ANSES Opinion
Request No. 2015-SA-0218

The Director General

Maisons-Alfort, 30 May 2018

OPINION
of the French Agency for Food, Environmental and Occupational Health & Safety

on the "Assessment of the expected health benefits of anti-pollution respirators"

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It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.

It provides the competent authorities with all necessary information concerning these risks as well as the requisite expertise and scientific and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).

Its opinions are published on its website.
This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 30 May 2018 shall prevail.

On 30 September 2015, ANSES received a formal request from the Directorate General for Health and the Directorate General for Labour to undertake an expert appraisal on the assessment of the expected health benefits of anti-pollution devices.

1. BACKGROUND AND PURPOSE OF THE REQUEST

Air pollution is a genuine public health challenge and is the main environmental risk to health worldwide according to the World Health Organization (WHO). The WHO considers that non-compliance with the guideline values it recommends for fine particles in ambient air is responsible for some 3.7 million premature deaths every year.

"Ambient air pollution" is a generic term encompassing the wide variety of pollutants released into the atmosphere by fixed and mobile natural and anthropogenic sources or formed following secondary reactions in the atmosphere. It is monitored via a few regulated tracer pollutants (e.g. NOx, ozone, SO_2, fine particles). Particulate matter ($PM_{2.5}$ and PM_{10}) is the tracer pollutant that has most commonly been studied in connection with health and is that most often used to estimate the health impacts of ambient air pollution.

Long-term exposure to ambient air pollution promotes the development of chronic diseases. There are numerous studies documenting the impact of ambient air pollution on the development or aggravation of cardiovascular and respiratory diseases as well as cancer. These effects lead to an increase in the use of health services and a decrease in quality of life and life expectancy. Recent studies also suggest a link between exposure to ambient air pollution and the occurrence of

neurological effects, reproductive disorders including adverse effects during pregnancy and at birth on neurological development and cognitive function, and other diseases such as diabetes.

Exposure to ambient air pollution, especially during pollution peaks[1], can also induce acute effects such as irritation and decompensation of chronic diseases including cardiorespiratory diseases within a few hours to a few days of exposure. This also leads to an increase in the use of health services and in all-cause and cardiovascular mortality.

The greatest impact on the health of the population comes from long-term exposure to ambient air pollution, compared to the health impact of pollution peaks.

While the main way to reduce this health impact is to act at the source, thus limiting overall polluting emissions, questions have also been raised about the effectiveness of certain personal protective equipment, such as anti-pollution masks, and the benefit of recommending their use:

- by the general population, especially the people most susceptible to air pollution in certain situations such as pollution peaks,
- by certain particularly exposed categories of workers, for example people working on public roads or working abroad in highly polluted areas of the world.

ANSES received the formal request in this context, and it was agreed that the Agency would undertake:

1. A study on the regulatory status of anti-pollution masks: review of existing standards and regulatory obligations, in France and, if possible, in Europe.

2. A review of the literature on the effectiveness of anti-pollution masks against chemical and biological pollutants and on various parameters, human in particular, that may affect the anti-pollution performance of the masks. The chemical pollutants considered were ambient air pollutants such as particulate matter and VOCs. The biological pollutants were pollen as well as moulds when possible, depending on the available data. Infectious contaminants were excluded from the scope of the request.

3. A review of the literature on the adverse health effects of wearing anti-pollution masks. Environmental effects were excluded from the scope of the request.

4. An analysis of the potential health benefits of wearing an anti-pollution mask, examining various scenarios of exposure to ambient air pollution. The definition of these scenarios was to take into account the French general population and population of workers, whether living in France or working abroad in highly polluted areas of the world, as well as the nature of the pollution: chemical and/or biological, composition, particle size, etc.

Industrial accidents were excluded from the scope of the request, given the wide range of possible scenarios.

[1] **Ministerial Order of 7 April 2016 on the triggering of prefectural procedures during episodes of ambient air pollution**: period during which the concentration of one or more atmospheric pollutants in ambient air is greater than the information and recommendation threshold or the alert threshold defined in Article R. 221-1 of the French Environmental Code, under the conditions set out in Article 2.

The following devices claiming personal protection against ambient air pollution were excluded from the scope of the expert appraisal:

- Simple surgical masks: "Surgical" anti-projection masks are medical devices regulated by Directive 93/42/EEC, as amended[2]. Under the regulations, they are not considered as personal protective equipment (PPE), since their function is not to protect the wearer's respiratory tract but rather to prevent them from contaminating the environment;
- Full-face masks, covering the mouth, nose, chin and eyes: the use of this type of mask by the general population for protection against pollution was considered unlikely considering the dimensions of these devices.

2. ORGANISATION OF THE EXPERT APPRAISAL

The expert appraisal was carried out in accordance with French Standard NF X 50-110 "Quality in Expert Appraisals – General Requirements of Competence for Expert Appraisals (May 2003)".

The expert appraisal falls within the sphere of competence of the Expert Committee (CES) on "Assessment of the risks related to air environments". In the framework of this request, ANSES appointed three expert rapporteurs (CES members, 2013-2017 mandate) in a personal capacity to assist the Agency's Air Risk Assessment Unit in carrying out the expert appraisal. The methodological and scientific aspects of the expert appraisal work were regularly submitted to the CES between 17 December 2015 and 1 February 2018 and were approved by the CES at its meeting on 16 March 2018. The report issued by ANSES and the expert rapporteurs takes into account the comments and additional information provided by the members of the CES.

