Voluntary Commitment: Progress Report 2019

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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 (members listed in Annex I). The purpose of 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.

Moreover, since September 2018, AJIT members and PCE have worked on the implementation of the air monitoring protocol, proposing a harmonised procedure to follow in order to reduce the variability of the results. In 2019, a measurement campaign involving AJIT companies was launched and it is expected to finish by January 2020. The results will be partially presented in this report through some case studies.

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

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

In December 2018, AJIT published the 2018 Public Consultation Report, also showing the progress made in the implementation of the Voluntary Commitment. The document herein reports on our progress since April 2018, when the last information on such an implementation was given.

Implementation of the Voluntary Commitment

Sample coverage

21 companies have signed the Voluntary Commitment. 3 of the signatories have operations involving anhydrides exclusively outside of the European Union[1]. In 2019, 13 of the signatories delivered the implementation reports, covering 22 sites.

AJIT Medical Diagnostic Guidance Implementation

Considering the results shown in Figure 1, in 2019 72.8% of the respondents indicated to have implemented the AJIT Medical Diagnostic Guidance, 18.2% declared to follow equivalent procedures, 4.5% does not consider it necessary and 4.5% have not implemented the Guidelines yet. It is worth noting that in one case the semi-closed process was substituted by a fully closed system: as a consequence, the risk of exposure is null. Comparing these results with those obtained in 2018, there was an increase of 25.1% in terms of Medical Diagnostic Guidelines implementation. Figures from 2018 and from 2019 are compared in a separate section of this report (page 6).

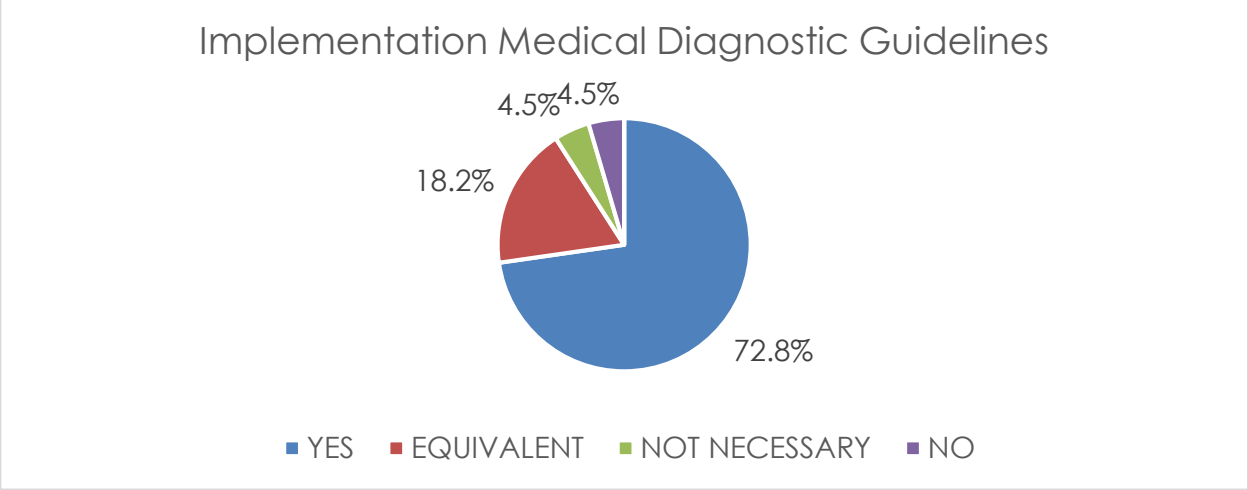

Figure 1 – Reported Status of the Medical Diagnostic Guideline Implementation.

AJIT Workers' Training Program Implementation

In 2019, 100% of respondents indicated to have implemented the AJIT Workers' Training Program (Figure 2). In particular, 28.6% are currently carrying out the workers' training, whereas 71.4% have declared that all workers have been trained. Comparing the 2019 results with those from 2018, there was an increase of 19.2% in terms of Workers' Training Program Implementation. Figures from 2018 and from 2019 are compared in a separate section of this report (page 6).

[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.

