

The Product Restricted Substances List of ANFAO: an Example of Innovative Document for the Risk Governance and Safety Management of Eyewear

Marco Calvi, Giuseppe Da Cortà

Certottica S.c.r.l. – Italian Institute of Certification of Optical Products, Villanova Industrial Area, 32013 Longarone, Italy
marco.calvi@certottica.it

On 30 December 2006, the REACH regulation was published in the Official Journal and it came immediately into force in the EU member states plus Norway, Iceland and Liechtenstein, which adopt it. Compared to the past legislation on the subject, the novelty introduced is the reversal of the burden of proof, i.e. the industry will guarantee that its goods that produces and merchandises are not harmful for the environment and *human* health. Manufacturers, importers and users are obliged to manufacture, use or place on the market substances that do not cause harm to health or environment, regulating the substance throughout its life cycle, and even in products in which they are present. The regulation also establishes the European Chemistry Agency, whose mission is to secure the use and circulation of chemicals in Europe. This change in scenario has created serious troubles in the conformity assigning to products. In order to deal with this situation and to support members in the chemical safety assessment process, the *Associazione Nazionale Fabbricanti Articoli Ottici* (Italian National Association of Optical Goods Manufacturers), through its Technical Committee, in 2010 prepared a list of materials used by glasses, lenses and cases manufacturers matching substances and their risk level. Therefore an *ad hoc* Product Restricted Substance List has been developed to define specific Market Limits with their related test methods, that take into account the main international regulations. The document has been divided into two documents, one for spectacles and lenses, and one for cases.

1. Introduction

Chemicals are essential for our daily life and our economy, but they have to be managed safely in order to protect human health and the environment. For this reason and with the aim to monitor their circulation within the entire European Economic Area (EEA), which includes European member states, plus Iceland, Liechtenstein and Norway (Eurostat), on 30 December 2006, the REACH regulation (Registration, Evaluation, Authorization, and Restriction of Chemicals, EC No 1907/2006) (Schwirn et al, 2020; Bergkamp, 2013) was published in the Official Journal. Since it is a Regulation, it came immediately into force in the EEA members, becoming a standard for companies regardless of their position in the supply chain and the products they manufacture, import, export, supply or use.

Compared to the past legislation on the subject, the novelty introduced by REACH is the reversal of the burden of proof, i.e. the industry will guarantee that its goods that produces and merchandises are not harmful. Manufacturers, importers and users are obliged to manufacture, use or place on the market substances that do not cause harm to human health or environment, regulating the substance throughout its life cycle, and even in the final product. The regulation also establishes the European Chemistry Agency (ECHA) (Bertolin, 2023), whose mission is to secure the use and circulation of chemicals in European countries by promoting a safe and sustainable use of chemicals in order to protect and improve the quality of human life and environment. According to REACH, manufacturers, importers and downstream users must: be familiar with chemicals used in the various parts of the assembled article; verify the obligations of the substances contained in the article; be compliant with any requested restrictions or authorisations. The registration process is required for all chemicals manufactured or imported into the European borders, and it is expected to be a collaborative process among companies, which will generate a dossier containing data on physicochemical characteristics, as well as

toxicological and ecotoxicological properties (García-Fernández, 2020; Biedenkopf, 2020). This change in scenario, combined with globalisation, has created serious troubles in terms of assigning conformity to products. REACH has impacted on companies across many sectors. In order to deal with this situation and to support members in the chemical safety assessment process, the Italian Association of Optical Goods Manufacturers (ANFAO) through its Technical Committee, in 2010 listed materials used by spectacles, lenses and cases manufacturers matching substances and their risk level.

Eyewear is a very complex item, since it consists of several parts and materials assembled together (Tian and Bal, 2023), often made by different suppliers by means different production process; moreover, it is an object in direct and prolonged contact with the skin. Eyewear is part of the fashion world and the Italian industry plays a leading role in international trade.

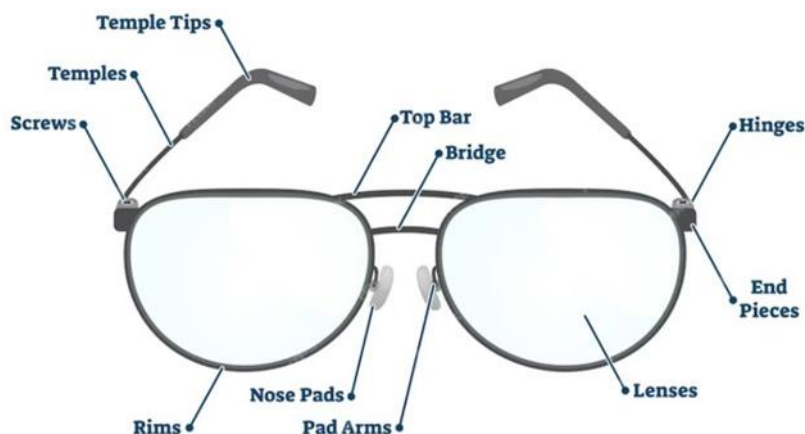


Figure 1: Picture that shows the complexity of a spectacle. In the picture, the main components are indicated.

