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CLEANROOM TECHNOLOGIES SOCIETY OF TURKEY

INFLUENCE OF EXTERNAL BIOLOGICAL CONTAMINATION ON PARTICULATE BEHAVIOR

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ABSTRACT :

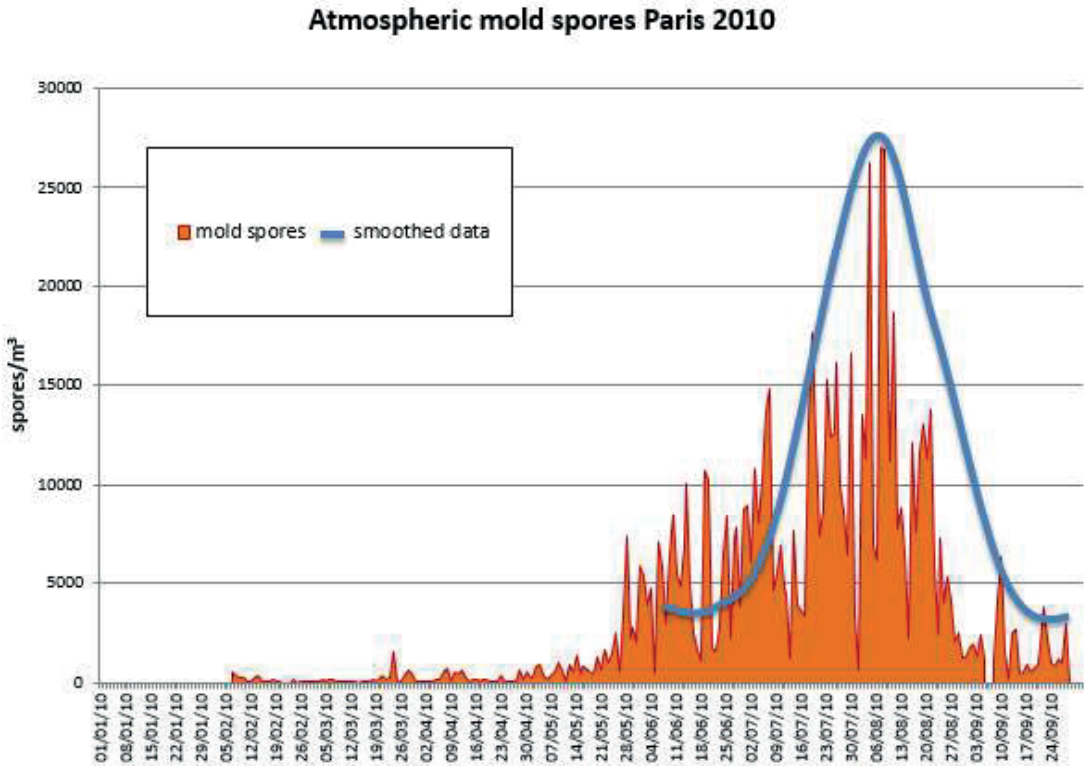
Seasonal Biocontamination is frequently observed both inside cleanrooms and in/on the product. When carrying out sampling of the cleanroom environment, it is necessary to also sample the outside environment. High levels of pollen and fungal spores outdoors in summer and autumn can correlate to detection of such contaminants inside the clean airlock and even inside the cleanroom, if appropriate non-cultural methods of detection are used for their detection, whereas classic culture methods are ineffective. Monitoring on a daily or weekly basis with appropriate method, it is easy to correlate outside levels of pollen and fungal spores with impact inside the installation, and identify the principal mode of transmission as the personnel, the devices, etc. This enables optimization of gowning and cleanroom cleaning practices to maintain effective control in response to the challenge.

1 INTRODUCTION:

Although the phenomenon is little known, particulate contamination of clean rooms has a seasonality in line with that of the plants surrounding the building. One study highlights the importance of continuous control measures, to be implemented taking into account this periodicity in order to maintain the effectiveness of the control of contamination intact.

It is very rare to hear about the relationship between outdoor weather conditions and the risks of contamination in clean rooms. Indeed, both the temperature, wind and precipitation conditions and the seasonality of vegetation play an important role in the concentration of external air in biological particles (spores, molds, pollen) (see Figure 1).

Figure 1: Example of air contamination in molds



Legend: The conditions of temperature, wind and precipitation, but also the seasonality of vegetation play a role in the concentration of external air in biological particles.