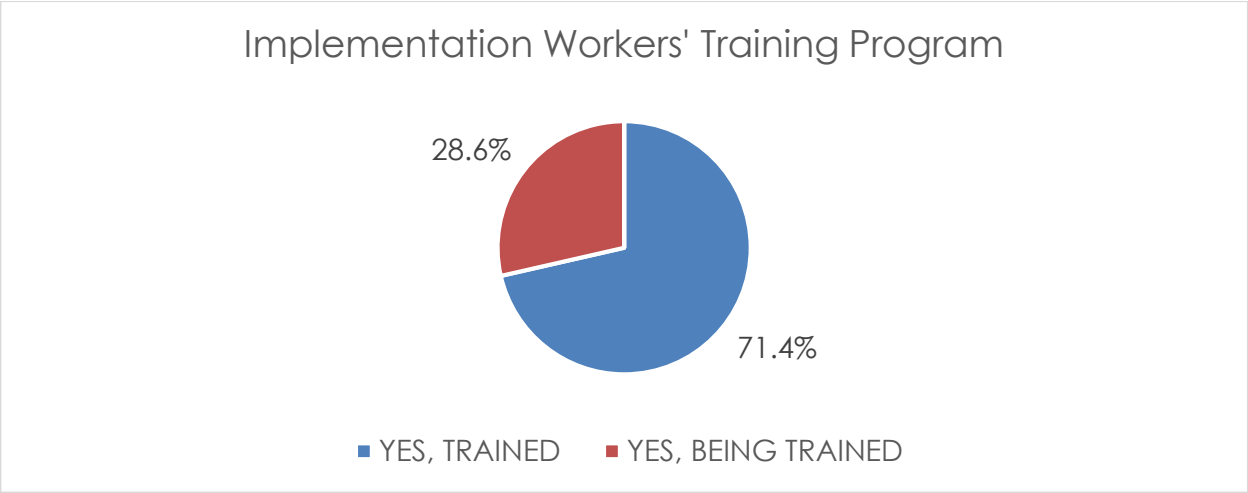

Figure 2 – Reported Status Workers Training Program Implementation.

Implementation of Exposure Minimization Measures

Considering the objectives set in 2018 for the implementation of the minimisation measures in 2019, 63.7% of the respondents declared either to have reached their objectives or to finalise the exposure minimisation plan by the end of 2019, 4.5% indicated that the exposure minimisation measures are planned but the process has not started yet and 31.8% answered that these measures are not necessary in their plant, since already very low exposure levels were achieved during the previous years. Results are shown in Figure 3. Comparing the 2019 results with those from 2018, there was an increase of 6.6% in terms of implementation of the exposure minimisation measures. Figures from 2018 and from 2019 are compared in a separate section of this report (page 6).

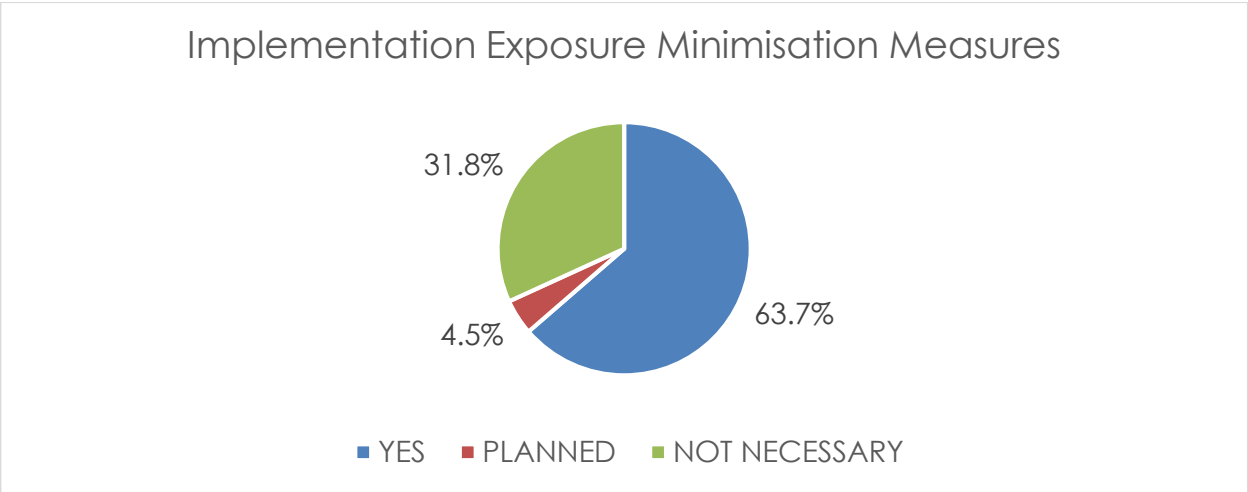

Figure 3 – Implementation of Exposure Minimisation Measures.

