Voluntary Commitment: Progress Report

Date: *30-10-2017*

Version: *1.0*

Table of Contents

Introduction

Hexahydrophthalic Anhydride (HHPA) and Methylhexahydrophthalic Anhydride (MHHPA) (hereinafter collectively referred to as Anhydrides) have been identified as Substances of Very High Concern (SVHC) for their respiratory sensitising properties, as this property is considered 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 Manufacturers, Formulators, and Downstream Users of the Anhydrides used as epoxy hardeners (member companies listed in annex I). The purpose of the AJIT is:

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

The potential socio-economic impact was described in the AJIT Public Consultation Report, which can be found on anhydrides.eu.

Over the course of the first semester of 2016 AJIT member companies performed exposure measurements and AJIT collected retrospective medical data from the members and non-members. This information was aggregated and presented in the AJIT Exposure and Medical Inventory. The inventory showed that since the 1990s, when the potential adverse health effects of anhydrides became apparent in scientific literature, industry improved risk management measures and operating conditions to protect the health and safety of workers.

However, as an additional precautionary measure AJIT member companies agreed to join a voluntary commitment whereby they agree to:

- Incorporate the AJIT Medical Diagnostic Guideline into annual medical surveillance
- Develop and implement an exposure minimisation plan per plant
- Implement a AJIT worker training program
- Improve the HHPA and MHHPA exposure measurement methodology

This document recaps the findings of the Exposure and Medical Inventory Report and reports on the progress that has been made in the implementation of the voluntary commitment.

Exposure and Medical Inventory Report

On 26 August 2016 AJIT published an Exposure and Medical Inventory Report that reported on a total of 226 exposure measurements from 13 plants and provided information on the worker health status of 20 plants.

Three exposure groups were identified based on uses and the currently obtained measurements: 1) manufacturers/formulators, 2) producers of switchgear, and 3) producers of high voltage rotating devices.

Manufacturers/Formulators observe concentrations in the range of 4.6 – 9.7 µg/m³. Amongst the reporting plants occupying 192 workers, there is no evidence of occupational asthma related to anhydrides.

Producers of switchgear face anhydrides exposure of 4.6 – 69.2 µg/m³. Amongst the reporting plants occupying 74 workers, there is no evidence of occupational asthma related to anhydrides.

Producers of high voltage rotating machines typically observe exposure ranging from <0.2 (in a control room) – 284 (in the production hall) µg/m³, with short term peaks up to 3670 µg/m³. The use of Respiratory Protective Equipment reduces exposure during peaks to 0.034 (calculated) – 23 (measured in lower standard masks) µg/m³. Amongst the reporting plants occupying 99 workers, there is only one plant where there is evidence that occupational asthma has occurred. In this plant 4 cases could be identified which occurred in 2004, 2005, 2006, and 2010. In two of these cases the workers had a severe atopic condition and might have developed asthma irrespective of whether they had been exposed to anhydrides or not. The workers were removed from exposure to different work places.

Already then **evidence from two plants demonstrated**, through historic measurements, **that it is possible to reduce exposure** through various interventions: improvements in the separation of the workers from the process (under pressure working halls, over pressure control rooms), scrubbers to prevent exhaust systems contaminating other parts of the plants, improvements in local exhaust ventilation, reduction of exposure times, and the use of better respiratory protective equipment (RPE).

The report concluded that:

AJIT acknowledges that occupational asthma related to anhydride exposure is something that can, and should, be prevented in industry. It is preparing a ***voluntary commitment*** *which aims as a precautionary measure to further minimize risk by decrease exposure to levels as low as reasonably achievable.*

Implementation of the Voluntary Commitment

Signatories

21 companies have signed the voluntary commitment. 4 of the signatories have operations involving anhydrides exclusively outside of the European Union[1]. Of the signatories 16 have provided one or more implementation reports[2], while 1 company has at present not yet submitted an implementation report (see Figure 1). In total implementation plans were obtained covering 23 sites within the EU.

[1] These members are either producing anhydrides for import into the European Union or are a member to obtain access to best practices, guidelines, an understanding of EU chemicals legislation, and other benefits that AJIT brings.

[2] Multiple implementation reports are submitted by various companies that have more than one site using anhydrides.