While clean room air handling systems are designed to meet requirements regardless of the concentrations of biological particles in the atmosphere, the entire process environment is affected by these contaminants. Normally the "personal" and "hardware" airlocks are designed to limit these transfers of contaminants, but often it is a statistical and not a total elimination. As a result, personnel entering the airlock

remain covered with biological particles, potential contaminants. The only setting up of protective clothing leaves a risk of suspending these particles in the air of the airlock and on the surfaces of stored articles.

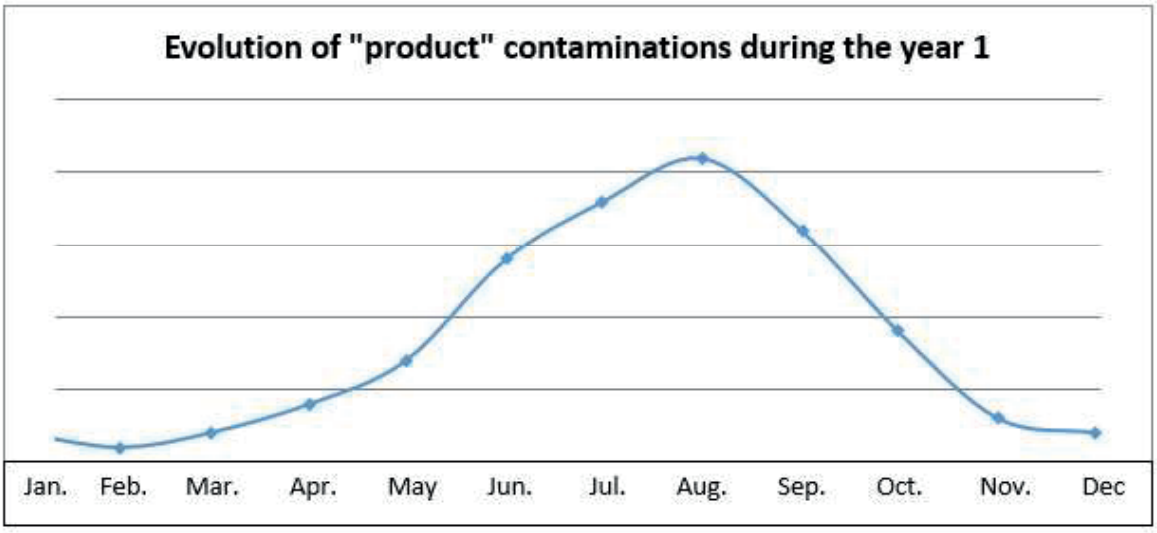
Similarly, in the "material" airlock, even advanced disinfections leave the possibility of transferring particles to the clean rooms. And the greater is the external concentration, the greater is the risk of transfer by staff and consumables, especially when the process requires a large staff and abundant consumables.

2 MATERIAL AND METHOD

Premises

An industry producing sterile, non-pharmaceutical products was facing a seasonal upsurge in product, control and environmental contamination, despite clean room work with appropriate entry procedures (see Figure 2).

Figure 2: Evolution of "product" contaminations in year 1



Legend: This seasonality of "product" contamination is perfectly superimposed on that of external air in biological particles.

A comparison of the contaminations observed by molds and the monitoring of the exterior of the premises follows a completely parallel curve (see Figure 1).

The most frequently encountered contaminants remained molds of various origins, moreover all these molds are not cultivable on standard culture media.

The production premises are a clean rooms comprising ISO 7 and ISO 8 zones and ISO 5 mini-environments. Access for the personnel is through a specific airlock with appropriate procedures. Consumables are introduced into the clean room through locks in which container envelopes are decontaminated manually or

disposed of. The productions are large series of products sensitive to mold and requiring the intervention in the clean room of several tens of people as a team.

