



Voluntary Commitment: AJIT Progress Report 2020

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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 an air monitoring protocol, proposing a harmonised procedure to follow in order to reduce the variability of the results. In 2019, an exposure measurement campaign involving AJIT companies was launched. It was expected to finish by Mid-2020, but due to the CoVid-19 pandemic this has been postponed.

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 2019, AJIT published the 2019 Voluntary Commitment Report, also showing the progress made in the implementation of the Voluntary Commitment. The document herein reports on our progress until December 2020.

Implementation of the Voluntary Commitment

Sample coverage

21 companies have signed the Voluntary Commitment. 2 of the signatories have operations involving anhydrides exclusively outside of the European Union¹. In 2020, 13 of the signatories delivered the implementation reports, covering 15 sites.

AJIT Medical Diagnostic Guidance Implementation

Considering the results shown in Figure 1, in 2020 60.0% of the respondents indicated to have implemented the AJIT Medical Diagnostic Guidance, 33.3% declared to follow equivalent procedures, and 6.7% can be listed as other: for this category further investigation is needed in order to check whether the method currently in use, is aligned with the AJIT Medical Diagnostic Guidance. Comparing these results with those obtained in 2019, in the worst-case scenario (i.e. the company following another methodology) there is a decrease of 2.2% in terms of Medical Diagnostic Guidelines implementation. However, it is important to highlight that the 2020 coverage in terms of plants is slightly lower compared to the 2019 coverage. Figures from 2019 and from 2020 are compared in a separate section of this report.

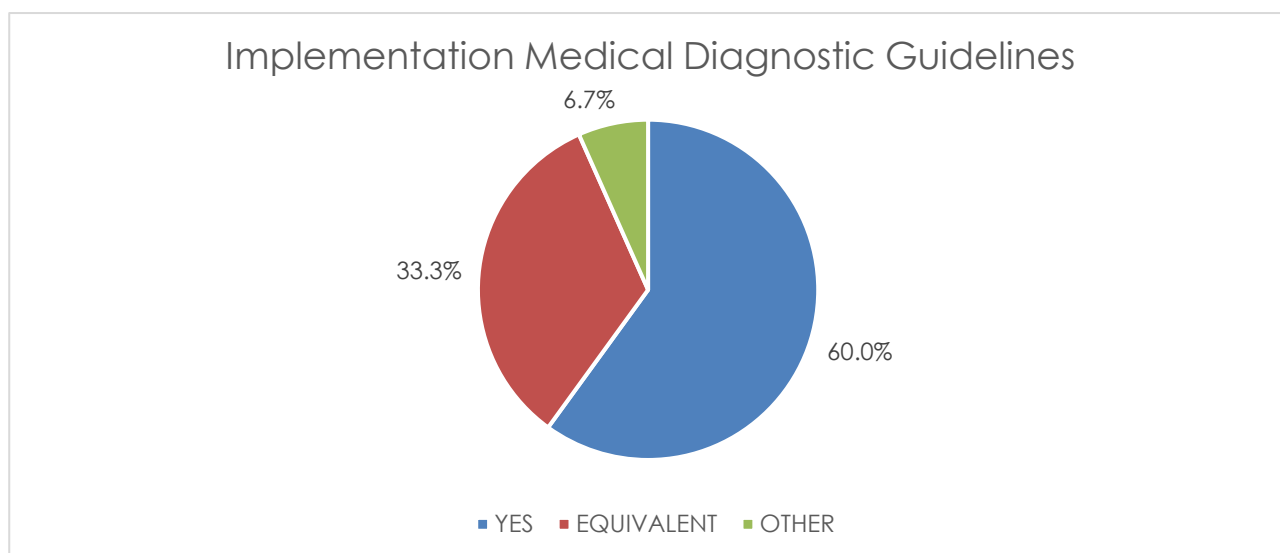


Figure 1 – Reported Status of the Medical Diagnostic Guideline Implementation.

AJIT Workers' Training Program Implementation

In 2020, 100% of respondents indicated to have implemented the AJIT Workers' Training Program (Figure 2). In particular, 41.7% are currently carrying out the workers' training,

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.

whereas 58.3% have declared that all workers have been trained. Comparing the 2020 results with those from 2019, the coverage of company sites was larger in 2019, and the lower response rate in 2020 has resulted in a larger percentage being trained. In 2019 28.6% was in the process of implementing the Training Program. A new version of the Workers' Training Program has been finalised in 2020, which should lead to a new round of training of workers. Figures from 2019 and 2020, respectively, are compared in a separate section of this report.