ANSES analyses interests declared by experts before they are appointed and throughout their work in order to prevent risks of conflicts of interest in relation to the points addressed in expert appraisals.

The experts' declarations of interests are made public via the ANSES website (www.anses.fr).

3. ANALYSIS, CONCLUSIONS AND RECOMMENDATIONS OF THE CES

I. Methodology

The expert appraisal methodology consisted of a market study of personal protective equipment for respiratory protection as well as a literature review supplemented by hearings.

- **Market study**

A market study was conducted in order to gain a better understanding of the personal protective equipment for respiratory protection available on the French market and of their claims of effectiveness against ambient air pollution. It was entrusted to a research firm following a call for tenders published by ANSES in 2016.
The results of the study undertaken in 2016 showed that cyclists were the main users of anti-pollution masks. An additional survey of cyclists was carried out by the appointed research firm in collaboration with the French Federation of Bicycle Users (FUB) to provide insight into the main motivations and practices of cyclists using this type of device.

[2] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

- **Literature review**

The literature review undertaken as part of this expert appraisal work aimed to survey knowledge on the effectiveness of personal protective devices against ambient air pollution and the health benefits and adverse effects of wearing these devices.
As early as March 2016, queries were performed in the Scopus and PubMed bibliographic databases with the following search equation: *(facemask OR mask OR respirator OR facepiece OR (respiratory AND protective AND device) AND air AND pollution).* These queries were updated on a regular basis until February 2018. The search period had no date restrictions.
The results of these queries highlighted 685 publications, 478 of which did not fall within the scope of the expert appraisal. These were excluded following the exclusion of keywords dealing with medicine (anaesthesia, dentistry, operating theatre, etc.) and specific work areas such as farm buildings.
A review of the titles and abstracts of the remaining 207 articles resulted in the analysis of around 40 original articles.

- **Hearings**

Various hearings were held as part of this expert appraisal in order to gather information about several points:

- Regarding the regulations applicable to anti-pollution masks, two representatives from the General Directorate for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) were consulted;
- Regarding the effectiveness of these masks and tests undertaken with them in the framework of their certification, hearings were held with professionals involved in the manufacture and control of respiratory PPE;
- Regarding the questions of potential users of anti-pollution masks and of expatriates living in particularly polluted cities, a physician focused on air quality representing the voluntary sector and the Counsellor for Health and Social Affairs of the French Embassy in Beijing were interviewed.

II. Results

1) Market study

The market study identified 215 products claiming effectiveness in terms of protection against ambient air pollution. The large majority of these products (94%) were half masks (203). The others included six portable air purifiers, two intranasal filters, two sprays, a filtration neck gaiter and a mask covering only the mouth.

It should be noted that more than half of the 203 identified half masks had ambiguous claims. For example, some distributors included a claim for protection against ambient air pollution in the e-commerce site description of a product initially intended by the manufacturer to provide protection against dust in the context of specific tasks such as handiwork. These masks could not be considered as protecting against ambient air pollution since their purpose was to protect only against the particle component of this pollution, not the gas component. Such misuses of masks not initially designed for protection against ambient air pollution, whether induced by distributors or voluntary by consumers, were difficult to quantify.

The French market for devices intended for personal protection from air pollution is relatively small, estimated at around €135,000 to €150,000 for 2015. In terms of turnover, the market is dominated by half masks with market share of 83%.

There are two types of half masks:

- **Filtration half masks**, which consist of a face piece, fully or partly made of filtration material that covers the mouth, chin and nose. Filtration half masks feature elastic bands or straps that go around the head and one or more exhalation valves in some cases.
- **Half masks** that also cover the mouth, nose and chin but are made of a flexible, airtight material. They are fastened around the head with straps and always include one or more exhalation valves. The half masks themselves do not provide protection. The filter element is attached to the half mask in the form of an often cylindrical filter via threaded connections.

There are single as well as multiple-use masks. According to the market study, there are three categories of multiple-use half masks:

- Half masks whose filter has to be replaced,
- Half masks whose filter can be washed but has to be replaced after a certain period of use,
- Half masks entirely composed of filtration material that can be washed but has to be discarded after a certain period of use.

The identified half masks were all fitted with mechanical filters, for the filtration of particles, and 27% were also equipped with active carbon filters whose manufacturers claimed protective action against gases and odours but with no further details in most cases on the e-commerce sites consulted during the market study.

Regarding claims, the masks claimed the filtration of particles[3] (80% of the masks), biocontaminants (viruses, bacteria, moulds, pollen, etc.) (27%) and organic pollutants (volatile organic compounds (VOCs), odours, etc.) (26%).

Cyclists and motorcyclists, susceptible people such as the elderly and people with chronic diseases, pregnant women, children, people with allergies to pollen in particular and travellers to highly polluted geographic regions were the main targets of these products.

Manufacturers of devices intended for the workplace showed no or little interest in this consumer market. According to manufacturer and distributor feedback, workers particularly exposed to ambient air pollution were also not particularly targeted. Only one manufacturer mentioned possible use by people working on public roads.