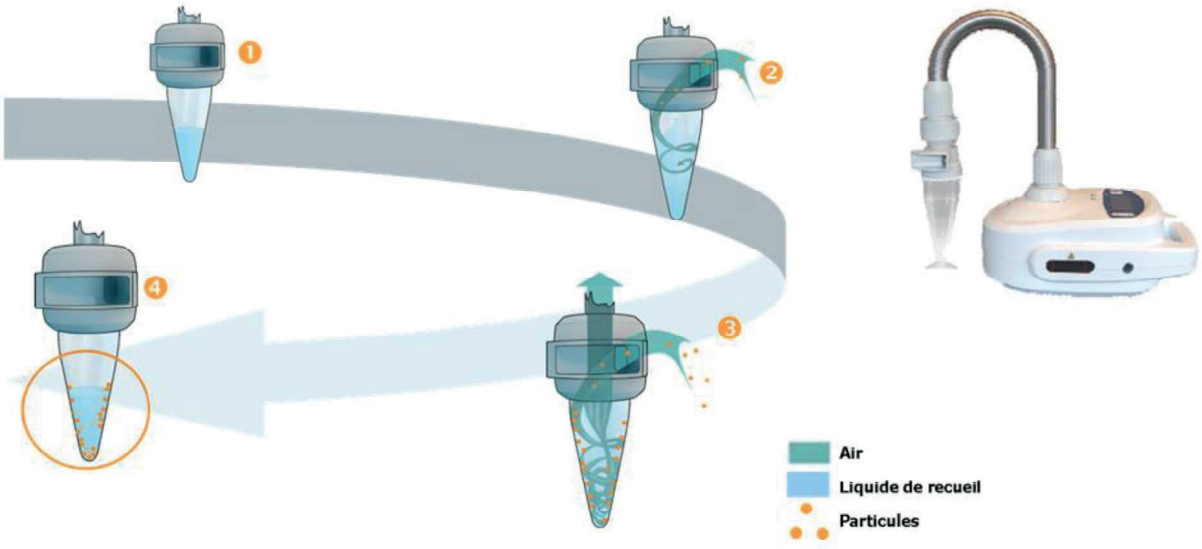
Monitoring

Traditional particle and microbiological (impaction) control procedures have never detected any relationship between external and internal contaminants and "product" contaminations.

Also it was decided to use a technique of sampling and analysis of viable or non-viable biological particles, cultivable and non-cultivable, with great sensitivity.

The chosen air sampler was the Coriolis, the operation of which allows the collection of airborne particles with a large air flow in a liquid sample (see Figure 3).

Figure 3: Operation of the sampler



Legend: The 300 L / min absorption rate of the Coriolis makes it possible to collect a large volume of air in a short time.

The high suction rate (up to 300 L / min) allows a large volume of air to be collected in a short time, which gives a better representation of the air quality, thus allowing a more accurate determination of contamination.

The recovery of biological particles in a liquid sample avoids the clogging of grids or filters and possible saturation of the collection medium, while offering the possibility of segmenting the sample for several analyzes.

The liquid sample obtained is compatible with traditional but also alternative analyzes: biomolecular, cytometry, microscopy, spectroscopy ... Response times are shorter than with conventional culture.

The use of alternative technologies makes it possible to quantify the total flora, without being limited to the cultivable flora, the results are therefore more representative of the microbiological content of the air. The analyzis are also more specific: PCR detection of specific microorganisms such as Legionella is not possible in conventional culture.

The analytical technique was developed within the laboratory of the National Aerobiological Surveillance Network (RNSA Laboratoire) and ANALYZAIR. It consists of a pre coloration of the biological particles in the liquid sample followed by filtration, deposition of the membrane on a microscopy slide, transparency of the membrane and fixation of the preparation.

The detection of biological (colored) particles is done using a light microscope, following the determination keys developed according to the morphological criteria of the particles observed.

These controls were carried out with samples of 3 m^3 of air inside the zones and 1.5 m^3 of air outdoor. The sampling frequency was established based on the results found in previous seasons, or during the period depending on the state of external contamination.