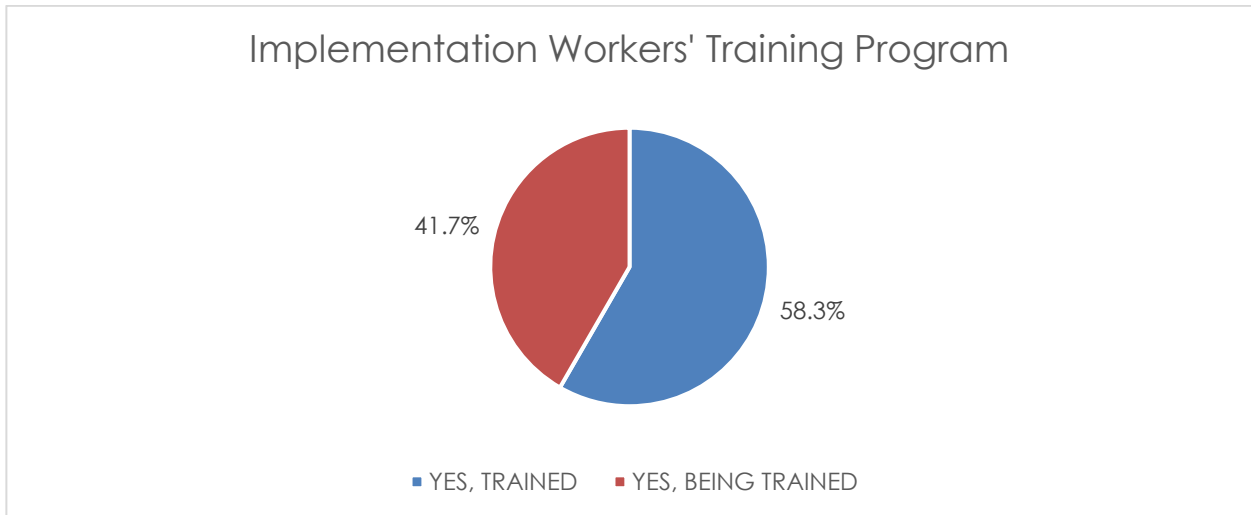


Figure 2 – Reported Status Workers Training Program Implementation.

Implementation of Exposure Minimization Measures

Considering the objectives set in 2019 for the implementation of the minimisation measures in 2020, 73.3% of the respondents declared either to have reached their objectives or to finalise the exposure minimisation plan by the end of 2020, and 26.7% 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 2020 results with those from 2019, there was an increase of 9.1% in terms of implementation of the exposure minimisation measures. It is considerable that several sites have optimised their production, e.g. with closed equipment, although exposure were already below $5 \mu\text{g}/\text{m}^3$ prior to the optimisations. Figures from 2019 and from 2020 are compared in a separate section of this report.