Comparison between 2018 and 2019

Comparing the results from the survey carried out in 2018 (shown in 2018 AJIT Progress report) and the one carried out in 2019, it is possible to observe an increase of the percentage of companies that implemented the Medical Diagnostic Guidance, the Workers' Training Program and the Exposure Minimisation Plans. Results are summarised in Figure 4.

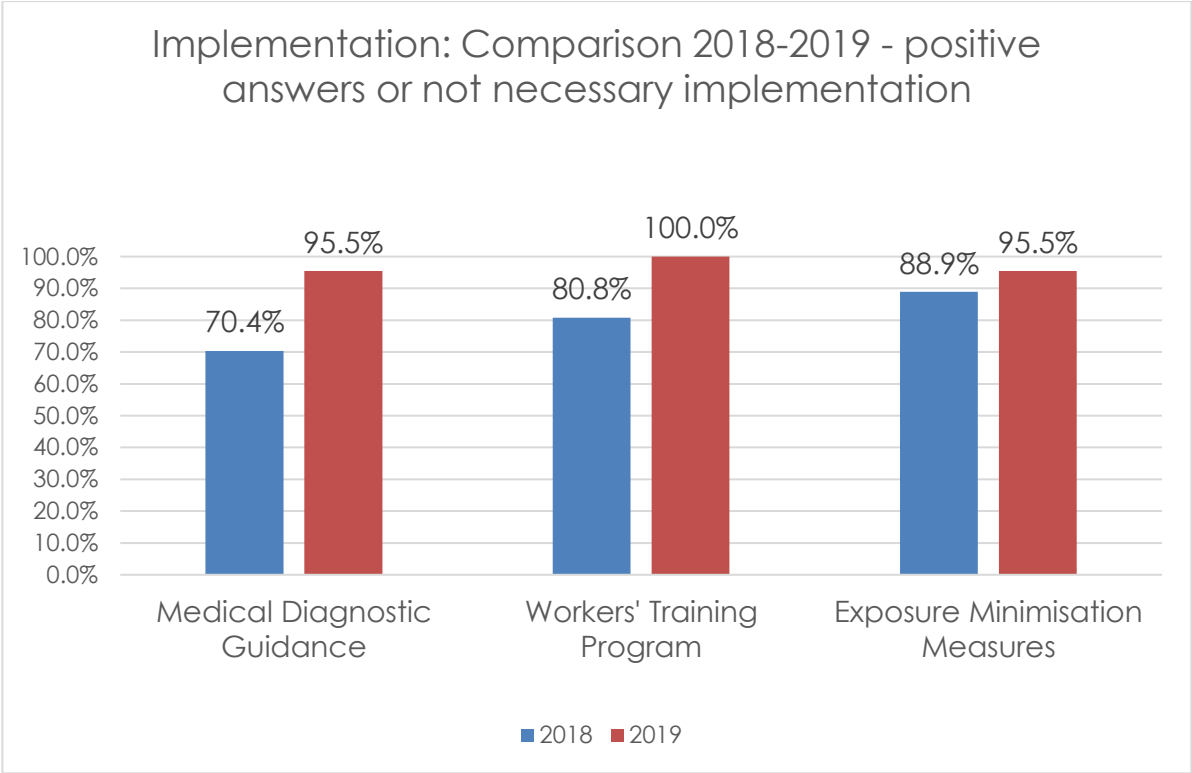

Figure 4 – Comparison of implementations in 2018 and 2019.

Exposure Minimisation Plan

Engineering controls

Of all signatory sites, 36.4% declared that it is not necessary to implement additional engineering controls and 36.4% indicated that this implementation has been already done, including:

- New vestibules with proper PPE changing facilities;
- Thermal camera installation;
- Local Exhaust Ventilation for impregnation tanks;
- Separation of production hall;
- Upgrade of Local Exhaust Ventilation;
- Improvement of air ventilation through the use of curtains/walls;
- Remote opening of the VPI room.

Moreover, 27.2% of the respondents have planned the implementation, including:

- Introduction of closed process steps;
- Automatic preheating oven;
- Oven extraction system;
- Increase of refreshing air frequency;
- Optimisation of ventilation system;
- Containment of the VPI hall open section.

Results are shown in Figure 5.