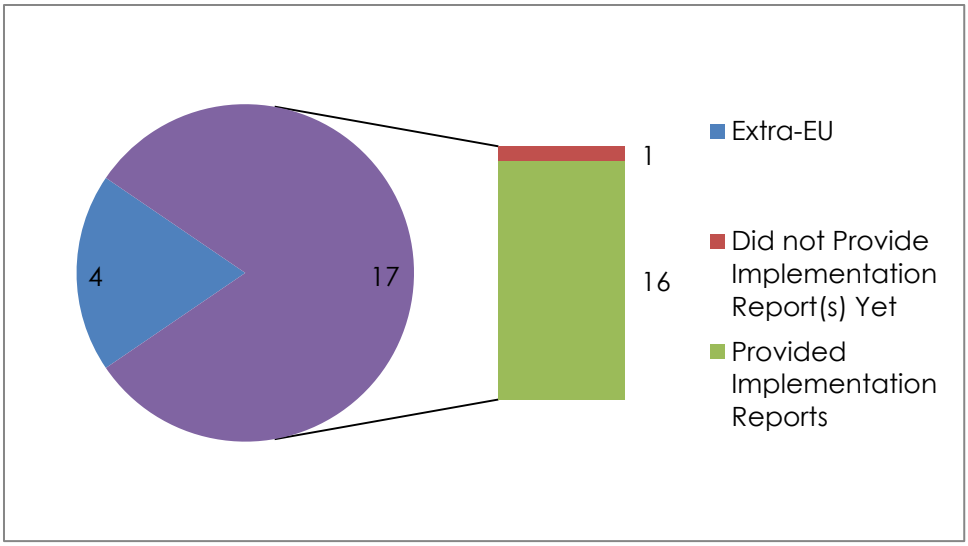

Figure 1 Current status of implementation of the AJIT Voluntary Commitment among the signatories.

Medical Control

Of the 23 Voluntary Commitment Reports all stated that they have either implemented the Medical Diagnostic Guideline or were planning to do so in the future.

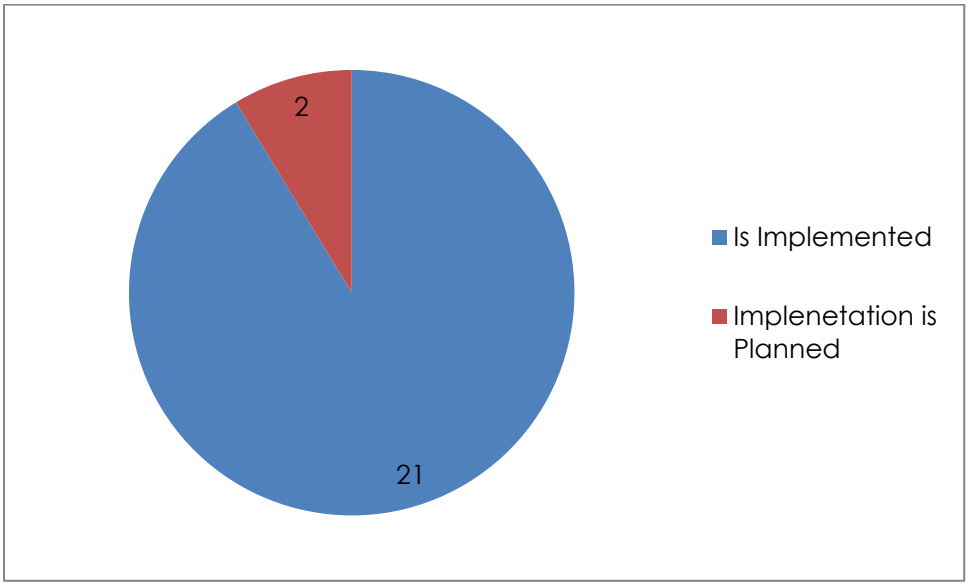

Figure 2 Reported Status Medical Diagnostic Guideline Implementation

Exposure Minimization Plans

Of all submitted reports there were two reports stating that exposure was below the limit of detection of 5 µg/m³ (with standard laboratory equipment), and that further measures were not foreseen. The remaindered all reported that they have implemented or plan to implement additional risk management measures (Figure 1).

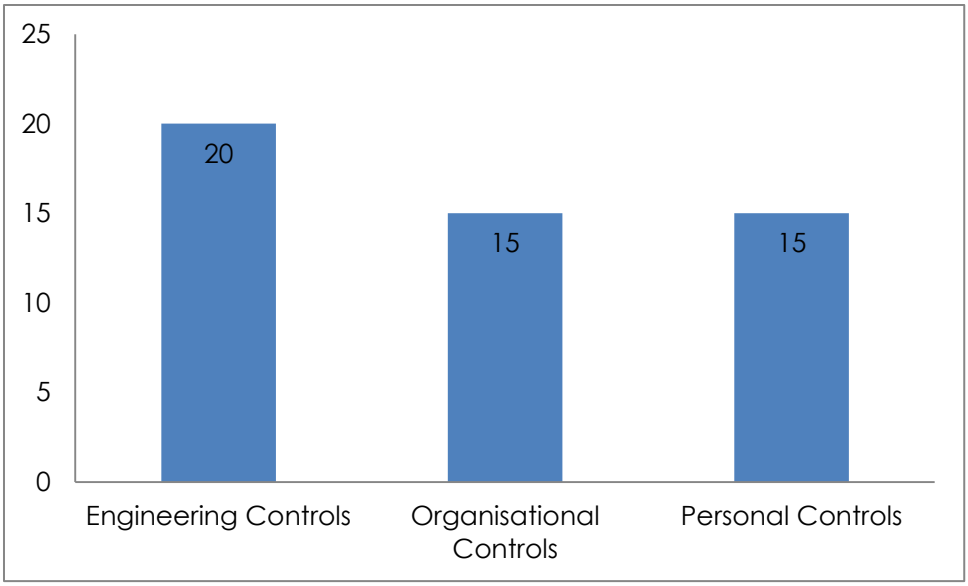

Figure 3 Reported Type of Measures to be Implemented (by site)