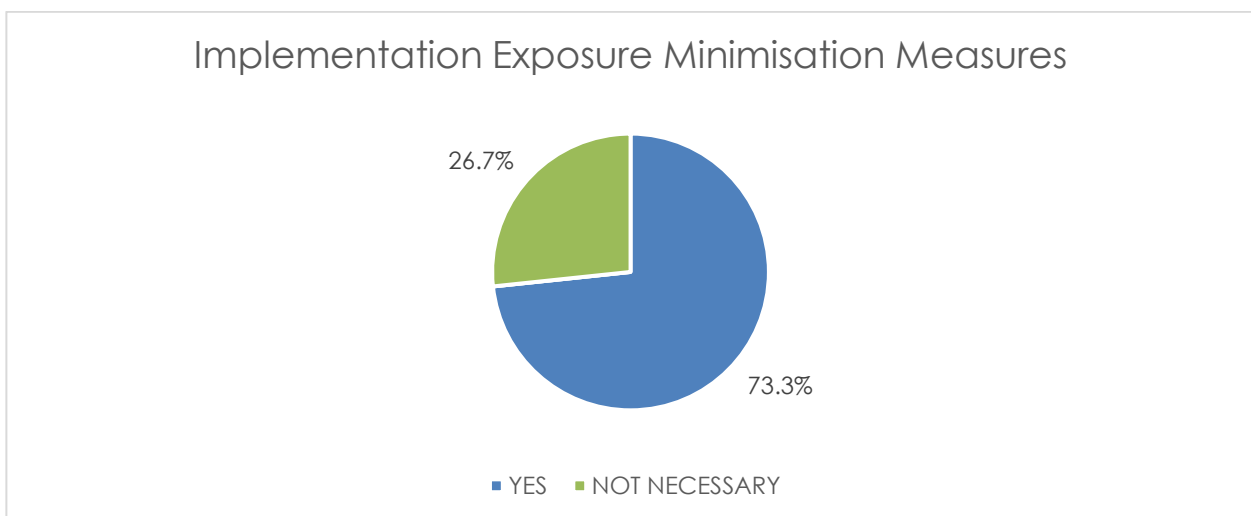


Figure 3 – Implementation of Exposure Minimisation Measures.

Comparison between 2019 and 2020

Comparing the results from the survey carried out in 2019 (shown in 2019 AJIT Progress report) and the one carried out in 2020, it is possible to observe a decrease of the percentage of companies that implemented the Medical Diagnostic Guidance, the Workers' Training Program was identical in percentage, and the Exposure Minimisation Plans increased in positive response percentage. Results are summarised in Figure 4. The lower response rate is reflected in these results.

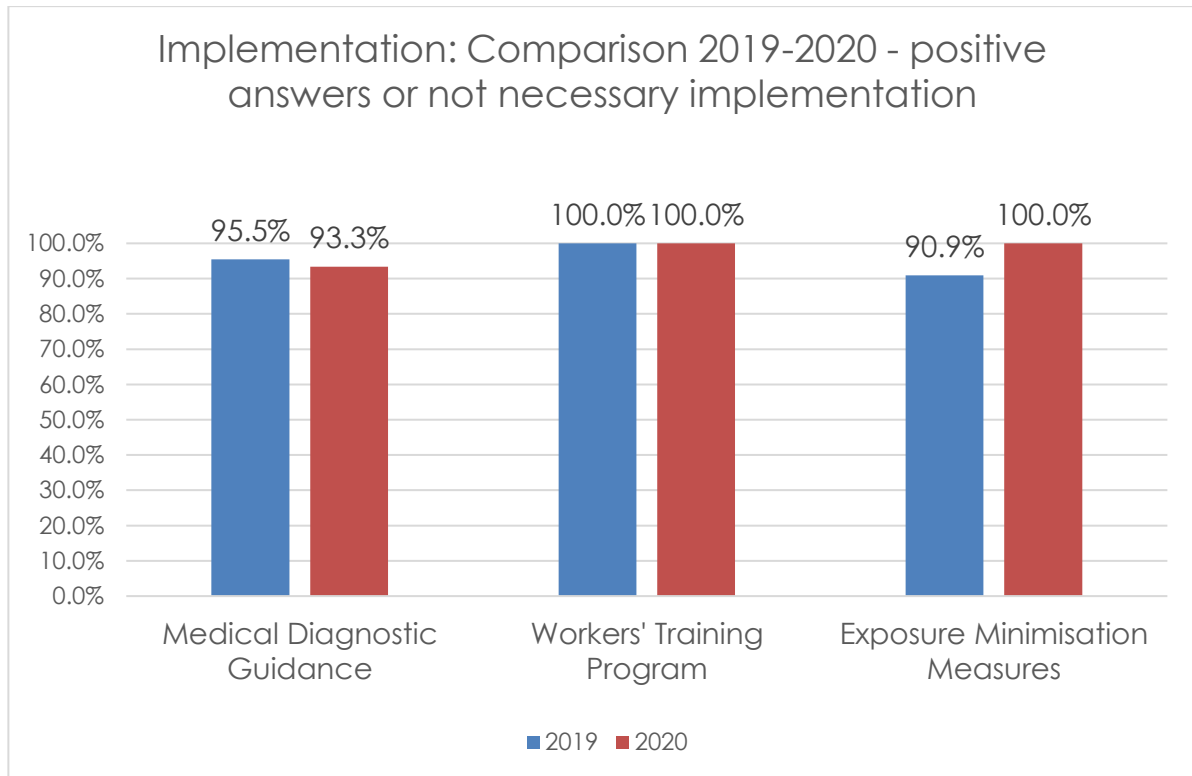


Figure 4 – Comparison of implementations in 2019 and 2020.

