatic central drive; (4) Lever arm system; (5) Stirrer; (6) Metering pumps; (7) Heat exchanger; (10) Static mixer; (11) Reactive mix outlet valve; (12) Vacuum casting chamber; (13) Pallet; (14) Casting mould; and (15) Resin flush valve. Source: (16)

8.3 Atmospheric Casting

When casting occurs under atmospheric pressure this is called atmospheric casting. This method has a number of downsides such as: the presence of moisture can interfere in the curing process and it might be more difficult to obtain a complete fill.

8.4 Vacuum Pressure Impregnation

During Vacuum Casting an object is placed in an impregnation chamber (Figure 13). The impregnation chamber is placed under vacuum and the resin/hardener mixture and impregnation chamber are preheated (Figure 14). This removes any moisture from the object. Subsequently, the object in the pressure chamber is flooded with the resin/hardener mixture, followed by the application of high pressure (Figure 15). Finally the resin/hardener mixture is evacuated to the storage tank and the impregnated object is moved to an oven for curing (Figure 16).

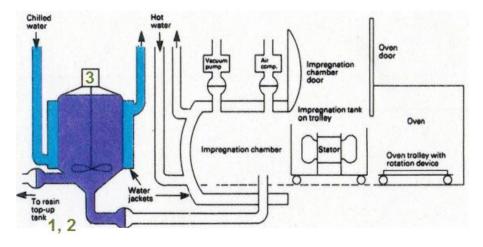


Figure 13 Vacuum Pressure Impregnation Step 1. Source: AJIT

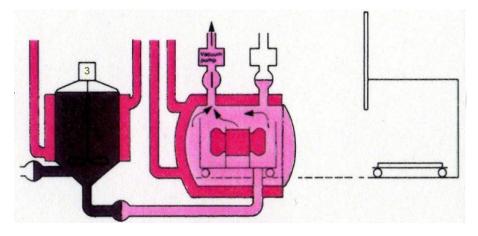


Figure 14 Vacuum Pressure Impregnation Step 2. Source: AJIT

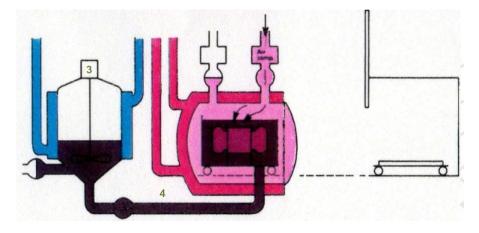


Figure 15 Vacuum Pressure Impregnation Step 3. Source: AJIT

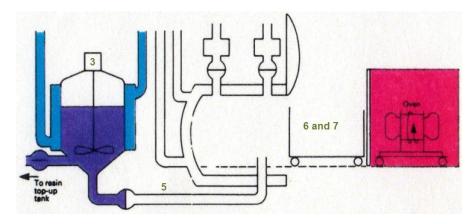


Figure 16 Vacuum Pressure Impregnation Step 4. Source: AJIT

8.5 Filament Winding

In filament winding filaments are straightened and pass through some form of resin bath are bundled and deposited on a heated rotating mandrel for gelation (partial curing). The finial cure takes place in an oven after winding.

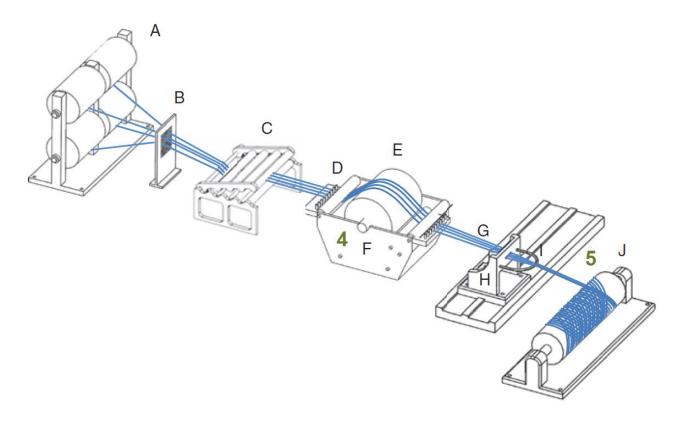


Figure 17 Traditional filament winding. Components are coded as follows: (A) fibre creels; (B) fibre guides; (C) tensioning system; (D) guide pins; (E) drum-impregnator with a doctor blade; (F) resin bath, (G) impregnated fibre bundles; (H) traversing carriage; (I) D-eye; and (J) rotating mandrel. Source: (17)

Due to environmental and economic reasons the resin bath is sometimes replaced by a closed system as described in Figure 18 and (17). The most important difference with respect to this questionnaire is that this is a more closed system than the resin bath dependent one.