Most implementation reports state that the companies are planning to implement some form of engineering control (n=20). Measures include:

- Upgrading General Ventilation
- Upgrading Local Exhaust Ventilation
- Reducing operating temperatures
- Redesign of the working hall
- Closure of processes

Organisational measures were planned in 15 companies and included:

- Performing certain operations at dedicated locations (purging of mobile mixers)
- More frequent quality inspections of ventilation systems
- Minimisation of exposure time by comparing the practice in multiple different sites
- Reducing the exposure time per shift by reorganisation of working practices.
- Improved worker training

Personal Controls were mainly including (n=15):

- Upgrades to better masks
- The use of masks during open handling steps
    - Non-High Voltage Rotating Machines sectors reported this. All High Voltage Rotating Machine producers were already using some form of respiratory protective equipment.
- Improvements in the quality/grade of gloves (e.g. Cat. II Nitrile → Cat. III Nitrile)
- Use of Coveralls

All high voltage rotating machine producers have implemented or pledged to implement EN 12942 TM3, or equivalent, masks.

Workers Training

The AJIT Worker Training Program has only recently been developed and implementation will be reported on in the next Progress Report.

Exposure Measurement Methodology

AJIT has commissioned a study by Institut universitaire romand de Santé au Travail (IST) to generate data to validate the AJIT Harmonised Exposure Measurement Methodology.

Case Studies

Formulation

During formulation processes anhydrides are loaded into a mixing unit together with other substances, mixed, and unloaded into another container.

Plant 001

Exposure during the semi-open loading step a exposure was measured of 62.5 – 66 µg/m³, which the owner of Plant 001 learned was far greater than other measurements that were performed in other Plants running similar processes.

Subsequent investigations by the HSE specialists revealed that the production process was optimized historically to minimize production time by preheating anhydrides to 100 °C before loading to reduce viscosity. Such elevated temperature results in an elevated vapour pressure that drives exposure.

The plant owner has committed to reduce exposure by (re-)optimizing the process parameters and reduce the amount of preheating to a level, which would result in sufficient viscosity to enable sufficiently rapid transfer and significantly reduced exposure. Such effort will be combined with improvements in local exhaust ventilation.

The responsible of Plant 001 stated that it is confident that this approach should result in a reduction in exposure to <5 µg/m³.

Switchgear

In switchgear production mainly Automatic Pressure Gelation processes are performed. Typically, an anhydrides-epoxy mixture is transferred to a mobile mixer which is subsequently moved to a clamping machine which injects it into heated moulds in which it cures to produce an article. The part is often post cured in an oven. The mobile mixture is closed during transport and use at the clamping machine. However, filling in some plants occurs in an open process and post shift the mixture needs to be discarded. Exposure during a shift is continuous and no significant peaks have been identified, although slight peaks may be expected during the loading/unloading of the mobile mixer.

Plant 002

Within Plant 002 exposure reduction measures have been implemented since 2003. Measures taken include:

- Separate storage of containers containing anhydrides
- Closure of mobile mixer loading system

- Local exhaust ventilation has been installed at clamping machines
- Installation of a general ventilation system (4.5 ACH)
- Covering the floor with paper which is renewed each week and is inspected during shift handover (3 times/24 hours)

This has resulted in relatively low exposure of 27.6 – 30 µg/m³ combined (HHPA + MHHPA) exposure.

After these measurements the company has decided to move the unloading of the mobile mixers to a dedicated location and plans to:

- Optimize the mobile mixer transport and exchange with respect to the handling of equipment.
- Investigate improvements in the injection system of the clamping machines
- Improvements in the ventilation system
- Investigate the possibility of switching from a mobile mixing system to a closed feeding system

Vacuum Pressure Impregnation (VPI)

During VPI processes an object is impregnated with an epoxy-anhydride mixture in a closed chamber, but is subsequently moved by an operator to an oven in which curing takes place (for a more elaborate description see Annex II). The critical step in this process is the transport of the impregnated object from the impregnation chamber to the oven. The entire process occurs in a separate working hall.

Plant 003

In Plant 003 the critical process step originally lasted for 105 minutes and resulted in a peak exposure of 1480 µg/m³, which was controlled by the use of a powered respirator (EN 12942 TM3) resulting in a 0.74 µg/m³ calculated personal exposure[3].

The company applied scientific management techniques to analyse the activities performed during the critical step and managed to reduce the duration of this activity to 42 – 48 minutes.

Plant management also increased the general ventilation capacity from 4.8 air changes per hour (ACH) to 14 ACH.

Both measures resulted in a peak exposure of 160 µg/m³, a reduction of 89.2%.

