BUSINESS PLAN

CEN/TC 347

METHODS FOR ANALYSIS OF ALLERGENS

EXECUTIVE SUMMARY

Business Environment

Based on the review carried by CEN/BT/WG 132, the task of CEN/TC 347 is to develop standards for analytical methods for determination of allergenic chemical in materials and products. Methods can be established for testing of any material on demand of the authorities. However, CEN/TC 347 focus on potential allergens in materials identified to cause health problems in the European community and limit the work program to those allergens that will be prioritized by the legislator.

The following materials and products are not considered by CEN/TC 347:

- allergens in food
- medicinal products
- medical devices
- natural latex proteins or other proteins

Benefits

Allergic reactions to substances, present in the accessible part of consumer products and materials, in both occupational and private life, are a significant and increasing health problem affecting large parts of the population in Europe. Several contact allergens, causing dermatitis, and some respiratory allergens, causing asthma and rhinitis, are chemical substances in materials and products. European and national authorities are trying to prevent the problem by regulation concerning limitations in use and by labelling.

Harmonized European analytical methods in the form of European standards represent a considerable improvement by increasing the possibility of allergy reduction. Such standards prove useful to support existing and future European legislation as well as for the industry in testing the raw materials and products using the same analytical methods that are used for compliance testing by the national authorities. Furthermore, such standards would also be useful in tendering procedures.

Priorities

Allergens in the following materials are currently considered: Metals, fragrances and colophony.

Plastic and rubber chemicals as well as preservatives will be considered as soon as priority will be given by the legislator.

1 BUSINESS ENVIRONMENT OF THE CEN/TC

1.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal, societal and/or international dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this CEN/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

Allergic reactions to substances in products and materials, in both occupational and private life, are a significant and increasing health problem affecting large parts of the population in Europe. Several contact allergens, causing dermatitis, and some respiratory allergens, causing asthma and rhinitis, are chemical substances in materials and products. European and national authorities try to prevent the problem by regulations concerning limitations in use and by labelling.

Common European analytical methods in the form of European standards represent a considerable improvement by increasing the possibility of allergy prevention. Such standards are also in tendering procedures. They prove useful to support existing and future European legislation with the aim of preventing allergies.

In the European Union and EFTA countries, the REACH Regulation 1907/2006 is the core legislation addressing the risks of chemical substances to the human health, including allergens. In addition, the Cosmetic Products Regulation 1223/2009 is defining the legal frame for the safety of cosmetics.

In particular, the Annex XVII of REACH is defining some limit values for the concentration or release of skin sensitizers in consumer products, amongst which nickel and hexavalent chromium. A more general restriction project to limit all skin sensitizing substances of category 1/1A/1B in textile and leather is currently under preparation at the EU level in the frame of REACH.

However, on the other hand, despite the known presence of allergens in rubber, no priority is given at the present time on this issue by the legislator.

In these REACH restrictions, the legislator is establishing expressly that the standards adopted by CEN shall be used as the test methods for demonstrating the conformity of articles to the REACH requirements.

With this respect, CEN standards are crucial to impose scientifically recognized test methods and thus provide legal certainty to enforcement authorities and economic operators.

Examples of significant reduction of the allergy problem by effective legislation are given. It is seldom stated how compliance with the requirements of legislation concerning allergens in products and materials shall be shown.

Allergens affecting skin and respiratory tract

Contact allergens

For more than 4900[1] chemical substances, patch tests are described to allow their diagnosis as contact allergens. They have a potential to induce cell-mediated allergy (delayed hypersensitivity) and allergic contact dermatitis after skin contact. A limited number of substances are responsible of sensitization in the majority of cases. Most contact allergens causing dermatitis are present in man-made products.

Some of the allergens are found in plants and other natural sources. It is described in the so-called EDEN[2][3] (European Dermato-Epidemiology Network) studies that 27 % of the adult population in Europe is sensitized to one or more contact allergens. Some occupations represent increased risks for sensitization to specific occupational allergens and to some common allergens.

[1] *https://www.patchtesting.info/book-fourth-edition.php*

[2] 201805 IJERPH (2018) 15 pg 1108-1146 Contact Allergy: A Review of Current Problems from a Clinical Perspective

[3] BJD 174-2 (2016) pg 319-329 Prevalence of contact allergy in the general population in different European regions

Respiratory allergens and other IgE-inducing allergens

More than 400 chemical substances have been implicated as allergens with a potential to induce IgE-mediated allergy (immediate type) and allergic asthma, rhinitis and also contact urticaria after exposure. The majority of allergens causing allergic asthma and rhinitis are proteins found in nature, such as pollen, fur-animals, mould, house dust mites and foods. Respiratory allergy due to chemicals, although numerically less in the general population than due to proteins, is important in some occupational settings. As to respiratory effects, some important sensitizing agents (isocyanates and acid anhydrides) act also through other mechanisms, which are not well understood.

Irritants

Irritant reactions are frequently caused by a number of exposures, single or repeated. Some of the most prominent skin irritants are defatting agents such as detergents, solvents (including water) and corrosive substances that may cause irritant contact dermatitis. Exposure to tobacco smoke, strong scents such as perfume and exposure to dust may cause hyperactivity reactions in the airways and make pre-existing asthma worse. These irritants are generally not allergens.

