The need for robust testing methods for validating anti-allergen and allergen removal claims

Perspectives from an allergen testing company

ROSS YARHAM
InBio, Cardiff, United Kingdom

Abstract

'Anti-allergen' or 'allergen removal' claims on cleaning & consumer products are gaining in popularity amongst companies looking to expand their markets and amongst consumers, as demand for effective management strategies increase, driven by the rise in prevalence & awareness of allergies. Along with the proliferation in product allergen claims comes the potential for their use without suitable testing to validate them. This presents numerous issues to consumers, trying to wade through the complex world of allergen exposure reduction to find the best products for themselves or loved ones; and for companies who strive to validate the performance of their products. This article explores some of the key considerations and importance of robust testing methods for allergen claims.

Keywords:

- Allergens
- Product claims
- Anti-allergen
- Allergen removal
- Allergen claim testing
- Product testing
- Allergen testing methods

INTRODUCTION

Allergies affect millions of people worldwide, triggering uncomfortable symptoms and potentially severe health complications.

It is estimated the average person in the western world spends up to 90% of their time indoors, and the indoor environment can be a major source of allergen exposure (1- 6). Common sources of these allergens include dust mites, with dust mite faeces containing most of the dust mite allergens; pets such as cats and dogs, although allergens can come from smaller pets like rabbits and guineapigs too; pests such as rodents and cockroaches; pollens from grasses, trees and weeds; and moulds and fungi such as Alternaria and Aspergillus.

Consumers often rely on cleaning products or appliances that claim to alleviate or remove allergens from their surroundings. With the proliferation of such claims, it is crucial to establish robust testing methods to validate these statements. By doing so, we can ensure consumer safety, enhance product transparency, and enable individuals to make informed decisions when selecting allergy-related products.

RISING CONCERNS AND AMBIGUOUS CLAIMS

For asthmatic and allergic individuals, it has been shown that allergen avoidance procedures in the home significantly improve the health of these individuals (7). Therefore, along with this growing prevalence and concern around allergies, the demand for 'anti-allergy' products has skyrocketed. This presents an excellent opportunity for cleaning and consumer product companies to cater to consumers' needs. But how are these claims validated, what methods were utilised, and what are the considerations that should be made when it comes to experimental design and testing parameters?

From air purifiers and vacuum cleaners, laundry detergents and cleaning sprays, to bedding, numerous products claim to reduce allergens and alleviate symptoms. However, the lack of standardized testing procedures and regulations allows room for misleading or unsubstantiated claims, potentially putting consumer health at risk. Given the range of such products and the relative paucity of consensus guidance, standards or regulations, this is where careful considerations of the product application context and simulated use design of testing methods becomes so important.

METHODOLOGICAL CONSIDERATIONS

An important consideration for all 'anti-allergen' product efficacy testing is the allergenic material that the product is to be tested on or against. At InBio, a range of allergens in different forms are utilised, including in a highly purified state in liquid suspension or in a naturally occurring form contained within a household dust matrix. The former are highly purified, single allergens of known concentration and are highly characterized, with protein identity and amino acid composition verified by mass spectrometry and amino acid analysis, and immune reactivity validated by IgG and IgE antibody binding. Generally speaking, purified allergens are mostly suitable for molecular diagnostic platforms, *in vitro* studies and structural analysis studies, although they can be used for bench top testing for cleaning products when the aim is to test the effect on specific allergens without the interactions of a natural matrix being present. The latter is characterised allergen spiked stock dust. This is prepared from normal household dust and spiked with sources of allergens found in their natural form such as pollen grains or spent house dust mite cultures.

Another advantage to the allergen spiked stock dust is that it can be customized to contain multiple different allergens within the same dust stock. Which allergens to use is an important decision to make and should take into consideration factors such as: which allergens are the

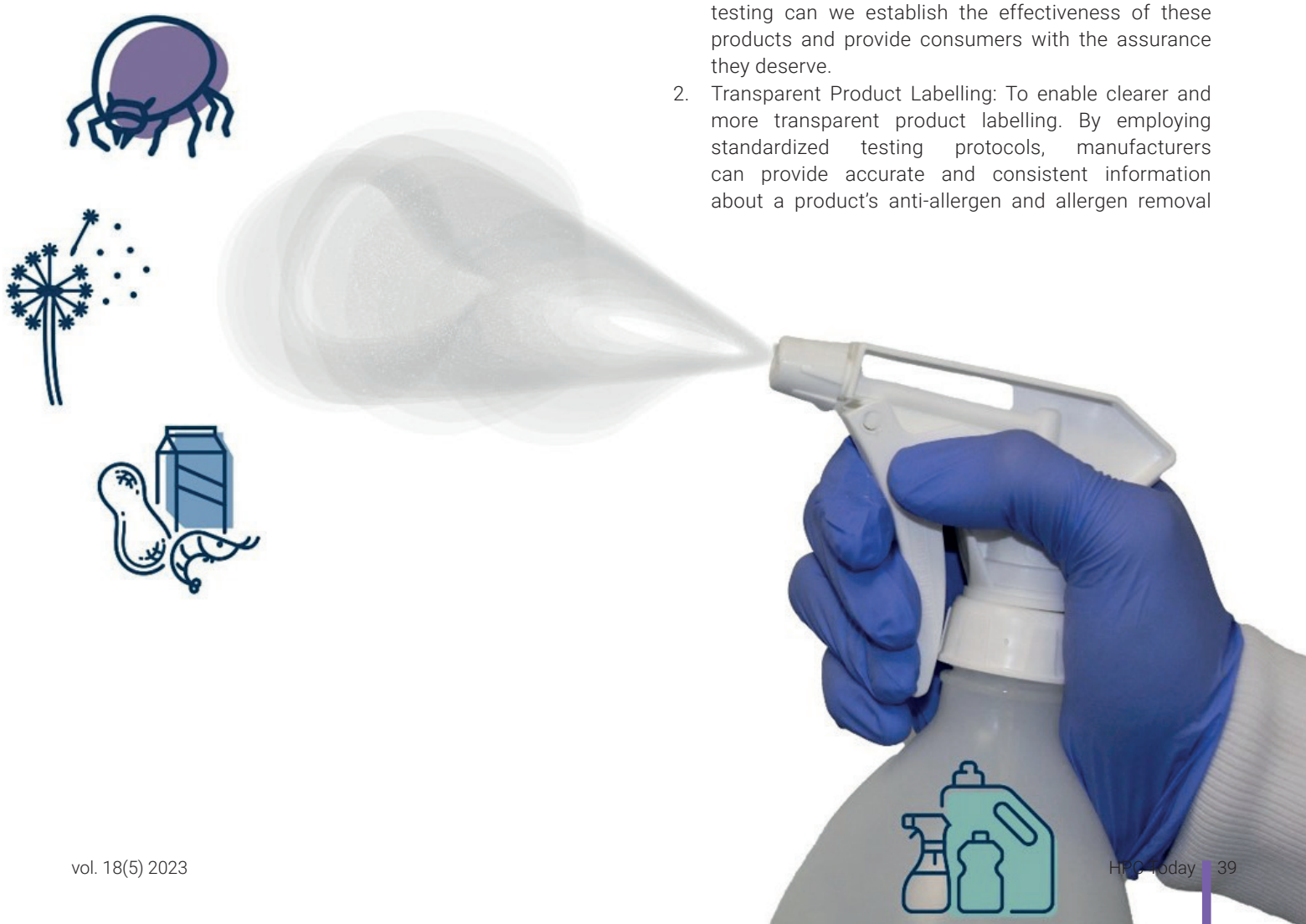
most clinically relevant; which are the most prevalent and easily measurable; which allergens will be stable in a dust matrix for reproducibility; and how easily those allergens can be recovered from test materials or surfaces. In addition to these considerations, not all allergens behave in the same way, therefore multiple allergens from different sources should be included in testing and/or tailored depending on the final product claim and region of sale i.e., geographically relevant pollen allergens.

Often at the outset of product testing, allergen removal may be compared with microbial removal. This thinking should be avoided as these do not necessarily go hand in hand. Allergens are proteins with many differing structures, functions and properties and are found in different forms within the dust matrix itself. Therefore, the approaches taken for testing the efficacy of allergen removal need to be designed in a way that takes these aspects into consideration. For efficacy assessment of cleaning products and appliances to remove allergens, a 'simulated use' approach to experimental design is preferential, which is where the product or appliance is used in a way to closely mimic how a consumer would use it. In these simulated use studies, a preferred method for allergen assessment is to utilise allergen spiked stock dust as it most closely resembles how consumers would be exposed to allergens in their own homes, and most accurately reflects how the allergen removal products or appliances are likely to work in indoor environments.

For example, if a cleaning spray product designed to remove allergens from surfaces inside the home was to be tested, the protocol should be designed to mimic not only the form that the allergens would be found in that environment but also to apply and use the product in a way that the end user would. Further considerations such as testing multiple different surface types should also be considered, as different surfaces may retain the allergens more than others. Alternatively, if an appliance such as an air purifier designed to remove aeroallergens was to be tested, the protocol needs to be designed in such a way that allergens in their natural form can be aerosolised in a reproducible manner and collected again following the use of the appliance as directed by the manufacturer. All these testing methods will require robust, reproducible controls to be run alongside them in order to confidently demonstrate the allergen removal claims being made.

THE IMPORTANCE & BENEFITS OF ROBUST ALLERGEN TESTING METHODS

1. Consumer Health benefits: Robust testing methods are essential for validating anti-allergen and allergen removal claims to ensure actual consumer health benefits. By subjecting products to rigorous testing, manufacturers can provide reliable evidence of their efficacy, helping consumers make informed decisions. This fosters trust between manufacturers and consumers, reducing the likelihood of individuals being exposed to subpar or ineffective products that may not reduce allergen exposure. Only through such thorough testing can we establish the effectiveness of these products and provide consumers with the assurance they deserve.
2. Transparent Product Labelling: To enable clearer and more transparent product labelling. By employing standardized testing protocols, manufacturers can provide accurate and consistent information about a product's anti-allergen and allergen removal



capabilities. This empowers consumers to make well-informed choices based on their specific allergies, sensitivities, and individual needs, ultimately with the aim of reducing the risk of adverse reactions.

3. Scientific Credibility: By employing reputable scientific practices, such as conducting controlled studies and independent testing, manufacturers can back their claims with empirical evidence. This not only boosts the reputation of the industry but also facilitates collaboration with testing companies, and potential recommendations for consumer use from allergists and other medical professionals, promoting a multidisciplinary approach to allergy management.
4. Building Trust and Accountability: Robust testing methods not only benefit consumers but also establish trust and accountability within the industry. Manufacturers that invest in comprehensive testing and validation demonstrate their commitment to providing safe and effective products. This builds trust among consumers, distinguishing reputable companies from those that make unsubstantiated claims solely for profit. Furthermore, it encourages transparency and accountability within the industry, fostering a culture of consumer protection.
5. Regulatory Compliance: With the relative lack of regulation or standards when it comes to allergen claim testing, development of robust in-house methods is an essential driver towards these more formal approaches. Governments and regulatory bodies could play a crucial role in ensuring the safety and efficacy of products. Currently, many authority positions and roles here are not clear. By implementing standardized testing protocols, which can draw on existing independent practices, authorities can enforce stricter guidelines, preventing misleading or false claims. This not only protects consumers but also fosters a competitive market where manufacturers must meet rigorous standards to enter and remain in the industry. However, it could be argued that complete standardisation may not be of benefit due to the varied nature of different products route of actions and so as not to stifle innovation, a more general approach to any standards or regulations (e.g. setting some general efficacy evidence requirements) may be more suitable. Currently there exists national and international accreditation bodies that provide 'seals of approval' to products. When they take into account all of the relevant factors above & discussed in this article, they can provide the framework and route for rigorous scientific testing through to consumer communication, acceptance and ultimately health benefits.
6. Continuous Improvement: By embracing robust testing methods, manufacturers are encouraged to invest in research and development to improve their products. Validating claims through rigorous testing facilitates innovation and drives the industry to develop more effective anti-allergen and allergen removal solutions. Testing can inform all parts of a product development cycle right from early ingredient formulations through to end product claim validation. As a result, consumers benefit from the availability of advanced, reliable, and genuinely helpful products that can improve their quality of life.

CONCLUSION

In a growing allergen focused cleaning and consumer product marker, the validation of anti-allergen and allergen removal claims made by consumer and cleaning products is of paramount importance. Robust testing methods are vital to ensure consumer safety, enhance product transparency, and promote a competitive market that delivers reliable and effective allergy-related solutions. Standardized testing protocols, coupled with better tailored regulations in the long-term, could help improve the situation but should not be too prescriptive as to stifle innovation and advancement in the industry, both from the cleaning/consumer product industry and testing industry perspectives. In the short-medium term, it is important to promote the use and importance of legitimate testing procedures to substantiate allergen claims to the cleaning and consumer product markets. Only by the implementation of such testing methods & related certification schemes, can we create a safer and more trustworthy marketplace for allergy-related products, ultimately improving the lives of millions affected by allergies.

REFERENCES AND NOTES:

1. World Health Organization. Combined or multiple exposure to health stressors in indoor built environments: an evidence-based review prepared for the WHO training workshop "Multiple environmental exposures and risks". 2014.
2. Klepeis N, et al. The National Human Activity Pattern Survey (NHAPS): a resource for assessing exposure to environmental pollutants. J Expo Sci Environ Epidemiol. 2001. 11:231–252.
3. Diffey BL. An overview analysis of the time people spend outdoors. British Journal of Dermatology. 2011; 164(4):848–854,
4. Salo PM, et al. Exposure to multiple indoor allergens in US homes and its relationship to asthma. J Allergy Clin Immunol. 2008; 121(3):678-684.
5. Hernández-Cadena L, et al. Indoor determinants of dustborne allergens in Mexican homes. Allergy Asthma Proc. 2015; 36(2):130-7.
6. Leaderer BP, et al. Dust mite, cockroach, cat, and dog allergen concentrations in homes of asthmatic children in the northeastern United States: impact of socioeconomic factors and population density. Environ Health Perspect. 2002; 110(4):419-25.
7. Le Cann P, et al. Home Environmental Interventions for the Prevention or Control of Allergic and Respiratory Diseases: What Really Works. J Allergy Clin Immunol Pract; 2017. 5(1):66-79.

ABOUT THE AUTHOR

***Ross Yarham**, Commercial Manager of InBio, is an experienced scientist and business professional with a strong background in the biotechnology industry & public sector. He's held technical and commercial roles at both project & programme manager level, including heading up a world leading food allergy research programme. Still active in the field of allergy research, he now works for InBio, a world leader in allergen detection and environmental exposure.*