Plant 004

Plant 004 has since 2002 been improving on a continuous basis its risk management measures. The measures taken include:

- Complete closure of working hall
- Improvements in general and local ventilation systems
- Switch to the more effective respiratory protection (EN 12942 TM3)

[3] The mask's standard has a maximum inward leakage requirement of 0.05% resulting in a calculated protection factor of 2000 ➔ 1480 µg/m³ / 2000 = 0.74 µg/m³

These measures have reduced the concentration in one hall from >37000 to 670 µg/m³, which is controlled through the use of a powered respirator (EN 12942 TM3) resulting in a 0.34 µg/m³ calculated personal exposure[4].

Update of Exposure Scenarios

As part of the voluntary commitment there is a collective commitment to: once a risk management measure becomes standard, communicate this risk management measure via an Exposure Scenario annex of the SDS of manufacturers/importers throughout the value chain, thereby making this risk management measure obligatory for all of the industry[5].

Last year, experts in the different processes were assembled into working groups and provided a training in the ECHA Use Description System and the principles of Exposure Scenarios. After which the working groups developed an initial Use Description and Exposure Scenario that would accurately reflect the current practices within industry.

Formulation

The representatives in the formulation working group were already well versed in the ECHA use description system and were able to rapidly agree on the assignment of PROCs and ERC to the contributing activities that were defined. Their experience was originating from the fact that these representatives were operating in the chemicals industry and some had even experience in the registration of substances. PCE was able to compile per contributing activity the exposure that was measured in the exposure measurement campaign.

Industrial End Users

The working groups High Voltage Rotating Machines (HVRM) and Switchgear consisted mainly of representatives from the electrotechnical industry, an industry that is more remote from the chemicals industry and were as a consequence less well versed in the Use Descriptor System and principles of Exposure Scenarios. However, once the system was explained, it's value was rapidly recognized by all participants[6].

High Voltage Rotating Machines

The working group HVRM held around 5 – 10 teleconferences over a period of several months to develop their Use Description and Exposure Scenario.

One clear observation from the previous exposure measurement campaign and data collection exercise has been included as an obligatory risk management measure, which is the use of masks according to EN 12942 with the certification TM3. During previous AJIT work it was found that although workers are currently well

[4] The mask's standard has a maximum inward leakage requirement of 0.05% resulting in a calculated protection factor of 2000 ➔ 670 µg/m³ / 2000 = 0.34 µg/m³

[5] With the exception for of those companies that would choose to perform a downstream user chemical safety assessment and notify ECHA thereof.

[6] Several representatives even indicated by the end of the development to be planning to produce more use descriptions and perhaps even use maps for their sector.

protected by a variety of masks, the harmonization to this mask would be a relatively easy to implement exposure minimization measure.

The final result is an understandable exposure scenario that accurately describes the current best practice

Switchgear

The working group Switchgear held around 4 – 8 teleconferences over a similar period of several months to develop their Use Description and Exposure Scenario.

Several key potential exposure sources were identified. The problem that this subsection of industry faces is that many of these potential exposure sources can contribute to the overall hall exposure which shows very little variation during a shift. Therefore, many of the solutions to these potential exposure sources have been included in the exposure scenario as best practice advice (i.e. not mandatory). Members are committed to developing understanding as to, which measures are most effective and in future exposure scenarios those measures are likely to be made obligatory.

As with the HVRM scenario, the Switchgear exposure scenario accurately describes the current best practices and will be interpretable by any plant management in the electrical industry.

Exposure Scenario Validation

The exposure scenarios that have been developed were circulated to the entire AJIT membership with specific instructions to see if the use description covers their use, the document is understandable, and if the recommendation contained therein are implementable. Several members provided positive constructive feedback which was incorporated in the final drafts that were communicated to the registrants.

Registration dossier update

At the moment, the use descriptions and exposure scenarios are going through a review by the registrants and their Substance Information Exchange Forum (SIEF) manager. It is expected that once this review is finalized the registration dossiers will be updated and **the manufacturers and importers will communicate the exposure scenarios to all users of anhydrides**, thereby ensuring a legal obligation for all users of anhydrides to apply the best practices as defined by AJIT.

Conclusion

The voluntary commitment is in the process of being implemented by the members of AJIT and will result in the provision of the best possible medical surveillance and exposure minimization amongst the signatories.

In a second step registrants have committed to use the full power provided to them by the legislator in article 39 in REACH to ensure that the remainder of industry is driven to adopt the same standards as signatories of the voluntary commitment.

The AJIT firmly believes that this alternative risk management measure is the most effective method for controlling the risk that is associated with anhydrides.

Annex I List of AJIT Members

Polynt	Polynt
Hitachi Chemical Working On Wonders	Hitachi Chemical Europe
Dixie Chemical The Element of Open Innovation	Dixie Chemical represented by REACH-Chemadvice
New Japan Chemical Co., Ltd.	New Japan Chemical represented by Envigo
HEXION	Hexion
ELANTAS Electrical Insulation	ELANTAS Europe
HUNTSMAN	Huntsman
ABB	ABB
Schneider Electric	Schneider-Electric
EPOXONIC® innovative epoxies	EPOXONIC
SIEMENS	Siemens
Veneta Isolatori	Veneta Isolatori

Andritz Hydro

DIAB International

VEM Sachsenwerk

ELIN Motoren GmbH

DRIESCHER WEGBERG

Aditya Birla Chemicals (Europe)

I.S.E.P.