Following this market study, an additional survey using an online questionnaire was conducted among members of the FUB. Although it was not representative of the use of anti-pollution masks by the general population or cyclists, it nonetheless provided some insight. Of the 1284 respondents, 5.9% said they regularly or occasionally wore anti-pollution devices and 8% said they had tried such a device but did not adopt it. Of the respondents who had tried anti-pollution devices but no longer used them, the majority said they were not convinced by the comfort of the device (85.5%) and 43.5% said they were sceptical as to their effectiveness.
Cyclists who had never worn them gave several reasons, in particular a lack of comfort and uncertainty as to their effectiveness. Many of them said they were lacking information or had never thought about wearing such devices. Beyond these practical reasons, some cyclists considered that wearing anti-pollution masks was not an acceptable solution and that the issue of air pollution should be addressed at the source.

[3] In the framework of the market study, the word “particles”, in claims of effectiveness, encompassed several terms used by manufacturers and distributors: particles, inert particles, PM_{10}, $PM_{2.5}$, dust and nanoparticles.

Lastly, while users of anti-pollution masks said they wore them for protection against pollution, one third claimed it was to provide themselves with protection from odours.

2) Regulations

Under the regulations, anti-pollution masks intended for the general public are considered as PPE in the same way as those used in the workplace. Indeed, they meet the definition in Directive 89/686/EEC[4] stipulating that PPE shall mean any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards, and intended for professional or private use (sport, leisure, domestic use).
They therefore must comply with the requirements of this Directive, transposed into French law in the Labour Code and Sports Code. This Directive was repealed as of 21 April 2018 and replaced with Regulation (EU) 2016/425 of the European Parliament and of the Council. The Directive will continue to apply for a transitional period of one year for the placing on the market of products. The requirements for respiratory PPE are the same in the Directive and the Regulation.
The Directive lays down conditions for the marketing and free circulation of PPE as well as essential requirements it must fulfil to protect the health and safety of users.
Certification and testing procedures differ depending on the type of PPE. They may consist of:

- simple self-certification for PPE of simple design (e.g. sunglasses, gardening gloves),
- “EC type” examination together with an EC quality control system or an EC quality assurance system for production with monitoring by a notified body, for PPE of complex design.

Respiratory PPE devices and therefore anti-pollution masks fit in the category of PPE of complex design. They are intended to protect against mortal danger or against hazards that may seriously and irreversibly harm health, the immediate effects of which the designer assumes the user cannot identify in sufficient time.
The Directive defines technical rules of design, most of which are included in harmonised European standards, as well as requirements for labelling and for information to be included in the instructions for use.
Regarding labelling, it should be noted that the market study showed that the main sales network for masks was online sales and that consumer information was seldom available in the product descriptions. This lack of information on e-commerce sites does not mean that such information is not provided when the products are delivered. However, it would be useful to purchasers when they are shopping online on websites. According to the FUB's survey of its members, more than 30% of the respondents mentioned either the lack of instructions, their lack of clarity or the fact that they were written in a foreign language.

Note that a product falling with the scope of the PPE Directive cannot be exempted from the constraints of the PPE regulations by arguing that it only provides the wearer with personal comfort or limited personal protection. It is of course first and foremost the manufacturer's responsibility to determine the destination of its products and assign them with claims, provided that these claims (or partial claims, or even lack thereof) are not misleading and do not conflict with the legitimate expectations of consumers or with the product's nature, design or appearance. Thus, a mask marketed with an “anti-pollution” claim but only claiming to improve “comfort” cannot escape the Directive's obligations.

[4] Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment.

3) Effectiveness of anti-pollution masks

The effectiveness of these masks is defined by the effectiveness of the filter medium combined with the leak-tightness of the face piece. It is important to distinguish between theoretical effectiveness and effectiveness in real-life conditions, assessed for this expert appraisal in the general population in normal conditions of use.

In this expert appraisal, theoretical effectiveness corresponded to the expected effectiveness level of a mask worn in ideal conditions of use, on the basis of standardised tests, for example. This theoretical effectiveness is different from actual or practical effectiveness or effectiveness of use. Theoretical effectiveness is assessed by laboratory or field tests in controlled conditions in subjects trained to wear masks, who correctly use, after verification, a properly fitted and well maintained device.

Effectiveness in real conditions of use is effectiveness assessed in individuals from the general population in normal conditions, or in workers in actual working conditions. Therefore, this effectiveness depends on many other criteria such as the fit on the face, maintenance of the mask, user information and training, and user activity. For example, physical activity increases respiratory rate, which increases pressure loss or airflow resistance and causes leakage around the face to increase. A clogged filter also leads to an increase in pressure loss.

In the end, a mask defined by very high theoretical effectiveness often has limited or even no effectiveness in real conditions of use by the general population. This difference between theoretical effectiveness and effectiveness in real conditions of use can even be observed with an effective and properly fitted mask used by a person trained to wear masks. Most of the masks identified in the market study featured a filtration technology targeting particles. And yet ambient air pollution is characterised by a complex mixture of particles and gases. Therefore, to be able to provide proof of effectiveness, a mask should be tested according to the standards applicable to each targeted type of pollutant.