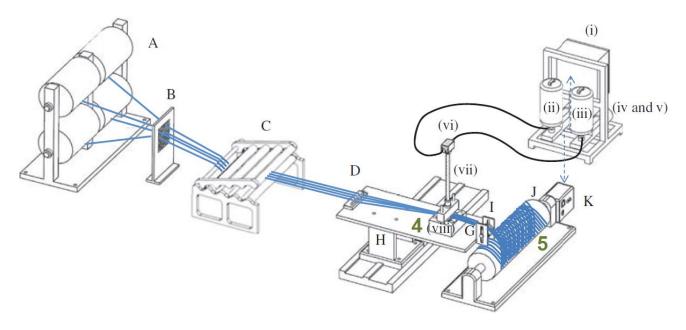


Figure 18 Clean wet-filament winding. (A) fibre creels; (B) fibre guides; (C) tensioning system; (D) Guide pins; (G) Resinimpregnated fibre bundles; (H) Traversing carriage with a platform; adaptor to house the integrated fibre spreading unit and resin impregnator (viii); (I) 'Collector' roller or D-Ring; (J) Rotating mandrel; (K) Feedback control unit to synchronise the resin dispensing unit to the fibre haul-off rate or rotation speed of the mandrel. Source: (17)

8.6 Pultrusion

The Pultrusion process is displayed in Figure 19. In short, fibres (commonly glass fibre) are pulled by a pulling system down the production process. The fibres get impregnated with resin at the resin impregnator and subsequently formed and cured in a die and is left to cool before passing the pulling system. The profiles produced are subsequently cut to appropriate length.

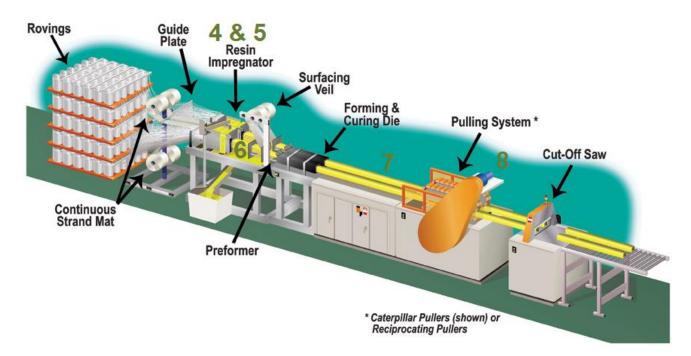


Figure 19 Pultrusion Process. Source: creativepultrusions.com

9 Annex II example Risk management measures questionnaire

Automatic Pressure Gelation. Which RMM (Risk management measure) do you use during the following process steps? Please answer by ticking the applicable boxes only and add specific information where requested.

Processing step	Closed system	Open system	Local exhaust ventilation	Gloves*	Respiratory protection (Mask)*	Goggles	Overalls protection clothing	Exposure time per shift**	Number of workers at this station**	Other measures
1. Raw material handling				Enter text here	Enter text here			Enter text here	Enter text here	Enter text here
2. Raw material feeding to mixing unit				Enter text here	Enter text here			Enter text here	Enter text here	Enter text here
3. Raw material mixing				Enter text here	Enter text here			Enter text here	Enter text here	Enter text here
4. Mixture feeding into mould				Enter text here	Enter text here			Enter text here	Enter text here	Enter text here
5. Curing in mould				Enter text here	Enter text here			Enter text here	Enter text here	Enter text here
6. Opening of mould				Enter text here	Enter text here			Enter text here	Enter text here	Enter text here
7. Transport of freshly cured material				Enter text here	Enter text here			Enter text here	Enter text here	Enter text here
8. Curing of product in oven, if necessary.				Enter text here	Enter text here			Enter text here	Enter text here	Enter text here
9. Other areas				Enter text here	Enter text here			Enter text here	Enter text here	Enter text here

*Please specify type of gloves/mask. Please mask specify according to <u>HSE Respiratory protective equipment at work</u> (Annex I, page 28 – 42).

**Data on the number of operators and other workers handling the product day by day and hours (e.g. 1-2 workers per shift and no more than 3 hours) covering all locations such as laboratory, warehousing. The same workers can be operating in multiple process steps, i.e. the numbers do not need to add up to the total number of worker.

10 Annex III AJIT member companies



Polynt





Hitachi Chemical Europe

Dixie Chemical represented by REACH-Chemadvice



Enriching lives through innovation

Power and productivity for a better world™



ABB

Huntsman



Schneider-Electric



EPOXONIC



ELANTAS Europe

SIEMENS

Siemens



Andritz Hydro





Veneta Isolatori

Hexion

DIAB International

VEM Sachsenwerk



Av. de Cortenbergh 71 1000 Brussels Belgium