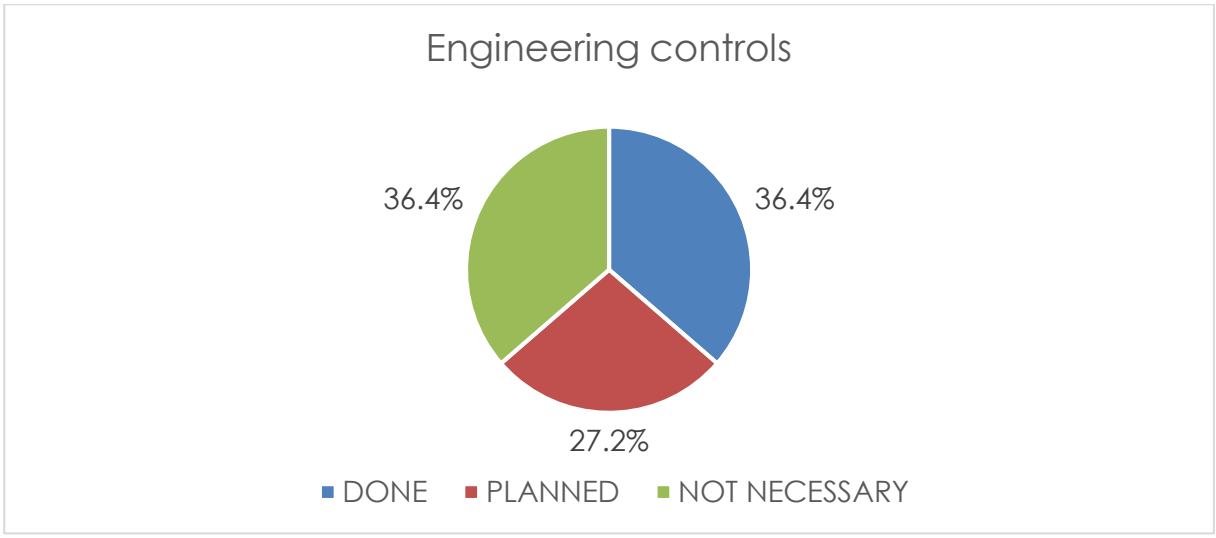

Figure 5 – Implementation of engineering controls.

Organisational measures

Of all signatory sites, 45.5% declared that it is not necessary to implement additional organisational measures and 45.5% indicated that this implementation has been already done, including:

- Higher rotation of workers with consequent exposure reduction of 50%;
- Reduction of time spent inside the VPI hall;
- Restricted access to VPI laboratory;
- Reduction of number of exposed workers;
- Reduction of time spent in the wet move area;
- Restricted access to oven;
- Filling and mixing anhydrides in a closed step.

Moreover, 9% of the respondents have planned the implementation, including:

- Installation of clean area before entry to impregnation hall (10% of time reduction);
- Updated work instructions and standardisation.

Results are shown in Figure 6.

Figure 6 – Implementation of organisational measures.

Personal measures

Of all signatory sites, 45.5% declared that it is not necessary to implement additional personal measures and 54.5% indicated that this implementation has been already done, including:

- Use of EN 12942 TM3 masks;
- Use of double safety shoes or other shoe protection;
- Use of nitrile gloves EN 374 inside the impregnation area;
- Use of EN 140 masks.

Results are shown in Figure 7.