In practice, the market study showed that anti-pollution masks are designed for and contain filtration technologies mainly targeting particles. The effectiveness of half masks filtering particles can be tested according to Standard NF EN 149 + A1 which defines requirements, testing and marking for these devices. This standard defines three classes of “filtering facepieces” (FFPs): FFP1, FFP2 and FFP3. These classes are defined based firstly on the effectiveness of the filter medium and secondly on the maximum total inward leakage (combination of penetration through the filter medium and leak-tightness of the face piece) (see Table 1). There are single-use masks, marked “NR” (non-reusable), whose use is limited to a working day. There are also reusable masks, marked “R”, which can be used for several working days.

Table 1: Criteria for classifying half masks filtering particles based on penetration through the filter medium and total inward leakage (according to Standard NF EN 149 + A1)

Classification	Maximum penetration of the test aerosols		Total inward leakage
	Test with sodium chloride (mass median diameter of 0.6 µm) 95 L.min^{-1} % Max.	Test with paraffin oil (log-normal distribution with a number median Stokes diameter of 0.4 µm and a σ = 1.82) 95 L.min^{-1} % Max.	Test with sodium chloride (particle size distribution of 0.02 to 0.2 µm aerodynamic equivalent diameter with a mass median diameter of 0.6 µm) % Max.
FFP1	20	20	22
FFP2	6	6	8
FFP3	1	1	2

In the scientific studies referenced in this expert appraisal, N95 masks were often used. These masks, approved by the National Institute for Occupational Safety and Health (NIOSH) in the United States, are tested against 0.3 µm suspended droplets at 85 L.min^{-1}. Regarding the marking, the letter refers to the filter's degree of resistance to loss of effectiveness when exposed to various types of airborne particles: "N" means not resistant to oil, "R" means somewhat resistant to oil, and "P" means strongly resistant to oil. The number refers to the filter's degree of effectiveness: 95% (N95), 99% (N99) and 99.97% (N100).

Masks certified by NIOSH and those certified by the NF EN 149 + A1 standard are subject to different test conditions, in particular with a greater median aerosol diameter and flow in the European standard. Therefore, there is no equivalence between the European and North American mask categories. However, it is generally accepted that the performance of an N95 mask is similar to that of an FFP2 mask while that of an N99 is close to that of an FFP3.

Lastly, it should be noted that some studies indicate that particle filtration performance can be affected by the presence of diesel emissions, assuming that gases influence filtration performance (Janssen and Bidwell, 2006; Penconek, Drayk and Moskal 2013; Satish *et al.*, 2017).

4) Potential health benefits of wearing anti-pollution masks

The aim of the expert appraisal was to assess whether the wearing of anti-pollution masks in real conditions of use by the general population can have health benefits. On the basis of the work undertaken, no conclusion could be drawn on this issue. The literature search only identified a limited number of studies comparing health markers for exposed subjects wearing or not wearing masks (generally N95 dust masks). These studies, mainly undertaken in Asian countries, targeted the general population or workers exposed to ambient air pollution.

Regarding workers exposed to ambient air, only four studies, conducted in South-east Asia, focused on the health consequences of exposure to road traffic for people equipped with masks recommended in the workplace (Anurekha, Devaki and Saikumar, 2015; Ruchirawat *et al.*, 2002; Wongsurakiat *et al.,* 1999; Wertheim *et al.*, 2012).
The majority of these studies were of poor quality or inconclusive. The authors compared certain biological and clinical responses of exposed people working near traffic and wearing masks with those of unexposed or exposed people working near traffic and not wearing masks. Two publications assessed measurements of urinary biomarkers of exposure to polycyclic aromatic hydrocarbons (PAHs) (DNA adducts) while the other two investigated the frequency of respiratory

symptoms and/or pulmonary function parameters. Three of these studies (Anurekha, Devaki and Saikumar 2015; Ruchirawat *et al.*, 2002; Wongsurakiat *et al.*, 1999), which led to non-significant results, had major limitations in terms of interpretation due especially to a lack of information about the masks worn and their conditions of use, small study populations and the measurement of unsuitable health indicators to identify the possible impacts of wearing a mask. The most recent and most robust study by Wertheim *et al.* (2012) compared urinary biomarkers of exposure to PAHs in workers exposed to traffic who wore or did not wear a mask. The participants wore an R95 particulate mask and had been trained to use it, in keeping with the recommendations of the Occupational Safety and Health Administration (OSHA-USA). The mask was to be worn or not for two consecutive days during working hours, over a two-week period. A new mask was provided for each day of use. This study did not demonstrate any influence of wearing the mask on markers of exposure to PAHs, stressing that the tested masks were mainly intended to filter particles, not gases. It also indicated that the participants reported discomfort from using the masks.

Regarding the general population, only three good-quality studies (Langrish *et al.*, 2012; Langrish *et al.*, 2009; Shi *et al.*, 2017) were identified in the literature. These three quasi-experimental studies, conducted in China, aimed to explore the short-term influence of the use of an FFP1 or N95 mask by subjects continuously or during prescribed walks. Depending on the study, the participants were either healthy non-smoking students or patients with coronary heart disease. The parameters investigated in the three studies included cardiovascular constants and the tolerability of the mask.