BRUSH HMA

MGC Moser - Glaser

Solid Cure

Participatory Sponsors:

T&D Europe

CEMEP

Annex II Process Descriptions

Below you will find a description of the processes used in industry

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 4 for a schematic diagram of such a clamping machine that is fed with a mobile mixer system.

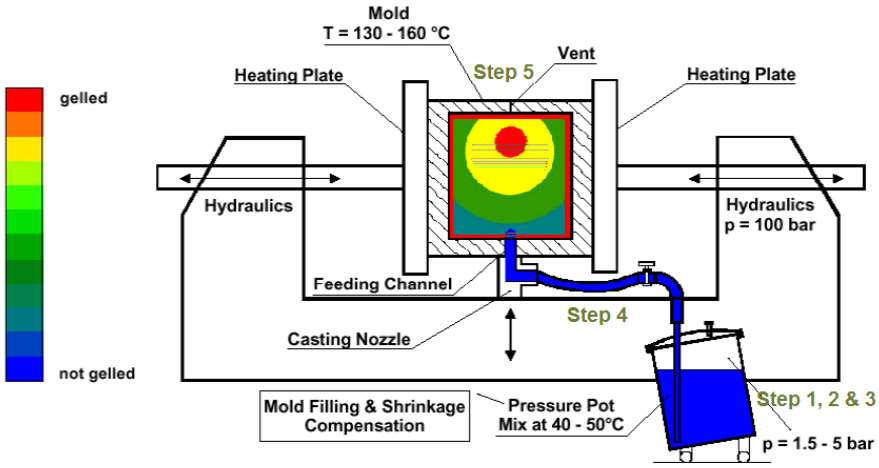

Figure 4 Automatic Pressure Gelation using a mobile mixer system. Source: AJIT

The clamping units can be fed with either a mobile mixer system or a closed feeing system. The mobile mixer system involves the filling of a mobile mixer at a dedicated facility as show in Figure 5; and transport of the closed mobile mixer to the clamping unit where it is connected as shown in Figure 4.

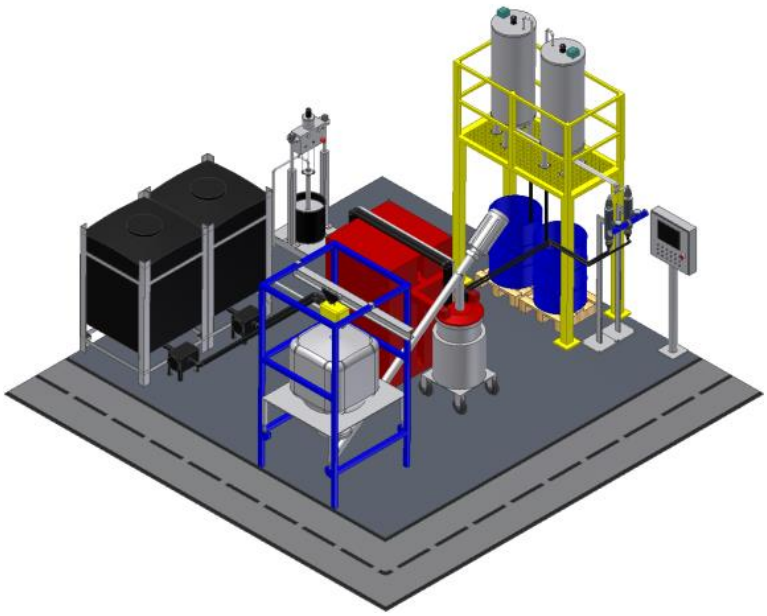

Figure 5 Mobile Mixer Preparation Station. Source: AJIT Members

Alternatively, clamping units can be fed and mixed in a continuous system as show in Figure 6 and Figure 7, whereby epoxy and anhydride arrive separately, are fed separately to the clamping machine and only at the last moment mixed in a static mixer before being injected into the clamping unit.