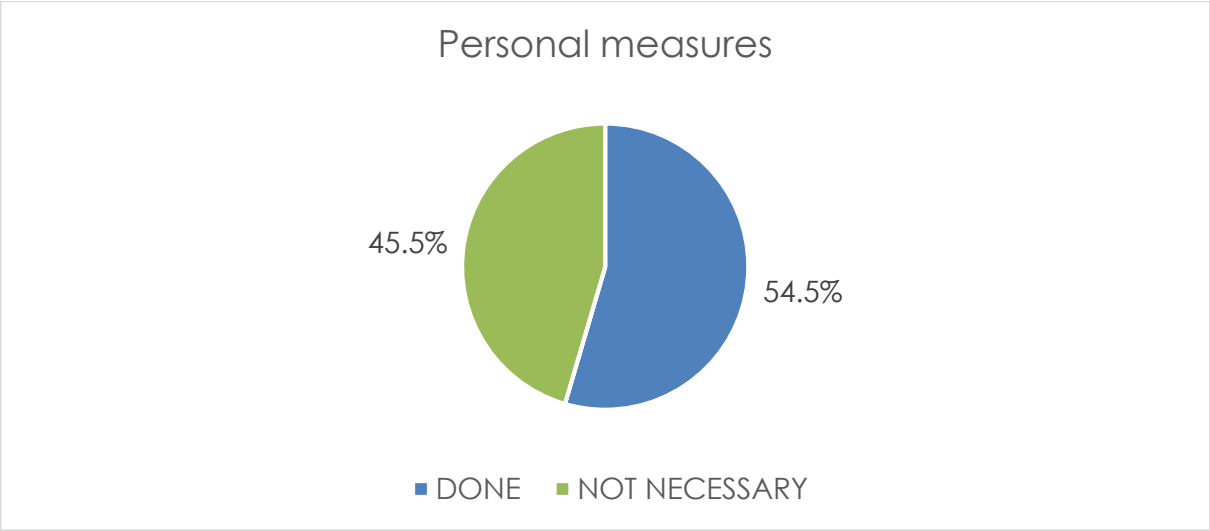

Figure 7 – Implementation of personal measurements.

Other measures

The main additional measure indicated by the companies is the partial or complete substitution or the reduction of use of HHPA and MHHPA to prefer other epoxy hardeners that, however, show the same sensitisation properties of HHPA and MHHPA. Therefore, this cannot be considered as a real substitution.

Medical data

Questionnaire implementation

On the occasion of the second industry consultation in 2018, an implemented version of the medical questionnaire was introduced and updated information from the plants was obtained. In the new version of the questionnaire two different occupational diseases were taken into account: occupational asthma and occupational rhinitis. The AJIT Medical Diagnostic Guidance defines the procedure to follow in order to assess the cases of occupational asthma and occupational rhinitis, as shown in the flowchart reported in Figure 8 and Figure 9, respectively. As shown in both flowcharts, the submission of the questionnaire is the first step for assessing possible cases of occupational diseases. In case of positive answers related to potential cases of asthma and rhinitis, specific medical tests have to be performed.