Exposure Minimisation Plan

Engineering controls

Of all involved sites, 40.0% declared that it is not necessary to implement additional engineering controls and 53.3% indicated that this implementation has been already done, including:

- Adapted hall layout and improved hall ventilation;
- Relocation of control room to a non-exposed area;
- Implemented Local Exhaust Ventilation;
- Upgrade/Modification of Local Exhaust Ventilation;
- Implementing closed equipment for production;
- Closing leaks in equipment;
- Remote control of VPI vessel introduced.

With some examples of engineering controls implemented in 2019:

- New vestibules with proper PPE changing facilities;
- Thermal camera installation;
- Separation of production hall;
- Improvement of air ventilation through the use of curtains/walls.

Moreover, 6.7% of the respondents have planned the implementation, including:

- Introduction of completely closed material supply system.

Results are shown in Figure 5.

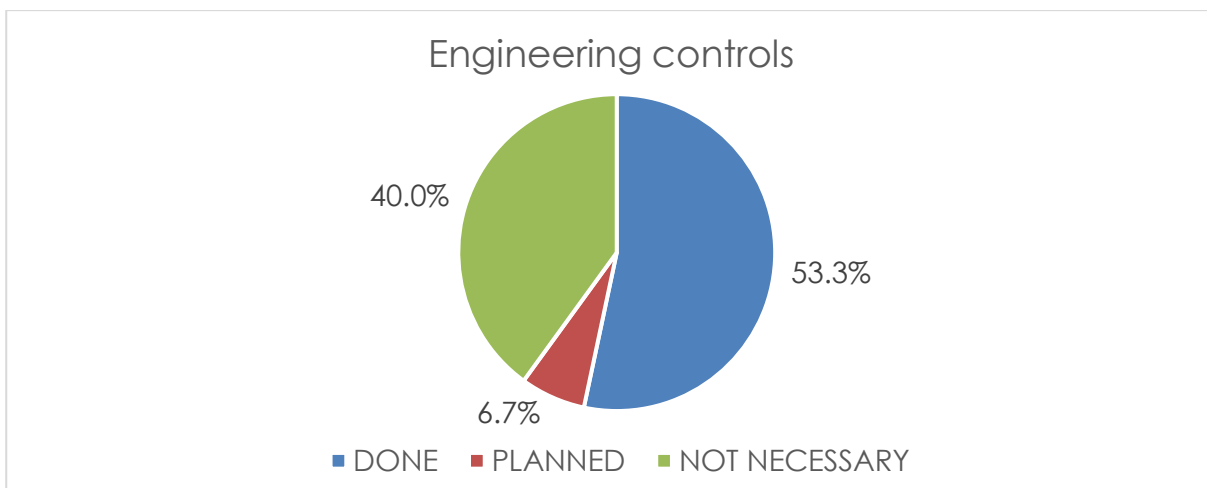


Figure 5 – Implementation of engineering controls.

Organisational measures

Of all signatory sites, 60.0% declared that it is not necessary to implement additional organisational measures. These are sites where sufficient organisational implementations have been conducted and reported in the foregoing years' surveys. Further, 33.3% indicated that they have made implementations since last survey (DONE), including:

- Minimized number of workers in VPI production area;
- Formalised work practice;
- Training and coaching of operators;
- Entry restrictions to exposed areas;
- Separated entry to VPI through the control room;
- Changing work cloth when entering/leaving exposure areas.

Moreover, 6.7% of the respondents have planned implementations, including:

- Split the exposure of workers, in shorter shifts;
- Updated work instructions and standardisation.

Results are shown in Figure 6.