3 RESULTS

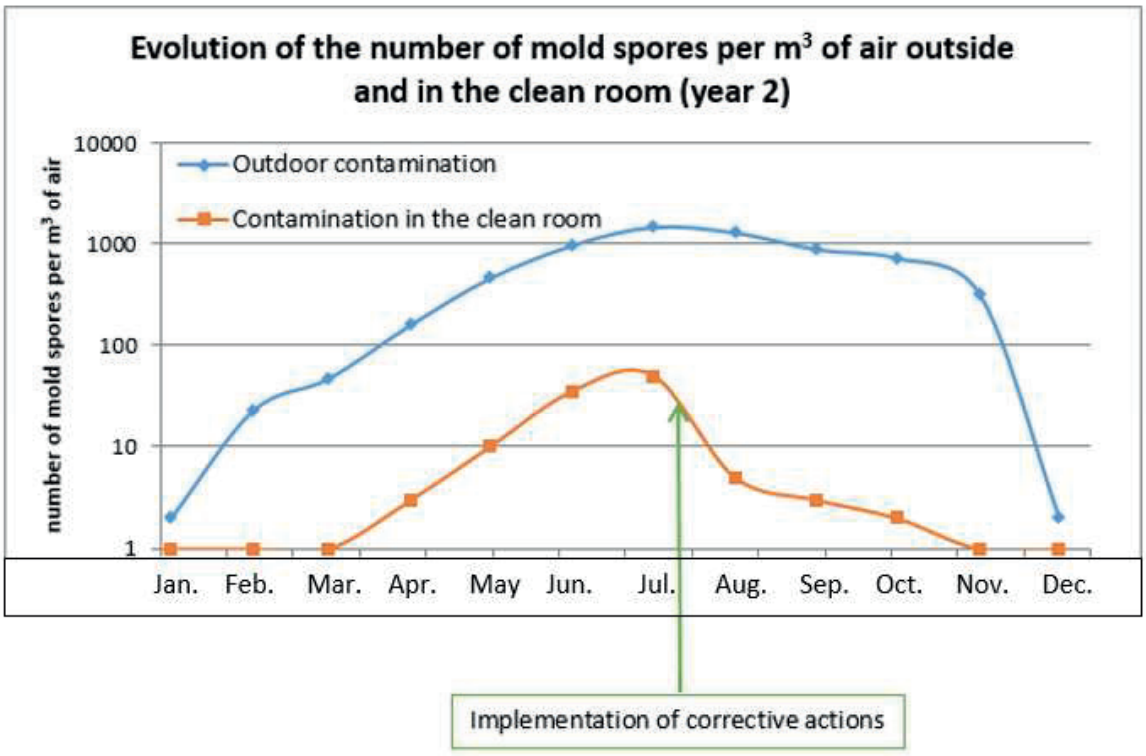
Indoor and outdoor monitoring conducted to determine the seasonality of contaminants in the first year (Figure 2).

In the course of these results, it was decided to set acceptability levels that we called "target level", "alert level" and "action level".

This visualization facilitated the implementation of corrective and preventive actions in case of high risk of contamination.

In year 2, it was decided to strengthen the monitoring and put in place more specific procedures as soon as atmospheric mold concentrations reached a certain level. All of these elements made it possible to obtain an extremely limited level of "product" contamination (see Figure 4).

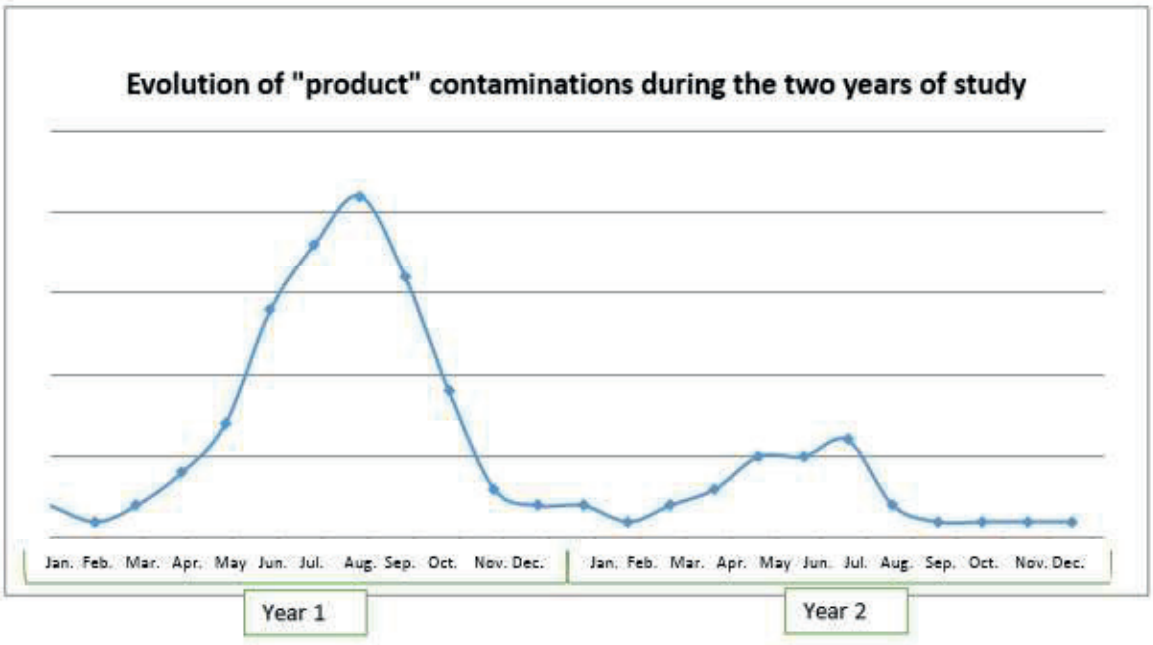
Figure 4: Evolution of "product" contaminations



Legend: In year 2, monitoring was strengthened and more specific procedures were put in place.