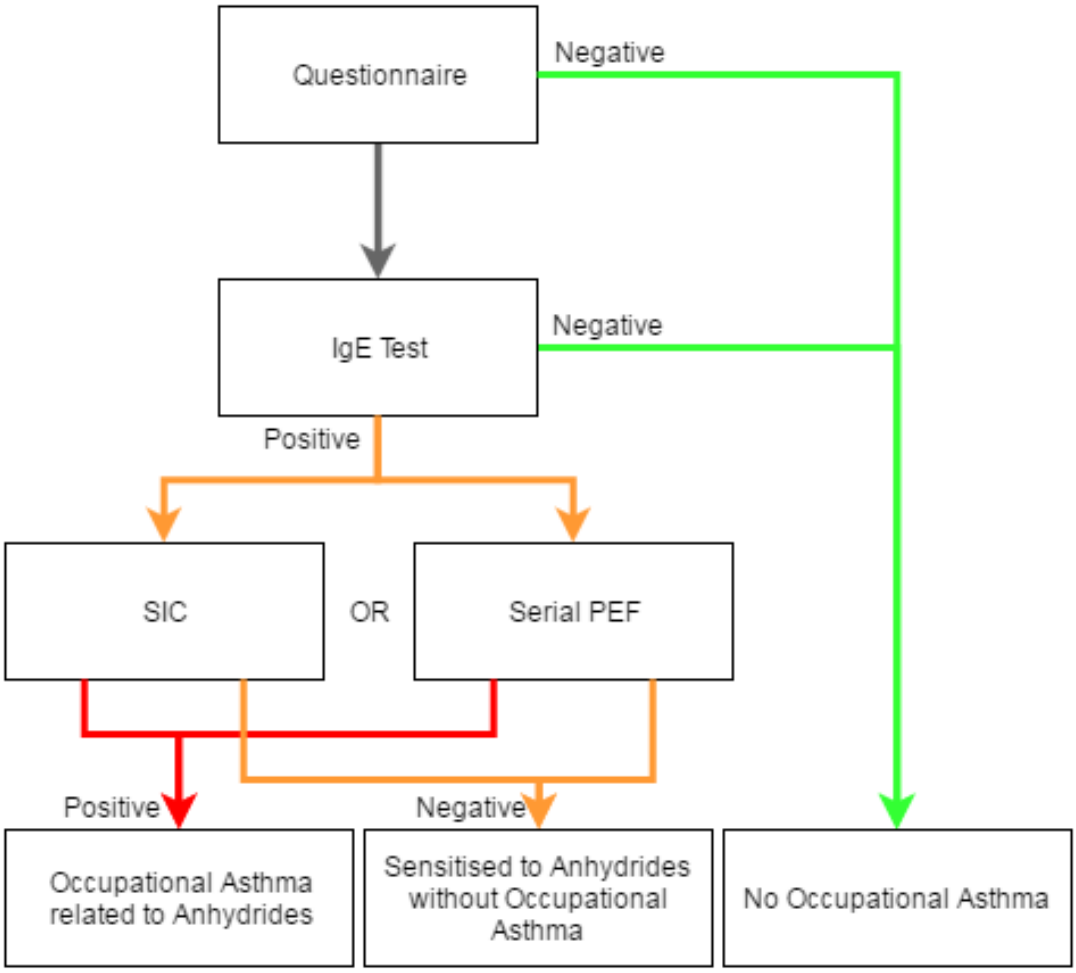

Figure 8 – Protocol for assessing occupational asthma. SIC = Specific Inhalation Challenge and PEF = Peak Expiratory Flow.

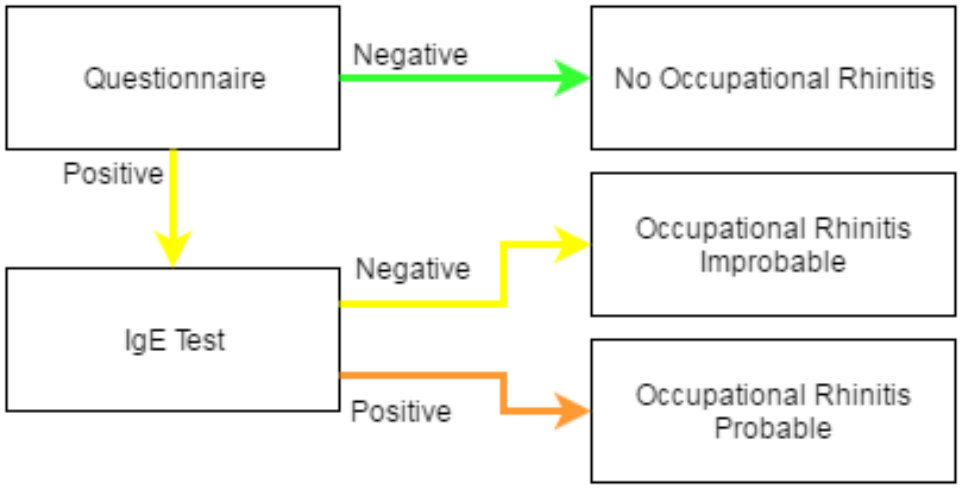

Figure 9 – Protocol for assessing occupational rhinitis.

Results and discussion

During the second industry consultation, 21 plants have submitted the updated medical surveys. A coverage of 753 potentially exposed workers has been considered, including the updated information sent at the beginning of 2019.

No cases of occupational asthma have been found during the past 10 years, except for 1 case of asthma that was already found in 2010 for one plant. No further cases were found later. However, this single case of asthma was possibly not related to anhydride exposure, but rather to atopic constitution. By comparing the results from 2018 to those from 2016 (first industry consultation), no changes in the number of asthma cases can be observed. Regarding occupational rhinitis, 6 cases were found in two different plants before 2016, whereas no cases were found in 2017. This is thanks to the implementation that was carried out in these plants for reducing the exposure.

Specifically, for the first plant, in 2017 the Anhydride concentration outside the wet move area was reduced to 2.5 µg/m^3 and the Anhydride concentration inside the wet move area was reduced from 1480 µg/m^3 to 160 µg/m^3. At the same time, the time spent by the worker in the wet move area was reduced from 105 min to 48 min. Finally, since June 2018 respiratory protective equipment following the standard EN12942 TM3 has been used.

For the second plant, a thermal camera was installed in order to check the temperature of the impregnated parts and the time spent by the workers in the VPI hall was optimised with the aim of reducing the time of potential exposure.

Exposure data

Harmonised protocol for air exposure measurements

On the occasion of this second industry consultation, an exposure measurement campaign has been organised. Preliminary data coming from a screening test performed in 2016 showed a considerable inter-plant and intra-plant variability, mainly due to the different kind of measurements performed (personal or static), the low number of data points and the different exposure scenarios considered. At the same time, the analytical protocol for the determination of the Anhydride concentrations was not harmonised.

As a consequence, in order to allow an easier comparison among plants and carry out a sector study, companies were asked to provide the information about the process steps in a harmonised way during the 2018 industrial consultation. The intra-plant variability was qualitatively reduced thanks to the submission of a questionnaire containing several closed answers (i.e. a limited number of answers available). More information about the questionnaire is given in the 2018 AJIT Public Consultation Report.