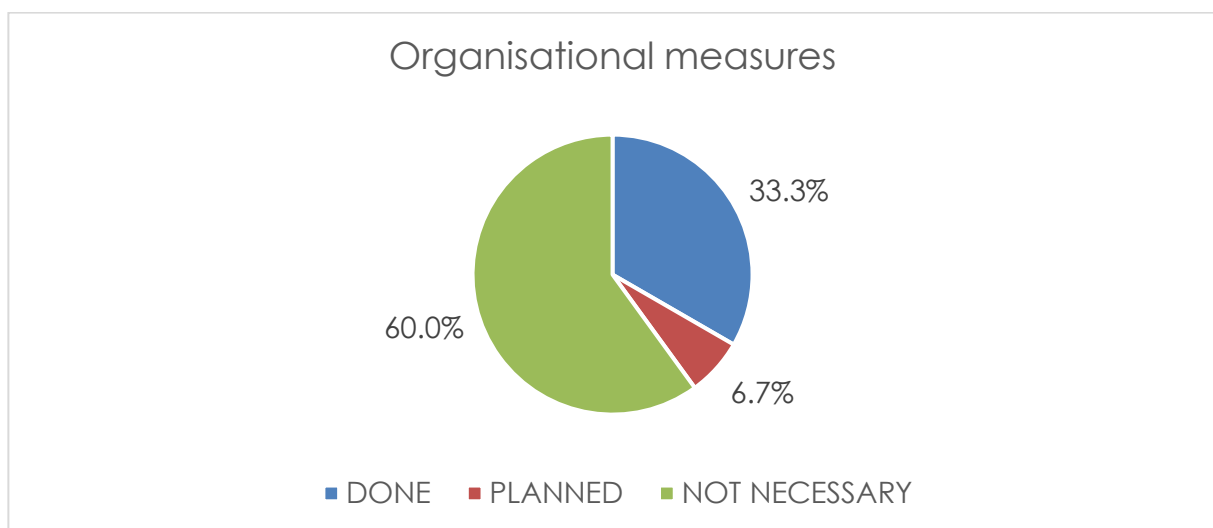


Figure 6 – Implementation of organisational measures.

Personal measures

Of all signatory sites, 73.3% declared that it is not necessary to implement additional personal measures. These are sites where sufficient personal implementations have been performed and reported in the foregoing years' surveys. Further, 26.7% indicated that new implementations have been made since last survey (DONE), including:

- Use of personal masks for staff;
- Use of adequate RPE;

The 2019 progress report further included the following measures:

- 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.

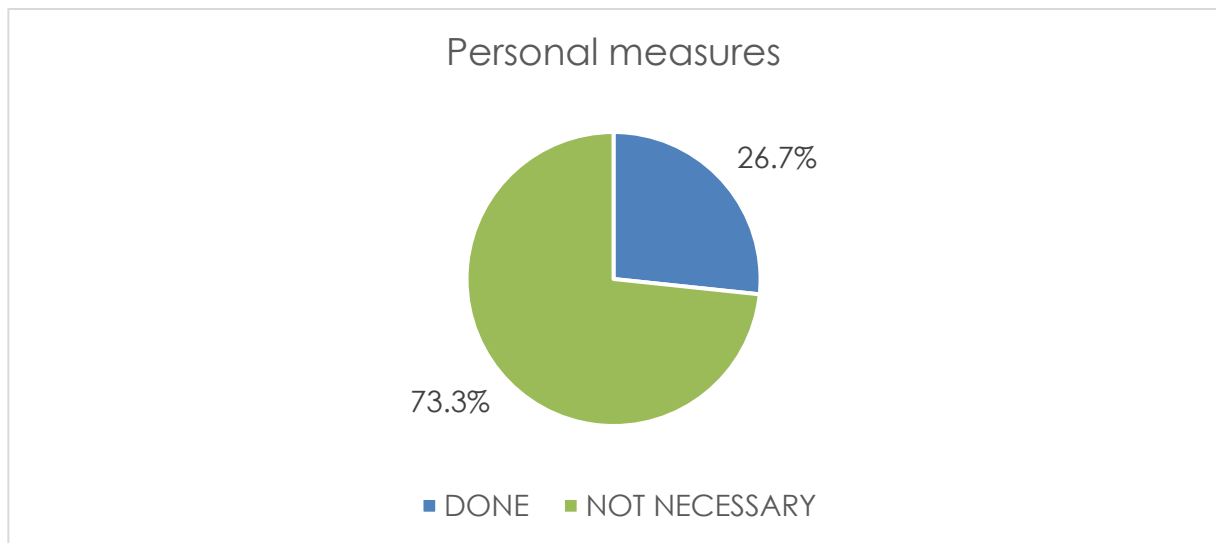


Figure 7 – Implementation of personal measurements.

In all three categories (engineering controls, organisational measures, and personal measures) the percentage of 'not necessary'-responses increased. This can be attributed to the various improvements and implementations that most of the companies have carried out in former years, as previously reported.

Medical data

Update of medical data

Moreover, additional information on medical data was collected through the submission of a retrospective medical survey. In this 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.