Some substances affect both the skin and the respiratory tract, but by different mechanisms. Typical examples are perfumes (fragrances) and formaldehyde that are contact allergens which may cause allergic contact dermatitis after skin contact, while inhalation of perfumes and formaldehyde may cause hyper-reactivity due to irritation of the respiratory tract.

In this sense, the standards are used to avoid technical barriers to trade.

1.2 Quantitative Indicators of the Business Environment

The following list of indicators describes the business environment in order to provide adequate information to support actions of the CEN /TC:

Allergic reactions to substances in products and materials, in both occupational and private life, are significant and causing increasing health problems.

Both the industry and the authorities have become more aware of the health problems linked to allergens. The trend within the industry is to minimize the use of harmful substances and to test the products before marketing.

Therefore, it is important to have European Standards for providing compliance with the legislation.

Stakeholders are the national authorities, the industries, the EU commission, scientific community, consumer and allergy organizations.

Cooperation with other CEN and ISO technical committees with related work items are established, so as to work effectively and to avoid duplication of work.

As the problems are linked to many different materials and industries, it is not possible to give specific indicators linked to the work.

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC

Allergic reactions to substances in products and materials, in both occupational and private life, are a significant and increasing health problem affecting large parts of the population in Europe. Several contact allergens, causing dermatitis, and some respiratory allergens, causing asthma and rhinitis, are chemical substances in materials and products. European and national authorities are trying to prevent the problem by regulation concerning limitations in use and by labelling.

Common European analytical methods in the form of European standards represent a considerable improvement by increasing the possibility of allergy prevention. Such standards prove useful to support existing and future European legislation with the aim of preventing allergy.

The European standards are also useful for the industry in testing the raw materials and products using the same analytical methods that are used for compliance testing by the national authorities. Furthermore, such standards are also useful in tendering procedures.

It is estimated that the cost involved by elaborating 1 European test method is less than the cost if national standards have to be elaborated. Therefore, it is decided to elaborate European standards so that all European countries can benefit by reducing the overall costs.

Not all European countries will have the possibility to develop national standards due to lack of resources and knowledge.

3 PARTICIPATION IN THE CEN/TC

All the CEN national members are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties. Participation as observers of recognized European or international organizations is also possible under certain conditions. Participants interested in taking part in these activities are requested to contact their respective national standards organization.

4 OBJECTIVES OF THE CEN/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN/TC

The objective is to develop standards within the scope of the committee.

If no new work item is proposed after the completion of the current program below, the committee will monitor its existing standards.

4.2 Identified strategies to achieve the CEN/TC.s defined objectives

Four working groups were initially established respectively for:

WG1: Metals

WG2: Preservatives

WG3: Plastic and rubber chemicals

WG4: Fragrances and colophony.

However, only two working groups were actually created and are currently active:

WG1: Metals

WG4: Fragrances and colophony

As it is closely linked to the European legislation, the strategy to achieve cooperation and support by the European Commission is the following:

Both working groups develop validated test methods as European Standard.

The objective is also to limit the number of standards to be developed by developing standards covering the area according to the above proposed structure.

If needed, other working groups will be created.

Other relevant CEN and ISO committees are informed and invited to participate in order to avoid duplication of work.

4.2.1 WG1 - Metals

The aim of CEN/TC 347 WG 1 is to develop analytical methods for the determination of allergenic metals which have been identified as causing health problems within the European community. These analytical methods can be used to support existing European legislation.

The work of WG 1 “Metals has concentrated upon the development of the European standards required to support the restrictions of nickel containing articles with direct and prolonged contact with the skin, according to annex XVII entry 27 of REACH.

As EN 12472 is also required for spectacles frames as well as for textile products, a liaison has been established with:

CEN/TC 170 “Ophtalmic optics” (due to CEN/TC 170/WG 8 “Nickel release testing of spectacle frames”

CEN/TC 248 “Textiles and textiles products”

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4.2.2 WG4 - Fragrances and colophony

The aim of CEN/TC 347/WG 4 is to develop analytical methods for the determination of allergenic chemical in materials and products. Methods can be established for testing of any material.

However, CEN/TC 347/WG 4 will focus on the identification and quantification of the volatile compounds suspected as allergens, which are present in the fragrance compounds and raw materials used in cosmetic products, and which are suspected to cause health problems in the European.

The work of WG 4 “Fragrance and Colophony” has concentrated upon the development of an analytical method by gas chromatography and mass spectrometry (GC-MS) on matrix samples which are “ready to be injected” and which are compatible with gas chromatography.

4.3 Environmental aspects

CEN/TC 347 will address environmental aspects in its standards when they arise. In particular it should be make reference to the **CEN Guide 4** "Guide for addressing environmental issues in product standards" which contains the environmental checklist. The latter is a useful tool to assess the environmental impacts of a field of activity related to a standard systematically. The CEN Guide for is amended that service and test standards are covered as well
The link to the CEN Environmental Helpdesk is:
https://www.cen.eu/about/helpdesks/environmental/Pages/default.aspx

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC WORK PROGRAMME

The current work items described above are foreseen to be finalized according the CEN/TC 347 work program.

Factors that could impact the work positively

- mandating the work by the European Commission;
- support by national authorities
- support from scientific experts within the respective fields
- support from the industry.

Factors that could impact the work negatively:

- lack of financial support by interested parties.