After receiving the feedback from the different companies/plants, PCE suggested the ideal amount of measurements to perform for each step of the process, considering the type of task performed by the operator, the time of each task and the number of workers. At least one personal exposure measurement for the full work-shift was recommended.

Together with the harmonisation of the process description coming from the different plants, also the air sampling protocol was harmonised. In particular, the following procedure was suggested:

- Personal sampling should be preferred to static sampling;
- Filter for air sampling: XAD-2 tubes (Orbo 609 Amberlite XAD-2 400/200mg);
- Sampling rate: 1 L/min. Depending on the process, the sampling time and the air volume need to be adjusted in order to keep this ratio constant;
- Sample transportation can be carried out at room temperature;
- Sample storage within the lab facility can be performed by freezing the samples.

The analytical step aimed at measuring the anhydride concentration was optimised as well. The procedure will be clearly explained in the next paragraph.

The aggregated data coming from the air exposure measurements cannot be disclosed since not all the results have been received so far. More results are expected to be received in January 2020 and will be published in the next 2020 report. However, some examples of results coming from individual plants are reported as case studies.

Optimisation of the analytical procedure

Development of a harmonised procedure for sample analysis

AJIT members gave their contribution to develop a harmonised protocol aimed at determining the concentration of both HHPA and MHHPA. Since September 2018 many progresses have been made, thanks to the collaboration with a laboratory contracted by PCE to carry out experiments aimed at finding the best analytical conditions for the determination of anhydride content.

Considering the procedures shown in the reports submitted by different AJIT companies on the occasion of the test measurement campaign carried out between 2015 and 2016, two main solvents were used for the extraction of the anhydrides from the filters used for the sampling step: toluene and acetic anhydride. These two solvents were used at different ratios, but the typical compositions were pure toluene, toluene:acetic anhydride 99:1 vol% and toluene:acetic anhydride 99.5:0.5 vol%. The preliminary experiments were focused on the role of the acetic anhydride for the extraction of HHPA and MHHPA. In particular, a potential reaction between the acidic form of HHPA (or MHHPA) and the acetic anhydride, leading to the formation of HHPA (or MHHPA), was hypothesised, as shown in Figure 10. These experiments proved that the presence of the acetic anhydride in the extraction solvent influences the amount of HHPA or MHHPA extracted, since a fraction of HHPA or MHHPA converted into the acidic form is reconverted into anhydride, causing an overestimation of the anhydride content in the extract.

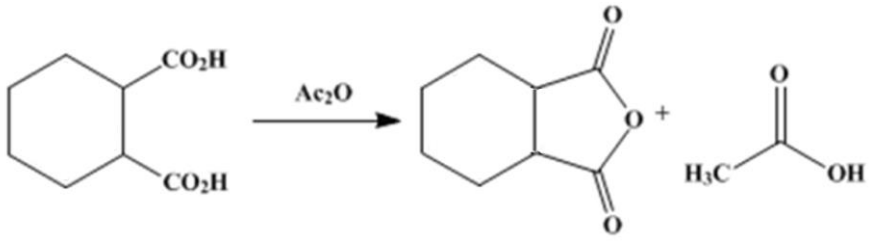

Figure 10 – Possible reaction between the acidic form of HHPA and acetic anhydride to form HHPA and acetic acid.

Once observed that the presence of acetic anhydride in the extraction solvent should be avoided, more experiments were performed in order to test solvents characterised by distinct polarities and to test different extraction protocols.

Case studies

Formulation

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

Case #1

In this plant, exposure was controlled through the implementation of a combination of engineering, organisational and personal measures:

- Some intermediate bulk containers were replaced by a closed system using tankers;
- The local exhaust ventilation around operators filling intermediate bulk containers was improved and fitted to the filling head, reducing exposure from 56 µg/m^3 down to a reproducible 5 µg/m^3;
- A safety area of 3 meters and respiratory protective equipment (factor 20) were enforced in the area were anhydride raw materials are transferred from drums.

High Voltage Rotating Devices (HVRD) production

HVRD production is carried out by using the Vacuum Pressure Impregnation process. During this process an object is placed in an impregnation chamber. The chamber is placed under vacuum and the resin/hardener mixture and impregnation chamber are preheated. This step 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. Finally, the resin/hardener mixture is evacuated to the storage tank and the impregnated object is moved to an oven for curing. More information about the description of this process is shown in the 2018 AJIT Public Consultation Report.