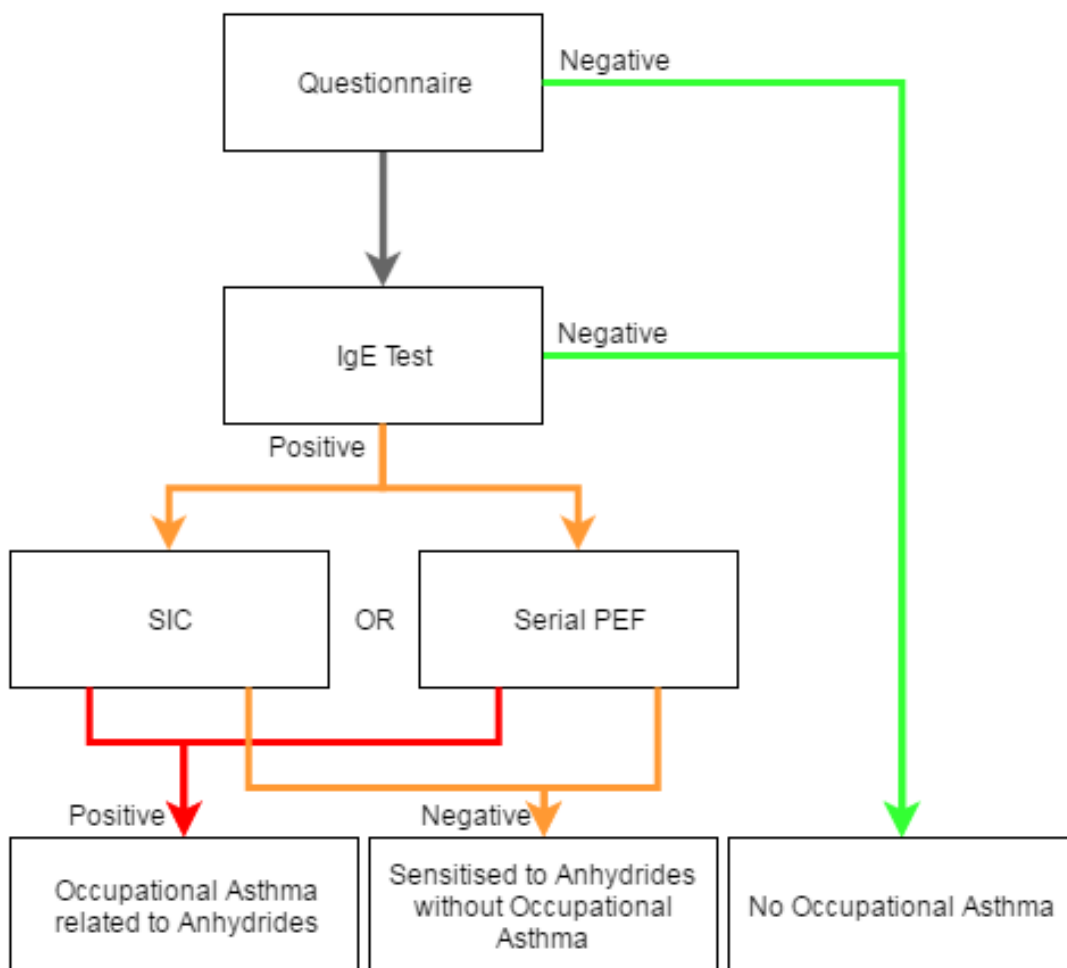


Figure 8 – Protocol for assessing occupational asthma. SIC = Specific Inhalation Challenge and PEF = Peak Expiratory Flow.