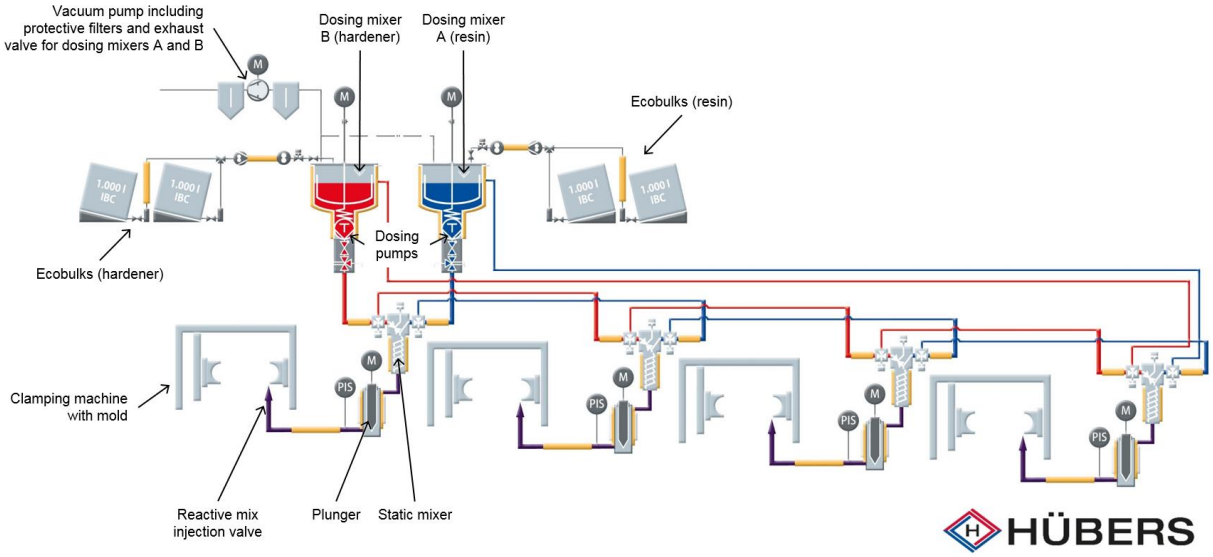

Figure 6 Process Scheme of an APG System with 4 Clamping Machines. Source: Hübers

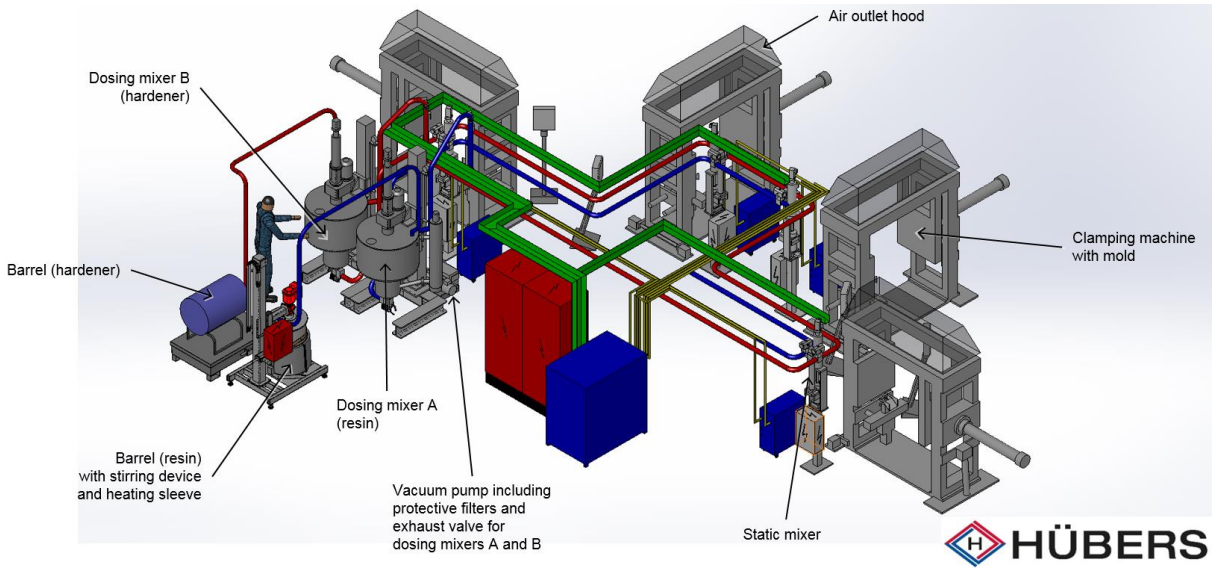

Figure 7 CAD rendering of an APG system with 4 Clamping Machines. Source: Hübers

Vacuum Casting

A Vacuum Casting process employs a continuous mixing system under vacuum as described in Figure 8 and Figure 9. The epoxy-anhydride mixture is fed into a mould under vacuum. The vacuum chamber is repressurised and the mould is moved to an oven into which the parts are cured.