Regarding the healthy non-smoking students, the results (Langrish *et al.*, 2009; Shi *et al.*, 2017) are difficult to interpret. The authors reported the observation of statistically significant improvements in certain cardiovascular parameters such as a decrease in systolic blood pressure and an increase in heart rate variability. However, the experts consider that these improvements can be interpreted as adaptive short-term changes in cardiovascular physiology. In addition, the speed of the walkers in the studies was not specified, even though blood pressure and heart rate variability are highly sensitive parameters.

Regarding the patients with coronary heart disease, the results of the study by Langrish *et al.* (2012) suggested better myocardial performance, with statistically significant improvements in certain cardiovascular parameters such as a decrease in ST segment depression, a decrease in systolic blood pressure and an increase in heart rate variability. However, other cardiovascular parameters also reflecting the degree of ischaemia were not significantly modified.

Although these three publications gave original and interesting results, their interpretation has limitations, especially in terms of their generalisation and extrapolation for all anti-pollution masks on the one hand and for the entire general population on the other hand. The main limitations were as follows:

- There was a low number of participants;
- A small number of days were considered with the assessment of short-term exposure only, based on physiological parameters;
- The study protocols were not representative of the potential use of an anti-pollution mask by the general population (use of the mask continuously outdoors and as much as possible indoors, for 24 hours before the day of the prescribed walk and 24 hours on the day of the walk, training on use of the mask (Shi *et al.*, 2017), a single type of tested activity (prescribed one to two-hour walk in a targeted area of an urban environment), only one type of anti-pollution mask tested);

- Only certain cardiovascular function parameters were assessed whereas the scientific literature stresses the impairment of various mainly respiratory organs and systems related to exposure to ambient air pollution;
- The issue of the masks' ineffectiveness against ambient air pollution gases and their possible health effects was not discussed by the authors;
- There was a lack of evidence demonstrating long-term changes and/or benefits related to the use of masks in the study populations.

In the end, the experts considered that these studies did not enable conclusions to be drawn as to the potential benefits of wearing a mask, in real conditions of use by the general population.

Furthermore, during the expert appraisal, the CES considered undertaking a quantitative assessment of health impacts including various exposure scenarios, in order to quantify the health benefits of wearing a mask. However, it ultimately deemed that this assessment could not be conducted, because such quantification work would mean implicitly acknowledging the effectiveness of masks in reducing exposure in real conditions of use, whereas the available data on the effectiveness of masks in real-life situations do not enable such a conclusion to be drawn.

Regarding pollen, only one quasi-experimental study dealing with 10 subjects was identified (Gotoh, Okubo and Okuda 2005). Healthy volunteers with a surgical mask and glasses with side guard frames as well as control subjects were exposed to pollen in real conditions. The authors indicated that the fraction of pollen reaching the nose and eyes was smaller when the subjects wore the mask. The aforementioned limitations regarding small study populations and subject training qualify the scope of the results.

Regarding the relevance of wearing a mask during wild fires, the two identified studies did not enable conclusions to be drawn as to the benefits of these devices in such situations (Künzli *et al.*, 2006; Mott *et al.*, 2002). These studies provided little information; for example, the nature of the masks used and the durations of use were not described. Moreover, their conclusions were not consistent.

Regarding the potential adverse health effects of wearing a mask, the data are also limited. Four studies by the same team (Bansal *et al.*, 2009; Harber *et al.*, 2009; Harber *et al.*, 2010b, a) used similar protocols to assess the tolerability of wearing cartridge half masks and N95 filtration half masks during mild to moderate physical activities. The studies focused on the general population and all included healthy subjects as well as subjects with moderate respiratory diseases (allergic rhinitis, moderate asthma, moderate chronic obstructive pulmonary disease (COPD)).

In the study by Bansal *et al.* (2009), all the subjects performed all the tasks and none were required to remove their mask. The results were averaged for all the subjects, making it impossible to draw specific conclusions on the physiological effects of wearing a mask for susceptible subjects. The authors concluded that the two tested types of masks (N95 filtration half mask and half mask with filtration cartridges) could be worn by the majority of individuals, including those with moderate respiratory diseases. However, they underlined that a small number of individuals may have adverse physiological reactions. In the study by Harber *et al.* (2009), the observed side effects were more pronounced with the cartridge half mask but were generally mild. They consisted of annoyance, a sensation of respiratory discomfort, perspiration and a sensation of heat. Harber *et al.* (2010b) sought to assess the personal characteristics that could influence the tolerability of these masks. The authors concluded that there was no universally well-tolerated mask but that tolerability depended on the underlying disease. Lastly, the final study by Harber *et al.* (2010a) aimed to assess physiological adaptation to the use of masks in subjects with moderate respiratory

diseases. This study showed that tolerability differed depending on the type of mask and the disease. The results indicated that people with asthma or COPD may have difficulties adapting to cartridge masks.

Thus, according to these studies, the use of masks can have adverse effects but they are well tolerated by the majority of individuals, including those with moderate respiratory diseases. However, tolerability depends on the diseases of the people wearing the masks.

The literature search did not identify any studies involving subjects with serious respiratory diseases or with cardiovascular diseases. However, in the study by Langrish *et al.* (2012) on the beneficial effects of wearing masks on the cardiovascular system of patients with coronary heart disease, the subjects reported that the masks had been well tolerated.

Lastly, two literature reviews were identified on the physiological parameters impacted by the use of masks. The goal of the first was to conduct a review of studies on human factors and the ergonomics of the masks. It concluded that the aspects to be taken into account for the development of new masks and the improvement of their performance were ergonomics, visibility, the physical, cognitive and psychomotor performance of users, odours, fit to face size and shape, weight, comfort for skin and anxiety generated by wearing a mask. The second study, conducted in workers, reviewed the metabolic, respiratory and cardiovascular effects of wearing a mask. It mentioned inhalation and exhalation resistance, increases in thermogenesis responsible for sweating, vasodilation and the emission of water vapour. While training to use a mask could improve the ability to adapt to working conditions, the physiological and psychological responses induced by wearing a mask, which could limit performance when carrying out tasks (decrease in intensity, limitation of working time, etc.), could not be eliminated.

III. Conclusions of the CES

Considering the data collected and analysed as part of this expert appraisal work, the CES notes that:

- The market for personal devices protecting against ambient air pollution is low in volume, estimated in 2015 at €135,000 to €150,000 annually, corresponding to approximately 20,000 units sold. The main manufacturers of respiratory personal protective equipment (PPE) remain focused on use in the workplace.
- Two hundred and fifteen devices were identified as claiming personal protection against ambient air pollution. They primarily included filtration half masks (203 products) and to a lesser extent portable air purifiers, sprays and intranasal filters. The half masks were all equipped with mechanical filters, for the filtration of particles, and 27% also contained active carbon filters.
- Half masks claiming to provide protection, prevention or comfort should be considered respiratory PPE. Therefore, they must comply with the requirements of Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment such as masks intended for professionals.
- Regarding the other devices identified in the market study, i.e. intranasal filters, portable air purifiers and sprays, they are not considered as respiratory PPE and are therefore not suitable for protecting against ambient air pollution. They were not assessed as part of this expert appraisal.

Considering that the objectives of the formal request were firstly to study the effectiveness of anti-pollution masks claiming to provide protection, prevention or comfort and secondly to assess the potential health benefits of wearing masks, in real conditions of use by the general public, the CES concludes that the analysis of the available scientific literature did not enable these issues to be resolved.

In accordance with Council Directive 89/686/EEC, effectiveness must be assessed by notified bodies, according to European standards or protocols defined by these bodies. It should be noted that the standards provide for tests in subjects familiar with wearing masks, which does not correspond to use by the general population. Furthermore, it is important to note that the testing standards for masks were designed for healthy adults. Thus, they are not suitable for children, due notably to the size of the standardised mannequin used in the tests, or for people with respiratory diseases.

The theoretical effectiveness of a mask depends on the filter medium's performance and the mask's design. Thus, even if a mask tested in a laboratory has high theoretical effectiveness, this does not necessarily reflect its effectiveness in real conditions of use, which may be limited or nil. In fact, inward leakage can be increased by face shape (child, beard, etc.), user behaviour such as physical exertion leading to an increase in respiratory rate, or a lack of training or information on conditions of use, storage, cleaning or renewal.

Moreover, most of the identified devices feature a filtration technology targeting particles. And yet ambient air pollution is characterised by a complex mixture of particles and gases. Thus, in order to be able to demonstrate effectiveness against “air pollution”, a mask must be tested according to standards applicable to each pollutant found in ambient air. In other words, a mask claiming protection against particles does not protect against substances found in ambient air in a gaseous state.

In the end, the CES considers that no data were identified in the literature enabling the potential benefits of anti-pollution masks to be assessed in real conditions of use by the general population:

- Aside from the studies in the workplace, only three studies focused on the health benefits of wearing a mask filtering particles, which are a component of ambient air pollution, but these were not deemed sufficient to draw any conclusion as to a potential benefit of wearing a mask in general conditions of use by the general population, in particular due to the limited number of participants and conditions of use that were not representative of standard use.
- Only one study involving pollen was identified. Its results indicated a decrease in exposure with the use of a mask. The aforementioned limitations regarding the small number of participants and the training of the subjects qualify the scope of the results.
- Regarding the relevance of wearing a mask during wild fires, the two identified studies focusing on the general population were not sufficiently descriptive, especially in terms of the nature and conditions of use of the protective devices used, and did not enable any conclusions to be drawn.
- Regarding the potential adverse health effects of wearing a mask, the data are also limited. They indicate that the use of masks can cause discomfort but that they are well tolerated by the majority of individuals, including those with coronary heart disease or moderate respiratory diseases. No studies were identified dealing with subjects with severe respiratory diseases.

The use of masks by workers can be associated with a decline in physical performance.

In addition to the positive and negative effects found in the literature, it is important to note that the act of wearing a mask could provide a false sense of security in users and lead to behaviour

resulting in overexposure. For example, a cyclist wearing a mask and riding on a road with heavy traffic could ultimately be more exposed than a cyclist not wearing a mask but choosing to take roads with less traffic.

In light of the above, the information currently available in the scientific literature does not enable clear conclusions to be drawn as to the health benefits of wearing an anti-pollution mask against background pollution or during a pollution peak.

Moreover, considering that in France, the health impacts of pollution peaks are much lower than those of long-term exposure to background levels, the CES reiterates that a protective measure only targeting pollution peaks would only very slightly reduce the total health burden that ambient air pollution places on the population.

Recommendations of the CES

Considering the results of the expert appraisal, the CES is issuing the following recommendations:

1. To reduce the impact of ambient air pollution on the general population:

1.1. Reducing emissions

The CES reiterates its recommendations for the public authorities as to continuing and intensifying the implementation of **all actions aiming to reduce air pollutant emissions.**

1.2. Reducing/limiting exposure in the general population

During pollution peaks, the CES reaffirms the recommendations of the Ministry of Solidarity and Health in its Order of 20 August 2014 on health recommendations for preventing the health effects of air pollution[5].

Outside of pollution peaks, the CES advises the public authorities to also inform the general population, in particular by establishing recommendations about personal behaviours to be adopted to reduce or limit daily exposure.

Considering the inadequacy of the data on the potential benefits of wearing anti-pollution masks in real conditions of use by the general population, the CES does not recommend wearing such devices in the current state of knowledge.

Without calling into question the above recommendations, and considering that the use of an anti-pollution mask is a personal choice, the CES would like to inform people using such devices that:

- Masks claiming protection against air pollution or certain of its components meet the definition of personal protective equipment (PPE) given in Directive 89/686/EEC. As such, they must comply with the regulations and therefore be labelled and have instructions for use. The "CE" marking must be affixed to all PPE or to the packaging if the characteristics of the PPE do not enable it to be directly affixed to the product. The instruction manual must be written in French and mention the following, among other things: the name and address of the manufacturer or its authorised representative established within the European Union, the instructions for storage, use, cleaning, maintenance and disinfection, the product's performance and class of protection, limitations of use, all data enabling the purchaser or user to determine a reasonable obsolescence date, as well as the name and identifying number of the “notified body”, solicited in the PPE's design phase. Any breach of

[5] https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000029413664&categorieLien=id

these obligations is an offence. Thus, a product that claims such protection but does not have a label or instruction manual compliant with the regulations in force is a fraudulent product.

- The "anti-pollution" masks available on the market are mainly masks with filtration technologies targeting particles; they thus do not protect against substances found in ambient air in gaseous form, unless there is an ad hoc specification compliant with the applicable regulatory requirements;
- The effectiveness claimed by masks remains theoretical; effectiveness in real conditions of use is very generally lower. Indeed, numerous factors can affect the leak-tightness of a mask: lack of user information or training, poor fit, face shape (beard, child, etc.), increase in respiratory rate related to physical activity, failure to maintain or replace the mask, etc.
- The use of a mask should be combined with behaviour limiting exposure to ambient air pollution.

2. To reduce the impact of ambient air pollution on workers:

The CES reiterates the obligations in the Labour Code requiring that employers take necessary measures to ensure the safety of workers and protect their physical and mental health.
These measures include:

1° Actions for the prevention of occupational risks,
2° Information and training actions,
3° The establishment of a suitable organisational structure and resources.

Employers should take care to adapt these measures to take account of changes in circumstances and strive to improve existing situations.

Regarding the use of occupational exposure limits (OELs) for the prevention of chemical risks in the workplace[6], the CES:

- Reiterates that compliance with the OELs should be considered as a minimum objective for the prevention of chemical risks. Exposure should therefore be reduced to the lowest level technically possible.
- Underlines that the existing OELs for dust deemed "without specific effects"[7] are not suitable in the context of exposure to particulate ambient air pollution and recommends initiating a discussion on the feasibility and relevance of establishing specific OELs for this issue.

6 DGT Circular No. 2010/03 of 13 April 2010 on the control of chemical risks

7 In facilities with specific pollution (where hazardous or unwanted substances are emitted), there are 8h-OELs for dust deemed "without specific effects", i.e. dust "that is not on its own capable of having effects other than overload on the lungs or on any other organ or system of the human body" (Ministry of Labour Circular of 9 May 1985). The 8h-OEL is 10 $mg.m^{-3}$ for the inhalable fraction and 5 $mg.m^{-3}$ for the alveolar fraction (Article R. 4222-10 of the French Labour Code).

3. To reduce the impact of ambient air pollution on travellers and expatriates in particularly polluted geographic areas[8]:

The CES recommends:

- That the public authorities provide information to travellers and expatriates, especially susceptible populations[9], about the health risks related to exposure to ambient air pollution in regions of the world where high levels are observed.
- That travellers and expatriates comply with the recommendations in this expert appraisal, issued above for the general population, in order to reduce their exposure.

Note that without calling into question the conclusions and general recommendations of the expert appraisal, one of the three expert rapporteurs stated a minority view[10]. This view is shared by four CES members.

4. Regarding the market for anti-pollution masks:

The CES recommends:

- Improving transparency for claims of effectiveness; a mask claiming effectiveness against pollution should provide proof of effectiveness against both particles and gases. A mask only filtering particles cannot claim protection against ambient air pollution.
- Ensuring that the devices sold are compliant with the requirements set out in Council Directive 89/686/EEC.

5. To improve knowledge related to the use of masks:

The CES recommends documenting the following in real conditions of use by both "healthy" and "susceptible" subjects:

- the effectiveness and tolerability of anti-pollution masks;
- the short- and long-term health benefits of wearing anti-pollution masks, including in high-exposure situations.

8 The World Health Organization identifies particularly polluted geographic areas through maps showing annual mean concentrations in $PM_{2.5}$ (http://maps.who.int/airpollution/ or http://gamapserver.who.int/gho/interactive_charts/phe/oap_exposure/atlas.html)

9 In its Opinion of 15 November 2013 on health messages to be disseminated during episodes of ambient air pollution involving particles, ozone, nitrogen dioxide and/or sulphur dioxide, the High Council for Public Health (HCSP) gives the following definition of populations vulnerable to atmospheric pollutants: pregnant women, infants and children under the age of five, people over the age of 65, and subjects with asthma, cardiovascular disease, heart failure or respiratory failure.

10 Minority view as reported by one of the three expert rapporteurs and shared by four CES members: *"Several times during the discussions with the expert group, I voiced a slightly different view regarding the recommendations to be given to expatriate families. It is a feeling much more than a scientific opinion. As a public health specialist, I completely agree with the group that measures aiming to reduce emissions of pollutants as well as the current recommendations on precautions to be taken to limit individual exposure are priorities. Nonetheless, my medical experience with individual consultations leads me to believe that there is room for special cases, such as expatriates highly exposed to ambient air pollution. These people can be highly motivated to learn to properly use an FFP2 or FFP3 half mask whose effectiveness could be non-negligible if worn when the person is outdoors. It should also be remembered that wearing a mask is socially well accepted in South-east Asian countries, which is not the case in Western countries".*

4. AGENCY CONCLUSIONS AND RECOMMENDATIONS

The French Agency for Food, Environmental and Occupational Health & Safety endorses the conclusions and recommendations of the CES on “Assessment of the risks related to air environments”.

ANSES insists on the distinction between the theoretical effectiveness of a mask and that assessed in real conditions of use by the general population. Theoretical effectiveness corresponds to the expected effectiveness level of a mask worn in ideal conditions of use, on the basis of standardised tests, for example. Thus, even if a mask tested in a laboratory has high theoretical effectiveness, this does not necessarily reflect its effectiveness in real conditions of use, which may be limited or nil due for example to poor fit to the face, failure to maintain the device, lack of user information and training, the user’s activity, etc.

ANSES stresses the inability of the available data to demonstrate any health benefits of wearing anti-pollution masks in real conditions of use by the general population, also considering that the majority of the devices available on the market claim protection against particles. And yet air pollution also consists of complex gas mixtures against which such devices are ineffective. Thus, the Agency does not have sufficient scientific bases to advise the public authorities to encourage the use of such devices by the general population. Furthermore, ANSES emphasises that the act of wearing an anti-pollution mask could create a false sense of security in the user and cause behaviour potentially resulting in overexposure. For example, a cyclist wearing a mask and riding on a road with heavy traffic could ultimately be more exposed than a cyclist not wearing a mask but choosing to take roads with less traffic.

At the national level, ANSES reiterates the importance of reducing exposure to atmospheric pollutants in the general population and thus of prioritising the reduction of atmospheric emissions of these gaseous or particulate compounds at the source. It should be noted that exposure to ambient air pollution is responsible, among other things, for the development and/or aggravation of respiratory and cardiovascular diseases. Pregnant women, infants and children under the age of five, people over the age of 65 and subjects with asthma, cardiovascular disease, heart failure or respiratory failure are particularly susceptible to the effects of air pollution. In addition, it is necessary to improve information for the general population, especially susceptible people, to enable them to adopt behaviours helping to reduce or limit daily exposure to off-peak levels of pollution in line with the recommendations of the Ministry of Solidarity and Health for pollution peaks[11].

Moreover, ANSES invites preventionists, including employers, to examine the issue of occupational exposure (for example, workers exposed to road traffic) to ambient air pollution and include it in their risk assessment approaches as part of the "single document" for the purpose of implementing suitable health risk prevention strategies. ANSES recommends the development of awareness-raising and prevention tools for employers to help them with this approach.

Lastly, more specifically regarding travellers and expatriates in certain regions of the world where levels of ambient air pollution are particularly high, ANSES advises the public authorities to provide people wishing to travel to or stay in these regions with clear and transparent information about the potential risks to their health. For example, the health recommendations for travellers laid down every year by the French High Council for Public Health (HCSP) could include a section on the potential health risks induced by exposure to particularly high pollution levels in certain regions of the world that have been identified by the World Health Organization (WHO). The existing sections

[11] Ministerial Order of 20 August 2014 on health recommendations to prevent the health effects of air pollution https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000029413664&categorieLien=id

of these recommendations on “Environmental risks” and “Personal precautions” could thus be usefully supplemented. Such information is currently available in part on the website of the Ministry of Foreign Affairs in an “Advice for travellers” section where advice is also available country by country. Efforts to align these various institutional channels of information should be considered.

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KEYWORDS

Qualité de l'air, pollution de l'air, air extérieur, particules, masques, demi-masques, équipement de protection respiratoire.

Air quality, air pollution, outdoor air, particles, mask, half mask, facemask, respirator, personal protective equipment.

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