Over the two successive years, this level of contamination dropped sharply (see Figure 5).

Figure 5: Evolution of the number of mold spores outdoors and in the clean room



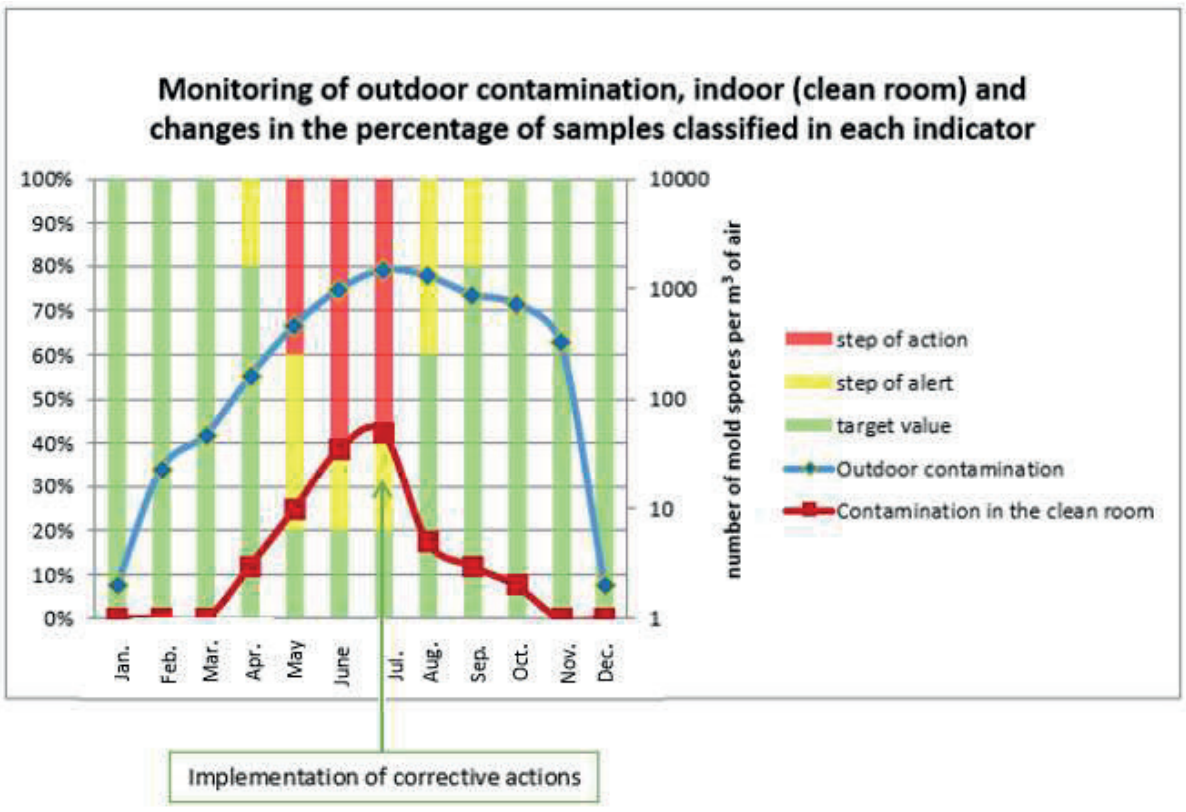
Legend: Over the two successive years, the level of concentration within the clean room has decreased.

4 DISCUSSION

Only reinforced monitoring actions and seasonally adapted procedures have significantly reduced the contamination levels of the products produced in this clean room workshop. The concept of red level, involving the implementation of these reinforcements, is only related to the monitoring of fungal biological particles from outside the premises.

The experience over two years has seen a significant decrease in contamination (see Figure 6).

Figure 6: External and internal contamination and evolution of the percentage of samples classified in each indicator



Legend: Only seasonal actions have significantly reduced contamination levels.

5 CONCLUSION

Whether in small production units, where airlocks are often not suitable for the removal of large quantities of contaminants, or in large units in which large quantities of consumables are used with large personnel number, the need to take into account external contamination is proven.

Continuous monitoring, with periods of monitoring more or less reinforced depending on the seasonality of contaminants, allows successful implementation of corrective and preventive measures.

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