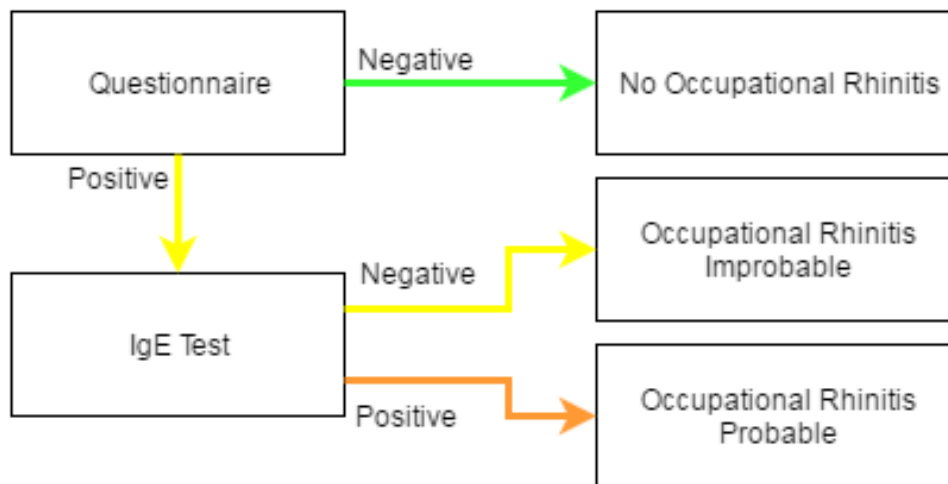


Figure 9 – Protocol for assessing occupational rhinitis.

Results and discussion

During the third industry consultation, 15 plants have submitted the updated medical surveys. A coverage of 317 potentially exposed workers has been considered, including the updated information sent at the beginning of 2020.

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 2019. 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 $2.5 \mu\text{g}/\text{m}^3$ and the Anhydride concentration inside the wet move area was reduced from $1480 \mu\text{g}/\text{m}^3$ to $160 \mu\text{g}/\text{m}^3$. 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.

Best Practice Guide & Workers' Training Program

Guidance Implementation

The AJIT Best Practice Guide (BPG) was made to enable companies to reduce exposure to anhydrides in the most effective way, by implementing the best practices in all anhydride-containing processes and handling. To ensure all processes are evaluated, it is advised to perform an exposure mapping. In 2019 the BPG was updated from the former version made in 2017. More specifically, the document contains additional instructions to:

- Install exhaust systems in a way so the air flow is directed away from working places. If not possible, the workers should wear adequate PPE;
- Equip hot surfaces, in contact with unreacted anhydride hardener, with exhaust nozzles;
- Designing tools and cleaning aids for single use only, to avoid contamination;
- Fit the workplace table with an effective local exhaust ventilation, if during an automatic pressure gelation process not fully cured objects are demoulded;
- Avoid open pouring of anhydrides all together, and use respiratory protective equipment in case of emergency (spillage/accidents);
- Use appropriated nitrile gloves and appropriated masks under EN 12942 with A-type filters (or similar with protection factor of 2000), in case of manual operations involving spillage cleaning or where spillage risk exists;
- Lowering of operational times from 1-2 hours to about 15 minutes, for transfer of wet devices to a curing oven.

The AJIT Workers' Training Program (WTP) was updated during 2020, from the 2017 version. The WTP includes instructions for trainers, and generic presentations for each application type (HVRM, SG, Manufacturers and formulators) which the trainers can amend to their specific cases. The 2020 version of the trainers' instruction, was amended with:

- Instructions to carry out periodic inspections as specified in article 5.2.a (EU Directive 2009/104/EC) once a month. At the minimum it should include a Smoke Pen test kit.
- Updated guidance on first aid measures, emphasising to contact a doctor if accidents/excessive exposure occur.
- Updated guidelines for proper respiratory protective equipment for producers of switchgears. EN 149 with A-type filters (for vapours and organic gases) or mask with P3-type dust filter (for solids) has to be considered, whenever anhydrides (or mixtures including them) are transferred in an open system.

The generic presentations have been updated accordingly, and following the ECHA Guidance on Safe Use on MHPA and HHPA.

Both AJIT Best Practice Guides and Workers' Training Program are available upon request. To access, follow the registration procedure here <https://anhydrides.eu/contact/>. Companies do not need be members of AJIT to register and request access.

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.

Due to COVID-19 related issues, it was not possible to have a complete update of the exposure data. Companies experienced a delay in delivering the results of the measurement campaign. New measurements will be planned in 2021.

However, updated information was obtained by some companies using HHPA and MHPA in formulation. Personal full shift measurements and personal single task measurements were carried out. The exposure values without the mask reduction factor range between 20 and 50 $\mu\text{g}/\text{m}^3$, which leads to exposure values of less than 5 $\mu\text{g}/\text{m}^3$ (more specifically, between 0.5 and 2 $\mu\text{g}/\text{m}^3$) when applying the mask reduction factor.

Additional measures are going to be taken in order to further decrease the exposure.

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 2019 and in 2020, it is possible to observe a general increase in terms of implementation. Moreover, the retrospective medical surveys carried out in 2019 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:

