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Technical Bulletin

October, 2021

Review on studies flagging non-compliant filtering facepiece respirators across the EU

Summary

The great demand for filtering facepiece respirators (also called FFP respirators), caused by the Covid-19 pandemic, has resulted in an increase in the number of manufacturers and a simplified procedure for the emergency authorization of products on the market. Evidence shows that this is causing several issues and may have an impact on the health and safety of users. Confirmation is provided by the number of cases identified under the European Rapid Alert system for dangerous products (RAPEX), concerning both formal objections and non-compliance with technical requirements. Numerous literature reports and independent studies carried out by external consumer organizations in various countries confirm that most of the 'earloop' respirators they assess do not meet the essential requirements. In particular, the negative results of the assessment concern the Total Inward Leakage (TIL), which is mandatory and should not be disregarded in the assessment of FFP by consumer or market surveillance bodies. This parameter confirms seal and facepiece fit which are essential for effective filtration, but it is assessed on a narrow group of users and does not reflect the actual fit for all types of faces. Conducting respiratory fit tests for each user, using commonly available fit testing methods, seem to be the best solution for protecting users.

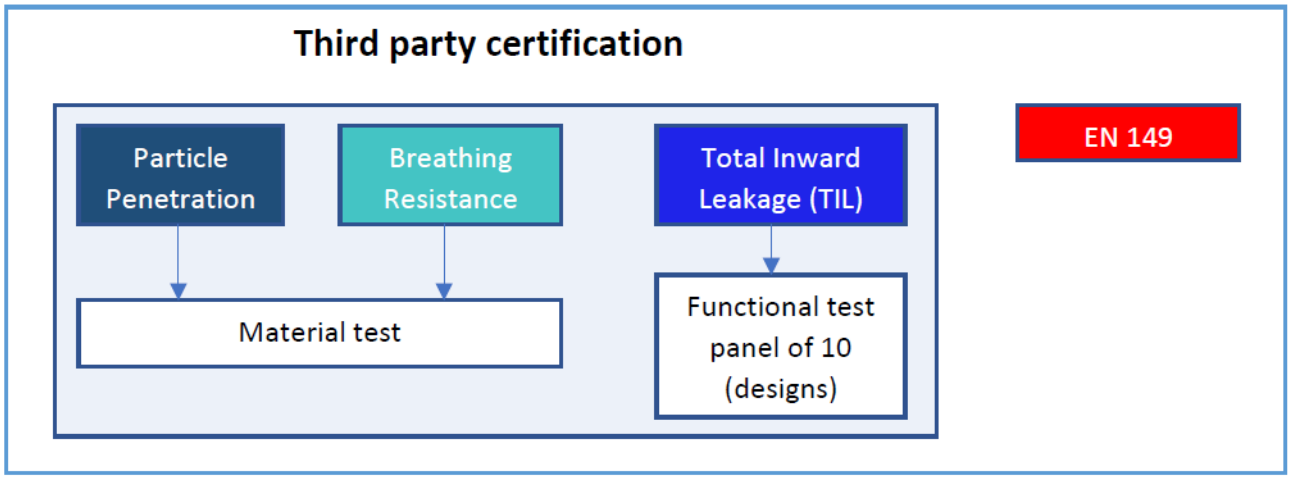
The purpose of the document is to draw attention to the worrying fact that there are respiratory protection on the market, which have obtained appropriate certificates but are not always able to provide sufficient protection for users.

Content

The effectiveness of respirators at risk

Today, the assumption of the quality and the safety of FFP respirators in the EU marketplace is at risk. Can wearers still trust that the filtering facepiece respirator, that they are using will give them the level of protection they expect or need? The Covid-19 pandemic triggered the emergence of new manufacturers of FFP. In order to reply to the shortage of Covid-19 countermeasures, European emergency authorization schemes have granted access for many new respirators to our Single Market. While not all new FFP on the market are a cause of concern, the shortage of respirators also triggered the emergence of suspicious safety certificates all across Europe. The European Anti-Fraud Office has opened an official inquiry into the illicit trade of countermeasures used for COVID-19 emergency, including respirators.

Every day, millions of workers are required to wear respirators for safety and health reasons. They might be working on a construction site or in a healthcare facility, for example. Respirators such as filtering facepieces have to meet high safety standards, to help protect wearers in a hazardous environment. To provide the right level of protection, FFP respirators need to fulfil the technical requirement described in the European Standard EN 149. The basic parameters are filtration efficiency and breathing resistance, which depend upon the technical properties of the filter media. Additionally, there is a third essential requirement; the capability of the respirator to fit the users' face, so that airborne contamination does not leak in through any small gaps. EN 149 addresses this by the "Total Inward Leakage Test" (TIL).



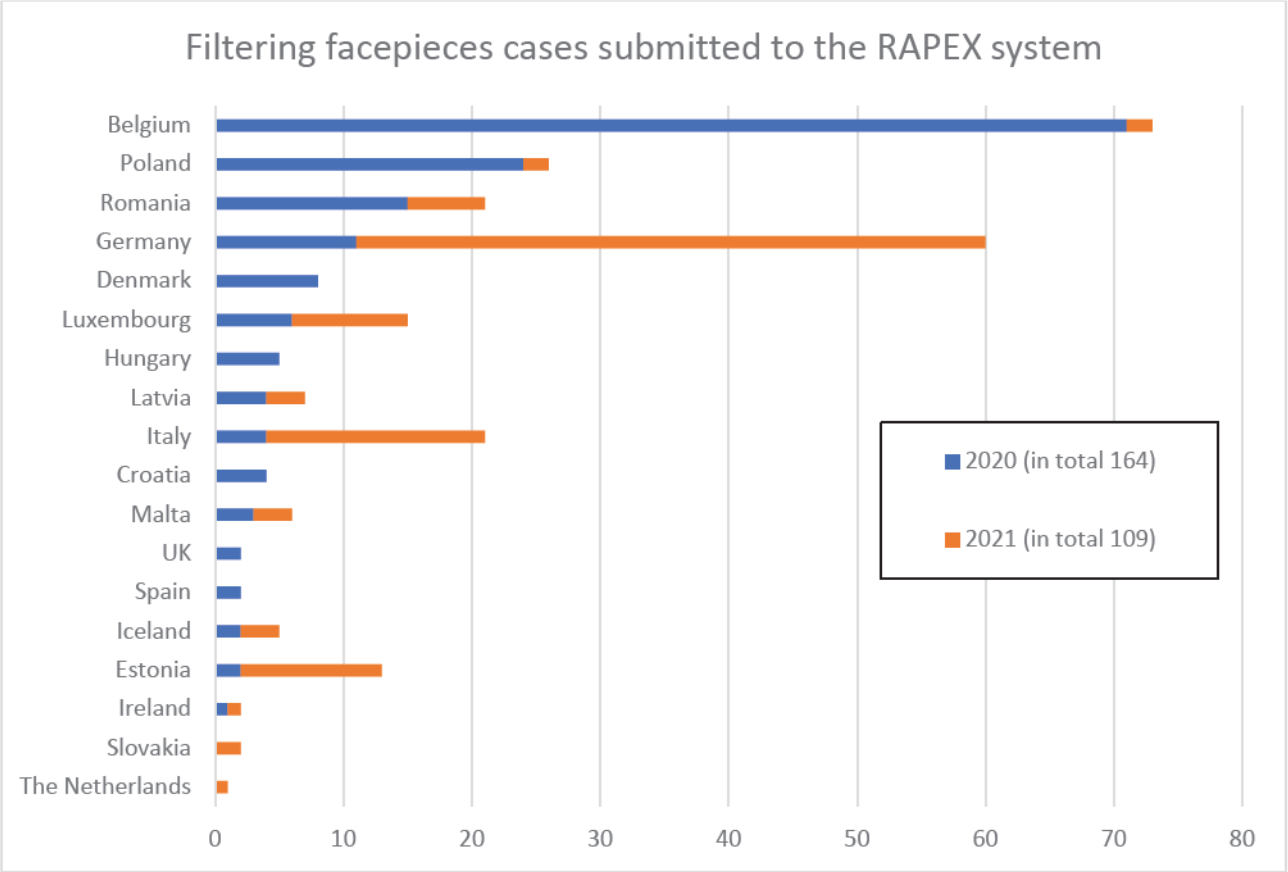
Reports and other studies flag non-compliant products

RAPEX Report

Complaints and associations' concerns have led national authorities to investigate the performance of FFP. The European Rapid Alert system for dangerous products (RAPEX) latest **report identified several cases of non-compliant FFP** due to formal errors (e.g., missing CE mark, third party not certified) as well as failing technical requirements. This activity has been reinforced by the last EU Recommendation 2021/1433 of 1 September 2021, to remind Member States that this is still an open issue.

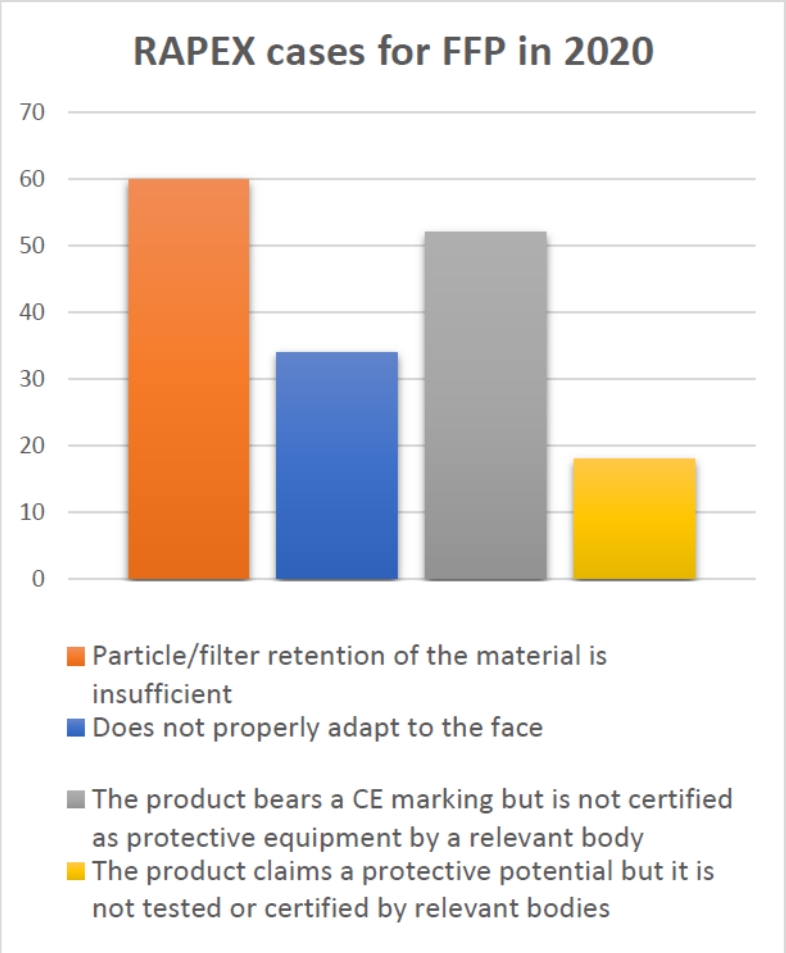
Below, the summary of the cases of errors and failures submitted by countries in the RAPEX system for FFP in 2020 and 2021[1] (2021 to end of August).

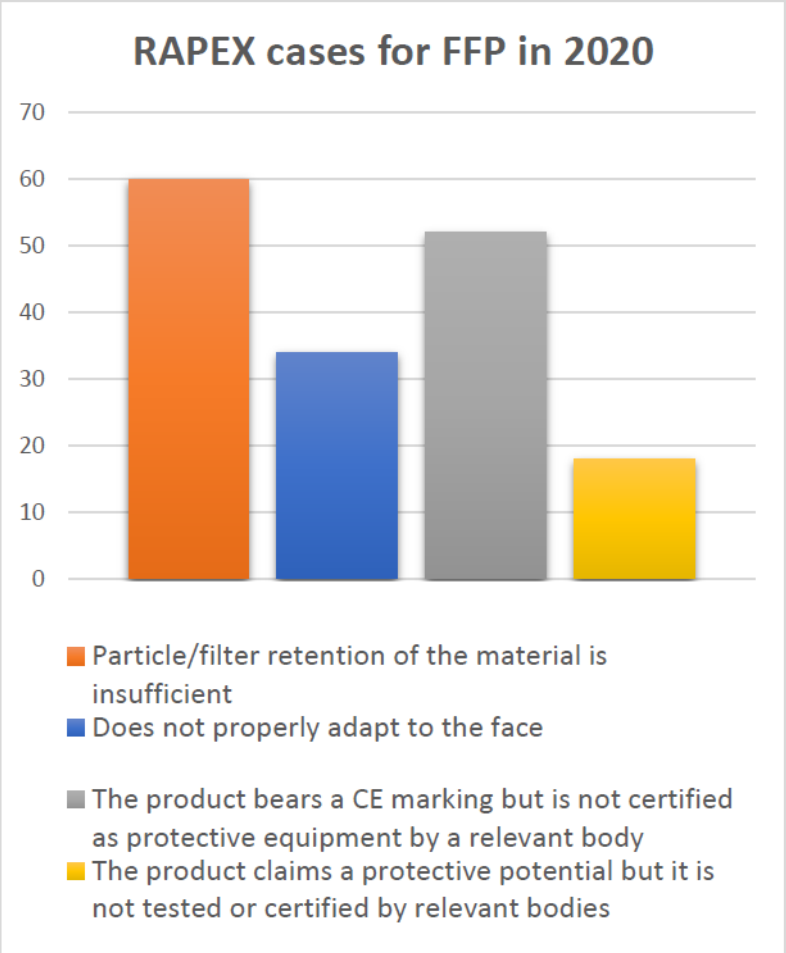
1. Safety Gate for dangerous non-food products (europa.eu)



Reported cases of non-compliant filtering Facepiece Respirators mainly concerned problems such as:

- Particle/filter retention of the material is insufficient.
- Does not properly adapt to the face.
- The product bears a CE mark but is not certified as personal protective equipment (PPE) by a relevant body.
- The product advertises a protective potential but has not been tested by the relevant body.


RAPEX cases for FFP in 2020
70
60
50
40
30
20
10
0
Particle/filter retention of the material is insufficient
Does not properly adapt to the face
The product bears a CE marking but is not certified as protective equipment by a relevant body
The product claims a protective potential but it is not tested or certified by relevant bodies



A total of **164 cases** of errors and failures were reported in RAPEX **in 2020**. As end of August **2021**, **109 cases** had been reported. Most of the cases reported are related to the poor performance of the material, inadequate to protect the users and / or missing certification for CE marked products.

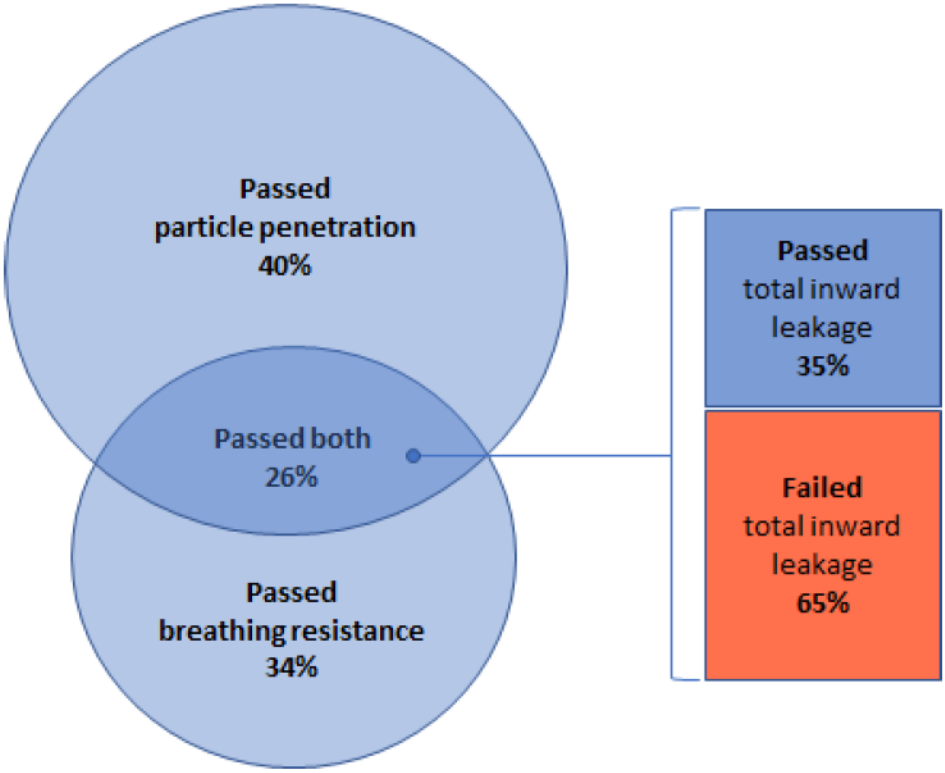
Stiftung Warentest and ZDF WISO test reports

On top of RAPEX analysis, other studies of FFP respirators carried out by the press and consumer organizations in Europe confirm that the technical requirements have not been met by several respirators already in the EU market.**Comparative FFP respirators' tests were performed and published by the independent German organizations Stiftung Warentest**[3] **and ZDF WISO**[4] (respectively in February/July 2021 and July 2021). The tests run by the two organisations on 32 respirators followed the general requirement of the European Standard EN149. They both found that not all the respirators provide the same level of protection, possibly allowing aerosol particles to get through the respirator.

3. FFP2-Masken im Test - Vier können wir rundum empfehlen - Stiftung Warentest
4. https://www.chip.de/news/FFP2-Masken-fallen-bei-ZDF-Test-duch-Das-muessen-Sie-jetzt-ueber-den-CE-Code-wissen_183599498 .html

Only 7 out of 32 FFP respirators passed all the test requirements to provide the stated level of protection for the wearer[3, 4]**.** It is important to note that the total inward leakage test, essential for measuring leakage of contaminants through the filter, was passed by only 35% of the respirators that met all other requirements.

Summary of test results for FFP2 respirators



Additional studies

Outside the RAPEX system, countries like France Spain and Austria[5] have run similar investigations and found similar failings. Another worrying result comes from an independent study requested by some companies (mostly from Italy) and performed in two accredited labs, one in China and one in Spain (published in March 2021). It found a similar picture of uncertainty of the level of protection. The study has been published by *Corriere della Sera*, the main newspaper in Italy and confirms that we have products on the market certified but not fully compliant to standard EN149:2001.[6]

5. Parlamentarische Materialien
6. Mascherine Ffp2 «non a norma»: ecco quali non hanno superato i test indipendenti- Corriere.it

Takeaways the studies on FFP respirators

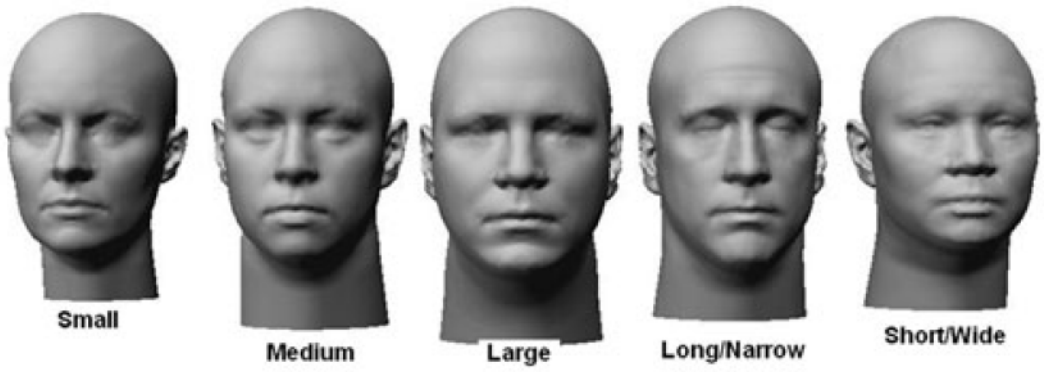
The importance of Total Inward Leakage and anthropometrics

Whilst the material performance of the respirator is key to provide filtering capacity and therefore protection to the users, this is not the complete picture. As revealed by the RAPEX analysis and the German and Italian reports, **the quality of the material is not enough to protect the wearer without a good seal and a good fit.**

When performing comparative tests on FFP, the **total inward leakage (TIL) test needs to be performed to confirm that the respirator is capable of forming a sufficient seal on the wearers face**. This parameter should not be neglected in the evaluation of respirators during market surveillance tests, and it is therefore required in the certification of FFP. In a Czech study, it can be observed that the TIL parameter for the FFP respirators was not evaluated in all case by market surveillance, which relied only on the efficiency of filtration and breathing resistance.[7]

Nevertheless, TIL test cannot stand alone to help protect wearers and ensure fit. Accredited laboratories test total inward leakage on a limited number of users. Faces can have difference sizes and shapes: the TIL assessment alone won't ensure the wearability and the fitting for all the workers. **A fit test on each worker is always necessary/best practice to help ensure protection on top of the TIL test.**

ISO Digital Head forms[8]



The difference in face sizes and the problem of fitting is noticeable especially since TIL tests can be carried out by accredited laboratories in locations outside Europe, when participants may have different anthropometric face shapes. This means, that in some cases a respirator, may have a positive TIL test results when it has only been tested on faces that are atypical of European faces. These test reports are accepted by some Notified Bodies, which may lead to the approval of respirators that may not provide a proper fit for users in the EU.

Facepiece seal difficulties and fit testing

Another issue noticeable in RAPEX cases and the German studies is the differences of safety performance between 'Earloop' respirators and 'Overhead' respirator. Proper seal of facepieces is associated with the construction of the respirator as well as with the type of strap. Earloop constructions often do not meet the requirements for the TIL test[2,3]. In the German studies, products with an overhead elastic tended to perform better in the TIL tests. **Overhead headbands helps to hold the respirator securely to the wearer face**, helping to enhance the seal, and improving fit.[9]

7. dTest: Test respirátorů 2021 - Nezávislé testy, víc než jen recenze
8. ISO - ISO/TS 16976-2:2015 - Respiratory protective devices — Human factors — Part 2: Anthropometrics
9. This statement is backed the abovementioned study of the German Stiftung Warentest. The results show that the headband mask was superior to the other masks, which had all earloops.

In UK, the national Health and Safety Executive has issued an alert on the quality of KN95 respirators[10] (most of them with earloops) for lack of compliance with European standards.[11] Currently the ear-loop-devices are not approved by the US National Institute for Occupational Safety & Health (NIOSH). Limited assessment of earloop designs indicates difficulty achieving a proper fit.

The study done in Italy reported a failures in breathing resistance and fitting, with similar to those found in the German study, resulting in similar conclusions with respect to the results. EN 149, and the total inward leakage test it defines, is designed to test if a FFP is capable of fitting a 'typical wearer'. Only fit testing an individual wearer on the make and model of respirator that they use will indicate of the respirator is capable of fitting that individual. Literature reports confirm the importance in anthropometric dimensions of the face of both sexes, which may affect the fit to the face and the effectiveness of the protection provided by the FFP.

In several countries, individual fit tests are mandatory for respiratory equipment, as meeting safety requirement is not based only on the TIL test. Due to the Covid-19 pandemic and the need to provide effective protection for healthcare personnel, the problem of respiratory fitting has gained additional importance. This is reflected in the current results of research published in scientific journals[12], drawing attention to the need to ensure appropriate fit for representatives of both sexes[13]. It should be stressed that good seal and fit applies not only to biological threats, it is essential in all types of hazards and sectors where FFP are used.

Conclusion: issues to be addressed by the market surveillance authorities and regulators

The outcome of the comparison studies confirmed that several FFP respirators tested have negative results for filtering efficiency and for the TIL test. Additionally, all respirators for which a negative result for TIL was obtained or for which no TIL test was performed due to failed filtering efficiency or breathing resistance were earloop design.

To conclude, the studies identified a series of issues that need to be addressed by the market surveillance authorities and regulators:

- Even CE marked respirators may not always fulfil safety requirements (i.e. filtering efficiency, breathing resistance, TIL)
- Fit test needs to become a common practice to help protect the workers and ensure the respirator wearability

10. Equivalent to the European FFP2 and the American N95, but they held to entirely different standards.
11. Use of face masks designated KN95 - Safety alert - HSE
12. A.Ascott et all. Respiratory personal protective equipment for healthcare workers: impact of sex differences on respirator fit test results. British Journal of Anaesthesia, 21 October 2020
13. E.O'Kelly et all. Comparing the fit of N95, KN95, surgical, and cloth face masks and assessing the accuracy of fit checking. PLOS ONE, 22 January 2021

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