Case #2

In this plant, exposure to anhydrides (substance not specified due to confidentiality) was assessed for three different steps of the process:

1) Resin refill step: resin and hardener are sucked separately in the VPI vessel. The resin is preheated via heating elements. The hardener is not preheated because the viscosity is sufficient to be sucked in the vessel. This task is performed twice per month.
2) Transfer step A and B – Transfer impregnation fixation to VPI and Transfer impregnation fixation from VPI to oven are done in one step. For the measurements of each step a short interruption was carried out to change the sampling tubes. This task is performed once per day.

Both steps are carried out at room temperature (not temperature controlled).

Measurements of anhydride concentration were performed through:

1) Static sampling;
2) Personal out-of-mask sampling (single step);
3) Personal in-mask sampling (single step);

Results are reported in Table 1a.

Table 1a – Anhydride concentrations for different steps of the process and samplings. The limit of quantification (LOQ) is 2.5 µg/m³.

Step	Sampling type	Details	Measurement time [min]	Concentration [µg/m³]
Resin refill	STATIC	-	476	88
	PERSONAL	SINGLE TASK, OUT-OF-MASK, WORKER 1	19	737
Transfer A	PERSONAL	SINGLE TASK, IN-MASK, WORKER 1	15	<LOQ
		SINGLE TASK, OUT-OF-MASK, WORKER 1		3133
		SINGLE TASK, IN-MASK, WORKER 2	13	<LOQ
		SINGLE TASK, OUT-OF-MASK, WORKER 2		1615
Transfer B	PERSONAL	SINGLE TASK, IN-MASK, WORKER 1	19	<LOQ
		SINGLE TASK, OUT-OF-MASK, WORKER 1		526
		SINGLE TASK, IN-MASK, WORKER 2	20	<LOQ
		SINGLE TASK, OUT-OF-MASK, WORKER 2		850

Observing the values reported in Table 1a, it is worth noting that the in-mask concentration values are below the limit of quantification, but they can be easily estimated taking into account the reduction factor of the mask used. Workers are equipped with an EN12942 respirator, with a reduction factor of at 2000: therefore, the estimated in-mask concentration values cannot be measured since they are well below the limit of quantification (2.5 µg/m³). The recalculated values are reported in Table 1b.

Table 1b – Concentration values recalculated by applying the mask reduction factor (2000).

Step	Sampling type	Details	Concentration [µg/m³]	Estimated concentration [µg/m³]
Resin refill	STATIC	-	88	-
	PERSONAL	OUT-OF-MASK	737	0.37
Transfer A	PERSONAL	IN-MASK	<LOQ	-
		OUT-OF-MASK	3133	1.6
		IN-MASK	<LOQ	-
		OUT-OF-MASK	1615	0.81
Transfer B	PERSONAL	IN-MASK	<LOQ	-
		OUT-OF-MASK	526	0.26
		IN-MASK	<LOQ	-
		OUT-OF-MASK	850	0.43

Switchgear (SG) production

Automatic Pressure Gelation (APG) and vacuum casting are used in switchgear production. Typically, an anhydride-epoxy mixture is transferred to a mobile mixer which is subsequently moved to a clamping machine injecting it into heated moulds to produce an article. The part is often post cured in an oven. If the mobile mixer is often closed during transport to and at the clamping machine, the filling occurs in a semi-closed process in some plants, and the mixture needs to be discarded after the shift. During a shift, exposure is continuous and no significant peaks have been identified, although small peaks are expected during the loading/unloading of the mobile mixer.

Case #3

The plant was equipped with a ventilation system for the vacuum pumps and pre-mixers, as well as a local ventilation for the clamping machine. Simple additional measures were

implemented, such as cleaning up the sum trays and eliminating leakages. These efforts resulted in a significant decrease in both HHPA and MHHPA levels.

For HHPA specifically, both samples were brought below 5 µg/m^3. MHHPA levels were reduced by 54% and 79% on workers' clothes and in the stationary sample, respectively. To further decrease these levels, this plant installed a new ventilation cabinet with a separate fan close to the demoulding table.

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.

Furthermore, 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.

Comparing the results from the questionnaires received in 2018 and in 2019, it is possible to observe a general increase in terms of implementation. Moreover, the retrospective medical surveys carried out in 2018 clearly report that no cases of occupational asthma that can be surely related to anhydride exposure were observed during the past 10 years.

At the same time, the introduction of a new harmonised protocol for assessing anhydride concentration in the workplace allowed obtaining reliable results from the plants that have already adopted this method.

Therefore, 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

Participatory sponsors: