COLLECTIVE EXPERT APPRAISAL:
SUMMARY AND CONCLUSIONS

Identification of works or processes to be included in the Order establishing the list of carcinogenic substances, mixtures or processes

work involving exposure to welding fumes

This document summarises the work of the Expert Committee on "Health reference values" and the Working Group on "Carcinogenic processes".

Presentation of the issue

In its Article R4412-60, the French Labour Code defines chemical agents that are carcinogenic, mutagenic or toxic to reproduction (CMR) as:

- any substance or mixture meeting the criteria for classification as a CMR in Category 1A or 1B set out in Annex I to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation);
- any substance, mixture or process **listed in the Ministerial Order establishing the list of carcinogenic substances, mixtures and processes**.

At present, the list in this Ministerial Order is essentially based on the transposition of Annex I of Directive 2004/37/EC (with the exception of formaldehyde, for which a decision was taken at national level) and includes the following processes:

- manufacture of auramine;
- work involving exposure to polycyclic aromatic hydrocarbons (PAHs) present in coal soot, coal tar, coal pitch, smoke or dusts from coal;
- work involving exposure to dust, fumes and sprays produced during the roasting and electro-refining of cupro-nickel mattes;
- strong acid process in the manufacture of isopropyl alcohol;
- work involving exposure to inhalable wood dusts;
- work involving exposure to formaldehyde;
- work involving exposure to respirable crystalline silica dust generated by a work process;
- work involving dermal exposure to mineral oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine;
- work involving exposure to diesel engine exhaust emissions.

As part of revisions to Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, currently under discussion at European level, ANSES received a formal request from the Directorate General for Labour (DGT) on 17 November 2017 to provide an opinion on new carcinogenic processes that could fall within the scope of this Ministerial Order.

ANSES was **initially** asked, through scientific and technical support, to determine whether four processes identified by the DGT (i.e. work involving exposure to welding fumes, work involving exposure to crystalline silica, work involving exposure to polycyclic aromatic hydrocarbons (PAHs) and work involving exposure to cytostatic agents), with strongly suspected carcinogenic properties (without a clear existing regulatory framework to define it) combined with a high occurrence in the workplace, could fall within the scope of the Ministerial Order.

ANSES was asked to indicate, if appropriate, whether there were any available data that could help further clarify the scope of these four processes, for the first quarter of 2018.
The work on these four processes was described in a Scientific and Technical Support Note published on 20 April 2018. Since no firm conclusions could be made in due time, it was recommended to further evaluate the following processes: work involving exposure to welding fumes, PAHs and cytostatic agents.

In its Scientific and Technical Support Note, ANSES recommended that work involving exposure to welding fumes should be included on the list of work in the Ministerial Order. However, since the monograph of the International Agency for Research on Cancer (IARC) had not been published when this scientific support was provided, and since the IARC was the only organisation (of the five considered) that had assessed the carcinogenicity of welding fumes, ANSES could only base its analysis on the publication by Guha *et al.* from 2017 summarising the IARC's assessment. It was therefore unable to thoroughly examine whether there were any data that could further clarify and/or limit the proposed scope.

Moreover, the IARC has also classified UV radiation from welding as “carcinogenic to humans” (Group 1) based on “sufficient evidence of carcinogenicity in humans” that it causes ocular melanoma. In its Scientific and Technical Support Note, ANSES considered it would be appropriate to more closely examine UV radiation from welding in the second phase of the work, in order to be able to rule as to the relevance of including it on the list of work in the Ministerial Order.
UV radiation emitted by welding processes has not been dealt within the context of this study, which refers to exposure to welding fumes and not to welding work. A further comprehensive reflection on UV radiation (natural and industrial sources) was considered preferable.

ANSES was **subsequently** also asked to propose a method for concluding whether or not a process can be classified as carcinogenic and to define classification criteria for justifying a process's inclusion in the Ministerial Order. This work will be covered in a collective expert appraisal report by ANSES at a later date.

The present work aims to determine the relevance of recommending the inclusion of work involving exposure to welding fumes in the Ministerial Order establishing the list of carcinogenic substances, mixtures and processes.

Organisation of the expert appraisal

ANSES entrusted examination of this request to the Expert Committee on "Health reference values" (HRV Committee). The Agency also mandated the Working Group (WG) on "Carcinogenic processes" for this expert appraisal.

The methodological and scientific aspects of this group's work were regularly submitted to the Committee. The report produced by the Working Group takes account of the observations and additional information provided by the Expert committee.

The Expert Committee on "Health reference values" adopted the collective expert appraisal work and its conclusions and recommendations, which are covered in the report, at its meeting of 01/07/2021, with a view to submitting them for public consultation with two abstentions.
This collective expert appraisal work and the summary report were submitted to public consultation from 27/09/2021 to 19/11/2021. The only comment received was reviewed and discussed by the Working Group (WG) on "Carcinogenic processes" on 6 December 2021. The Expert Committee on Health Reference Values adopted this final version on 16/12/2021. Two experts abstained. Their positions are set out in Annex 1 of this document.

This expert appraisal work was therefore conducted by a group of experts with complementary skills. It was carried out in accordance with the French Standard NF X 50-110 "Quality in Expertise Activities".

Prevention of risks of conflicts of interest

ANSES analyses the interests declared by the experts prior to their appointment and throughout the work, in order to avoid potential conflicts of interest with regard to the matters dealt with as part of the expert appraisal.
The experts' declarations of interests are made public via the website https://dpi.sante.gouv.fr/.

Description of the method

To improve understanding of the issue of welding fumes, various welding processes and related techniques emitting metal fumes were identified, as were exposure data, through the consultation of technical documents and an exchange with a staff member from the *Institut de Soudure* (welding institute). Data were extracted from the COLCHIC database, created by the INRS in 1987; this involved collecting data on occupational exposure to chemicals (personal and ambient measurements) over the 2002-2018 period in France. The goal was to identify initially, the list of chemical agents measured in the context of welding work, and then the workstations that can lead to similar exposure to that generated by work involving exposure to welding fumes.

In Europe, the Classification, Labelling and Packaging (CLP) Regulation ((EC) N° 1272/2008 is the regulatory tool that enables substances and mixtures to be classified based on their carcinogenicity. There are also other international and scientific organisations that assess the carcinogenic properties of substances, including the International Agency for Research on Cancer (IARC), and in the United States, the National Institute of Environmental Health Sciences (NIEHS) with the NTP, the United States Environmental Protection Agency (US EPA), and the American Conference of Governmental Industrial Hygienists (ACGIH®).

Of these different organisations, only the IARC has assessed welding fumes, which have been covered by two monographs (IARC, 1990 & 2018).
A literature search was conducted to supplement the IARC's assessment of the carcinogenic properties of welding fumes based on the most recent data.
To investigate whether or not the wording of the "work involving exposure to welding fumes" entry should be extended to other processes that can generate similar fumes, a literature search was undertaken in May 2021 with a view to documenting related techniques: brazing, soldering,

thermal spraying, gouging[1] (arc, plasma, flame), cutting (arc, flame, plasma, laser), hardfacing field welding, surfacing, building up, and deposition welding. This search was performed in the two databases (Scopus and PubMed) without any time limits. The following keywords were used: Type of process considered (see above) AND worker OR occupational AND cancer OR carcinogen*.

Conclusions and recommendations of the collective expert appraisal

Scope of the expert appraisal

The request from the DGT concerned the justification for including work involving exposure to welding fumes in the Ministerial Order establishing the list of carcinogenic substances, mixtures and processes, order enabling in particular the transposition of Annex I of Directive 2004/37/EC into French law when this Annex is required to evolve. In order to be included in the Ministerial Order, a substance, mixture or process must meet the criteria for classification as a Category 1A or 1B carcinogen as set out in the CLP Regulation, or criteria that can be considered equivalent to them. It should be emphasised that the aim of this expert appraisal was not to assess in detail the carcinogenicity data with respect to the classification criteria under the CLP Regulation, but to draw on existing carcinogenicity assessments.

The expert appraisal covered by this report deals with work involving exposure to welding fumes. The activities and processes studied were limited to those emitting metal fumes. Therefore, welding, brazing and other operations on plastics were not addressed as part of this expert appraisal. Moreover, concerning the soft soldering of metal parts, the fumes released contain very low levels of metal particulate compounds due to the low temperatures reached (180°C to 250°C). Regarding the issue of UV radiation from welding processes, the WG did not wish to address it in this expert appraisal, which focused only on exposure to welding fumes and not overall exposure to welding work.

- **Carcinogenicity of welding fumes**

Description of the methodology used

The WG examined the work of the various organisations and agencies assessing the carcinogenicity of chemicals. Of the various organisations consulted (the ECHA, the IARC, the US EPA, NTP, ACGIH®), only the IARC (the sole organisation assessing the carcinogenic effects of processes) has assessed welding fumes, which have been covered by two monographs (IARC, 1990 & 2018). These assessments take into account the carcinogenic effects reported in humans and in experimental studies in animals, the relevance of the mechanism of action, and the quality of the available dataset (only public data are considered). Whereas welding fumes had been classified as possibly carcinogenic to humans (Group 2B) in 1989, a new review of the data in 2017 led the IARC to classify them in Group 1 (carcinogenic to humans) in Volume 118 of its Monographs, based on sufficient evidence of carcinogenicity in humans (sufficient evidence for lung cancer and limited evidence for kidney cancer) and limited evidence of carcinogenicity in animals (stainless steel welding fumes) (Guha *et al.*, 2017). According to work conducted at ANSES on the equivalence of various systems for classifying carcinogens, Group 1 of the IARC was considered equivalent to Category 1A of the CLP Regulation (Farion, 2019). The WG therefore referred to this IARC Group 1 classification of welding fumes to issue its conclusions and recommendations.

[1] This study deals only with thermal gouging (and not mechanical gouging).

The WG conducted a literature search to take into account possible data published after the conclusions issued by the IARC in its 2018 assessment of the carcinogenic properties of welding fumes. Since the IARC had concluded there was sufficient evidence of carcinogenicity in humans, the literature search undertaken by ANSES focused on updating the epidemiological data.

Analysis and results

Since the IARC's 2018 monograph was released, there have been nine new publications deemed of interest in the epidemiological literature: one meta-analysis (Honaryar *et al.*, 2019), one cohort study (Michalek *et al.*, 2019b), and seven case-control studies (Parent *et al.*, 2017, Michalek *et al.*, 2019a, Pesch *et al.*, 2019, Talibov *et al.*, 2019, Barul *et al.*, 2020, d'Errico *et al.*, 2021, Chen *et al*., 2021). ANSES's analysis of these studies' results showed that overall, they were consistent with those of the studies analysed in the IARC monograph (IARC, 2018) and confirmed the carcinogenicity of welding fumes.

With regard to lung cancer, the meta-analysis of Honaryar *et al.* (Honaryar *et al.*, 2019), the cohort study of Michalek *et al.* (Michalek *et al.*, 2019b) and the case-control study of Pesch *et al.* (Pesch *et al.*, 2019) corroborated the IARC's conclusion as to an increased risk of lung cancer in welders that is attributable to exposure to welding fumes and cannot be explained by biases, other concomitant exposures or other risk factors (sufficient evidence).

ANSES's analysis of the epidemiological data published after the IARC's 2018 assessment concerning the risk of kidney cancer associated with occupational exposure to welding fumes did not provide reason to modify the IARC expert assessment (limited evidence).

Concerning cancers of the upper aerodigestive tract, the IARC's 2018 monograph noted that due to the small number of cases of oral cavity, pharyngeal and laryngeal cancers analysed in the studies, no clear conclusions could be drawn as to the role of welding fumes in the incidence of these cancers. ANSES's WG considers that the recent case-control study by Barul *et al.* (Barul *et al.*, 2020) provided strong additional evidence in favour of a causal relationship between exposure to welding fumes and laryngeal cancer (sufficient evidence) and, to a lesser extent, oral cavity cancer (limited evidence). This conclusion on laryngeal cancer is also supported by the link established between welding fumes and bronchopulmonary cancers, the respiratory tract being considered as one of the main target organs of welding fumes.

Lastly, for sinonasal cancer, the studies analysed in the IARC's 2018 monograph had reported inconsistent results. The study by d'Errico *et al.* (d'Errico *et al*., 2020) focused on a high number of cases of this rare cancer and constitutes an element strongly in favour of a link between exposure to welding fumes and squamous cell sinonasal cancer (limited evidence).

Results reported in the literature for other types of cancers previously analysed by IARC, such as urinary tract cancer, glioma, pharyngeal cancer and nasopharyngeal cancer, did not provide any new information which could modify the conclusions of the IARC monograph (the available data do not permit any conclusion to be drawn).

No new data were identified by the WG for the following cancers mentioned in the IARC monograph (2018): leukemia, non-Hodgkin's lymphoma, brain cancer other than glioma, pancreatic cancer, rectocolic cancer, stomach cancers, oesophageal cancer, prostate cancer, cancer of the testis and cancers in descendants. Furthermore, while no data were reported for breast cancer in the IARC monograph, the study of Talibov et *al.* 2019, identified by the literature search, does not support a conclusion as to an association between male breast cancer and exposure to welding fumes.

It should be noted that in general, exposure to welding fumes was not measured directly in these studies but rather was assessed indirectly using, for example, questionnaires on occupational activities. The fact that welding fumes are welders' main source of exposure and contain carcinogenic substances supports the conclusion that the risk of cancer in welders is related to their exposure. Moreover, the increased risk of lung and laryngeal cancers reported in the epidemiological studies could not be explained by concomitant exposures and can therefore be attributed to welding fumes according to ANSES's WG.

Most of the studies only reported the job title or work task without providing additional information about the welding technique used. Therefore, the onset of cancer could not be specifically attributed to the type of welding process, the types of metal welded or the method used to treat the surface to be welded.

In order to investigate the carcinogenicity of processes that can generate similar fumes, a literature search was conducted focusing on related techniques. Only one publication of interest was found with the "soft soldering" query. The cohort study undertaken by Ekenga *et al.* (Ekenga *et al.*, 2015) reported a significant association between exposure to welding materials and the risk of breast cancer, exclusively in premenopausal women. ANSES's WG notes that this result, obtained for a low number of tumours, would need to be confirmed by other studies. Furthermore, two other studies – those of Pesch *et al.* (2019) and Barul *et al.* (2020) mentioned above – also dealt with certain related techniques (torch cutting, thermal spraying, brazing and oxy-cutting).

Work involving exposure to welding fumes or metal fumes from related processes

Hot assembly is the most widespread technique involving exposure to welding fumes. It encompasses various processes such as welding and brazing and should be distinguished from other assembly techniques such as bonding and mechanical assembly. Other processes (including hard soldering, cutting, gouging, thermal spraying, etc.) can also emit metal fumes and thus expose workers. Multiple welding techniques are now used and the choice of one or another depends on the characteristics of the materials to be welded and the desired final weld quality. In 2021, with regard to the various welding processes used, the MIG-MAG process seems to be the most widely-used process in France, closely followed by the TIG process and shielded metal-arc welding. Submerged-arc welding (mainly in metalwork) and resistance spot welding also seem to be regularly used in France but not as much as the aforementioned processes[2].

Many professionals in various areas of activity are required to carry out welding work, without this being their main activity, and can be exposed to welding fumes in particular. Moreover, various professions not involved in welding work per se may be indirectly or passively exposed to welding fumes when working near people performing welding operations.

The variety of welding processes is a major consideration when assessing occupational exposure since it is uncommon for welders to use only one welding technique throughout their professional careers. Furthermore, it should be noted that the composition and quantity of emitted fumes to which welders are exposed differ depending on several parameters: types of processes and electrodes used, composition of parts to be welded and welding consumables, welding parameters (current and voltage, and flow rate and composition of shielding gases), etc.

Welding fumes consist of a gas phase (various gases such as nitrogen oxides, carbon monoxide and dioxide, hydrogen fluoride, ozone, etc.) and a particulate phase (primarily metal and metal oxide particles including known carcinogens such as nickel compounds, chromium VI, etc., as well as silicates and fluorides from fluxes). They are initially generated by the high temperatures required for metal melting inherent in the various welding processes. These particles are mixed with hot air and gases that form a rising cloud. Ninety five percent of the components of welding fumes come from welding consumables and less than 5% from the base material.

Related techniques, except for soft soldering, also emit fumes composed of metallic particles similar to those from welding processes.

Conclusion

In light of the above, ANSES's WG suggests **adding the following wording to the Ministerial Order: "work involving exposure to welding fumes or metal fumes from related processes including hard soldering, gouging, oxy-cutting, thermal spraying, and hardfacing".** This wording makes it possible to cover not only professionals exposed to welding fumes but also those exposed to metal fumes from related processes whose composition with regard to carcinogenic agents is similar to that of welding fumes. It also make it possible to take into account

[2] Communication of M. Scandella from the *Institut de Soudure*

workers regularly carrying out activities involving exposure to metal fumes from welding or related processes even though they are not directly classified as welders, as well as workers who are **indirectly exposed**.

Lastly, it should be stressed that this expert appraisal focused exclusively on the carcinogenicity of metal fumes but that metal welding fumes can also have other health effects that should also be taken into account for the prevention of occupational risks. For example, they can induce acute (irritation of the airways, metal fume fever, etc.) and chronic (pneumoconiosis, asthma, bronchitis, etc.) respiratory effects and cause damage to the kidneys and central nervous system (Ricaud, 2018).

- **Recommendations**

In light of the points set out in the French report, the WG issues recommendations for:

- updating the Ministerial Order establishing the list of carcinogenic substances, mixtures and processes (and possibly Annex I of Directive 2004/37/EC);
- protecting and raising awareness of workers potentially exposed to carcinogenic metal fumes;
- improving knowledge on the carcinogenic risk associated with exposure to metal fumes.

In order to update the Ministerial Order establishing the list of carcinogenic substances, mixtures and processes, the WG recommends adding the following to this Order:

work involving exposure to welding fumes or metal fumes from related processes including hard soldering, gouging, oxy-cutting, thermal spraying, and hardfacing.

In order to protect and raise the awareness of workers potentially exposed to carcinogenic metal fumes, the WG recommends:

- in accordance with the provisions of the French Labour Code**,**
  - carrying out an assessment **at least annually** of the risk of carcinogenicity for the various personnel involved, in order to implement adequate preventive and protective measures;
  - establishing the monitoring of occupational exposure, in particular by carrying out atmospheric metrological monitoring as well as biological monitoring of exposure, and developing the associated tools;
  - inform exposed personnel of the carcinogenic risk associated with direct and indirect exposure to welding fumes or metal fumes from the listed related processes and train them using appropriate collective and individual protections;
- inform and train employers about the carcinogenic risk associated with direct and indirect exposure to welding fumes or metal fumes from the listed related processes in order to encourage them to use the most appropriate and less emissive processes according to the welding operations to be performed.

In order to improve knowledge on the carcinogenic risk of exposure to metal fumes, the WG recommends:

- carrying out epidemiological studies on the risk of cancer, especially cancers other than bronchopulmonary cancer and laryngeal cancer, associated with exposure to metal fumes including in professionals implementing related techniques;
- to specify at best, in these epidemiological studies, the details of the processes, metals and alloys used and associated exposures.

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Annex 1: Presentation of abstention positions

This collective expert appraisal report was validated at the meeting of the Expert Committee on "Health reference values" of 1 July 2021, with a view to submitting it for public consultation. At this meeting, two experts abstained during the vote on submission for public consultation. The reasons for the two abstentions are given below.

Expert 1:
"I consider that the epidemiological data are too limited to conclude there is 'sufficient evidence' for laryngeal cancer".

Expert 2:
Arguments of Expert 2 justifying his abstention during the validation of the report on including exposure to welding fumes on the list of carcinogenic processes:

"With regard to the Working Group's objective, which was to assess the relevance of adding exposure to welding fumes to the list of carcinogenic processes for workers, the approach consisting in considering human epidemiological data was obviously appropriate and cannot be called into question. However, since 'welders' can implement several techniques over the course of their careers, the epidemiological studies conducted in the past decades have unfortunately been flawed in that they have incorrectly used the general word 'welding' to encompass very different activities involving the hot assembly of metals. The conclusions of the WG's work, attributing the carcinogenic effects observed to the various methods used for the hot assembly of metals, were therefore inevitable, as the studies undertaken have not been appropriate for distinguishing between the health effects of the different techniques.
Nevertheless, simple technical and metallurgical data make it clear that the 'related techniques' listed in the report's conclusion are highly disparate; the statement that these techniques emit 'similar metal fumes' is very questionable. As is clearly stressed in the report, the metal composition of fumes varies depending on multiple parameters, foremost among them being the composition of the alloy and the technique used, which determine the temperature reached in the melting zone.
Considering that from its melting point, a given metal will increasingly emit metal particles consisting of its atoms as the work temperature approaches the boiling temperature of the components, it can be said that the techniques causing it to melt, whether these are welding, oxy-cutting or gouging, can indeed emit particles with 'similar' compositions, on a qualitative level in any case. Many ferrous alloys, steels (unalloyed, low- or high-alloy steels), cast irons, nickel-based alloys, etc., will therefore emit fumes that may contain carcinogenic metal oxides, regardless of the technique used to melt them.
However, following through with this reasoning leads hard soldering to be considered differently. This assembly technique, which is NOT welding, currently uses copper, tin, zinc or silver alloys in the vast majority of cases, and at half the temperatures observed with welding techniques. While hard soldering does indeed lead to the emission of metal fumes, these have compositions that are fundamentally different from those with welding techniques. Since the ban on cadmium in brazing sticks, and excluding niche applications for specific alloys, none of the components of these fumes have been recognised as carcinogenic to date. Moreover, hard soldering techniques are also used in specific trades, such as jewellery-making, for which no data are available to be able to suggest a carcinogenic impact related to fumes from gold, silver or platinum brazing for example.
I therefore consider that including hard soldering as a whole on the list of related processes, although it results from the chosen methodology, is inappropriate and related solely to the legacy of decades of studies that have been insufficiently discriminatory with regard to the techniques used. In short, a clear distinction needs to be made between soft soldering, hard soldering and welding. At this stage of data, assigning a carcinogenic effect to hard soldering fumes based on the majority of the available studies is tantamount to ignoring a major confounding factor: exposure to welding fumes! In other words, just because the epidemiological database on the effects of exposure to welding fumes does not rule out the possibility of brazing fumes also being

carcinogenic, it is not appropriate to affirm that they are, especially when very simple technical and metallurgical data demonstrate that these metal fumes in no way have 'similar compositions'. Therefore, just as this work considered that soft soldering fumes were QUANTITATIVELY low in metal fumes, it could have been considered that metal fumes from hard soldering were QUALITATIVELY different from the welding fumes to which workers were exposed in the majority of the epidemiological studies. Determining whether exposure to brazing fumes, and to which brazing fumes, should be included on the list of carcinogenic processes should be another issue – covered by another formal request – for this other process.
Since I am nonetheless in favour of including (true) welding fumes on the list of carcinogenic processes, I therefore prefer to simply abstain from validating this report, which incidentally is very convincing on this point".