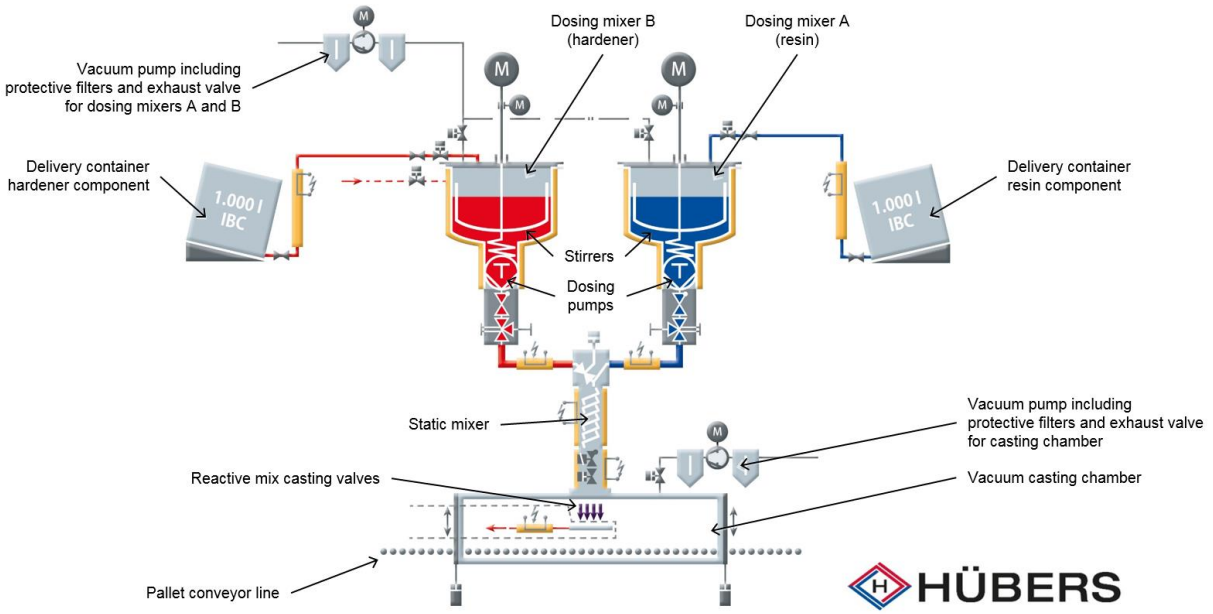

Figure 8 Vacuum Casting Process. Source: Hübers

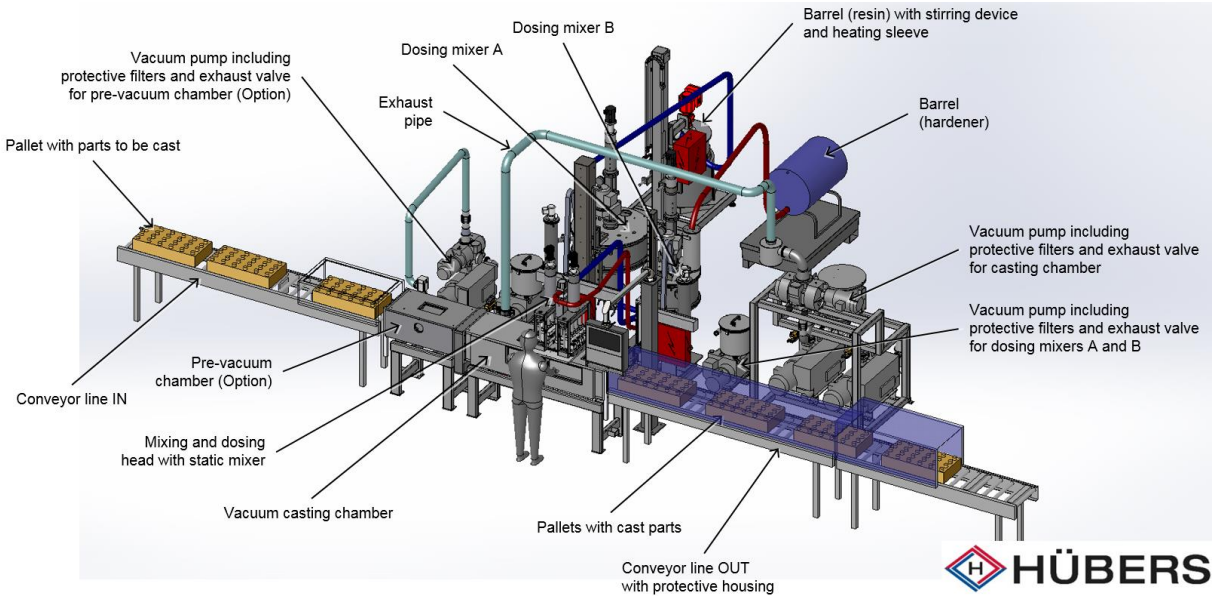

Figure 9 CAD Rendering of a Vacuum Casting Process. Source Hübers

Vacuum Pressure Impregnation

During Vacuum Pressure Impregnation an object is placed in an impregnation chamber (Figure 10). The impregnation chamber is placed under vacuum and the resin/hardener mixture and impregnation chamber are preheated (Figure 11). 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 12). Finally the resin/hardener mixture is evacuated to the storage tank and the impregnated object is moved to an oven for curing (Figure 13). During the movement of the impregnated object from the impregnation chamber to the curing oven the impregnated object is not in a closed environment, therefor the VPI process is categorized as a "semi-open" process.

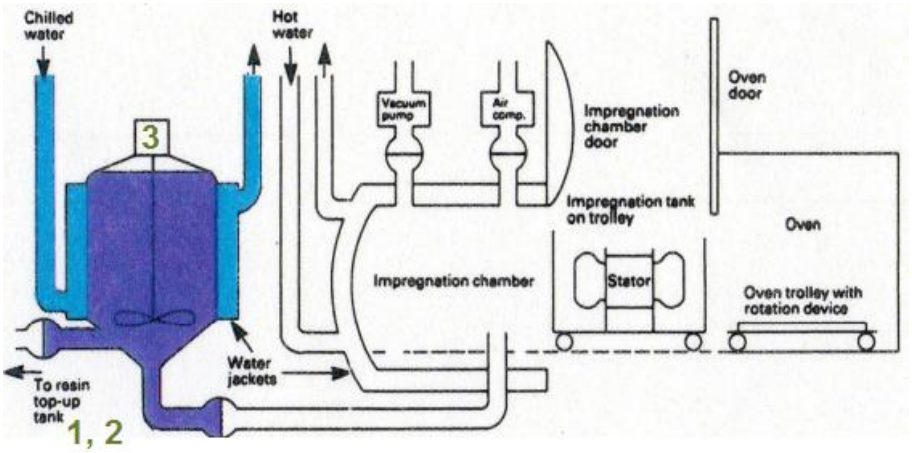

Figure 10 Vacuum Pressure Impregnation Step 1. Source: AJIT

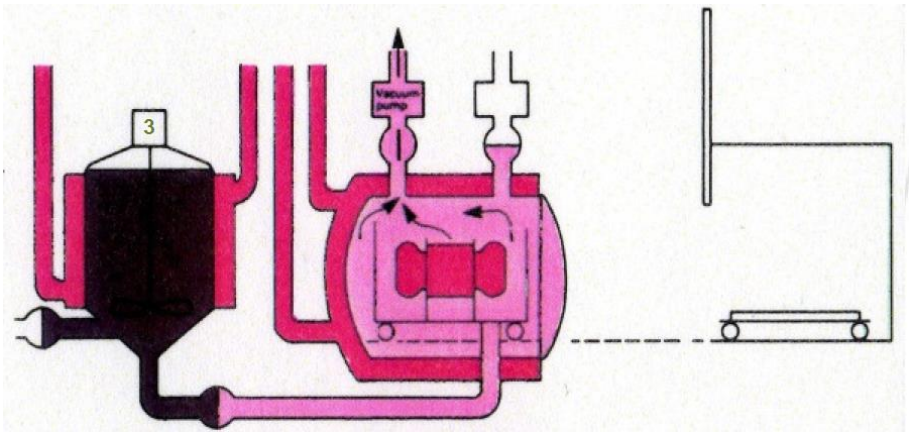

Figure 11 Vacuum Pressure Impregnation Step 2. Source: AJIT

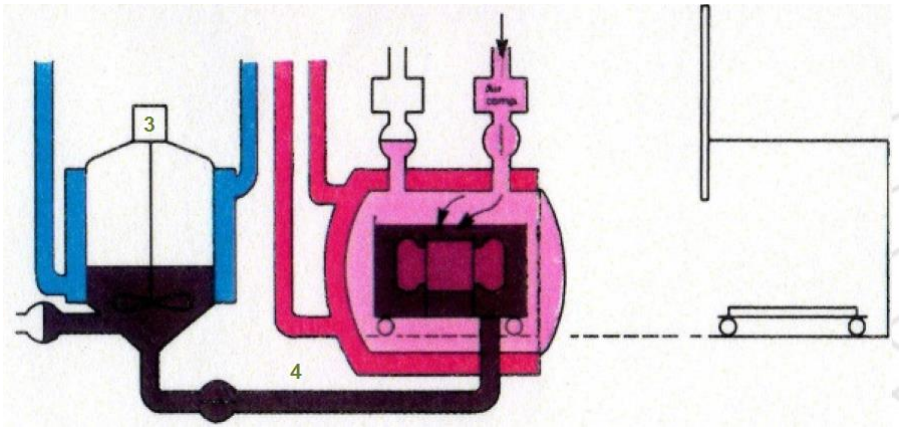

Figure 12 Vacuum Pressure Impregnation Step 3. Source: AJIT

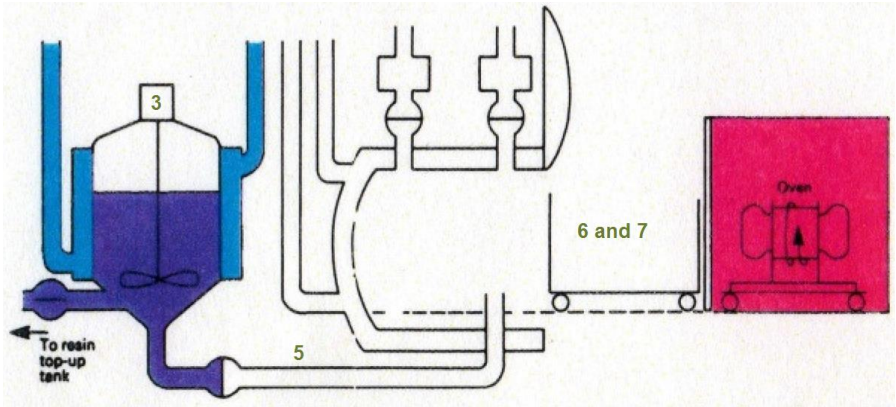

Figure 13 Vacuum Pressure Impregnation Step 4. Source: AJIT