Big brands, whose main business are textiles and leather goods, frequently apply limits concerning substances taken from other sectors, to the eyewear products. Hence, the licensees are requested to subscribe commitments that put them in a situation in which they must comply with limits that are not related to spectacles, lenses or cases. For these reasons, an ad hoc Product Restricted Substance List has been drafted by ANFAO to define specific Market Limits with their related test methods, that take into account the main international regulations, in order to: not to be forced to follow parameters and limits from other sectors; simplify the work of eyewear companies; simplify relationship with customers and suppliers; increase the safety of consumers and employees; define an ad hoc and a sector-specific document. The PRSL has been divided into two documents: one for spectacles and sunlenses and one for cases, and it is constantly updated and revised.

2. Materials and methods

In this PRSL are listed the Hazardous Chemicals to be monitored with reference to the materials in which there is a reasonable chance of finding them. This section summarises the employed procedures for the development of the Product Restricted Substance List (PRSL) of the Italian Association of Optical Goods Manufacturers. (ANFAO).

2.1 Procedure

In order to develop the PRSL, the first step has been the definition of the list of materials used in the eyewear sector, specifically for spectacles, lenses and cases materials. This was possible by means the realization of a survey with the companies registered in the Technical Committees of ANFAO (TCA). Then, the research on state-of-the-art on chemical formulation of the materials listed before, was carried out with the support of the eyewear companies involved. These companies also provided Technical Data Sheets (TDSs) and Material Safety Data Sheets (MSDSs) for the transmission of technical or safety-related information about substances and mixtures used in a specific material or product. Once defined the list of materials used in the eyewear sector (for spectacles, lenses and cases materials) and the related substances and mixtures, researchers collected the results of laboratory's analysis made by accredited labs on the selected materials, in order to evaluate the presence of substances of concerns.

For the definition of the Market Limits (MLs) of restricting substances of very high concern, related to the listed materials, an ad hoc study was conducted on the main international regulations for the chemicals to be taken

into account. In this case, the following regulations were identified: Europe: General Product Safety Directive (GPSD), REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals), Restriction of the use of certain Hazardous Substances (RoHS), AGECA, a French act of law against waste and for a circular economy; China: China national standards, also called as *Guobiao* Standards (GB); Turkey: Turkish regulation for produced and imported chemicals (KKDIK); USA: the Consumer Product Safety Commission (CPSC), The Consumer Product Safety Improvement Act (CPSIA), Proposition 65; South Korea: KC Certification; Saudi Arabia: Saudi Product Safety Programme (SALEEM). Furthermore, the restricted substances lists of the most important fashion retailers and brands were taken into account for the establishing of the limits of the ANFAO's PRSL. For each substance, a table has been created showing the MLs for each considered country or standard or regulation. Following, thanks to the scientific support of a dermatologist member of the scientific Board on Allergens of the Technical Committee of ANFAO, a medical investigation that associates skin reactions to the selected substances was performed. A thorough analytic report of data of the scientific literature relevant to single substances or group of chemicals potentially implied in the eyewear production cycle has been performed, based mostly upon PubMed and PubChem citations for biomedical literature from MEDLINE, and on the paper of Walsh et al. (2006), focused on materials and allergens within spectacle frames.

3. Results and Discussion

The Product Restricted Substance List (PRSL) has been developed by the Italian Association of Optical Goods Manufacturers (ANFAO) to establish specific limits of hazardous chemicals in eyewear sector in order to offer a reliable guideline for the product compliance to the main global regulation and the restricted substances lists of the most important fashion retailers and brands.

The researchers defined a double document, one for spectacles and sunlenses, and one for cases, and it is divided into four main sections. The first one is titled "General" and gives principles and definitions used within the document; The second one is titled "General safety requirements of chemicals" and it has been structured in tabular form, easy to understand. The table includes the materials used in eyewear sector for spectacle, lenses and glass cases manufacturing, grouped in categories identified by Key Codes for a rapid consultation on the "PRSL Match Table". In this section it is possible to define, once identified the material and the product use, a risk assessment for the hazardous chemicals in order to set all the control and monitoring activities along the supply chain. For this purpose, the steps to follow for the consultation are: I) identification of the material (Table of Materials), II) assignment of Risk Code (Risk Code and Match Table), III) evaluation of chemicals (Risk Code and Match Table), and IV) control/monitoring/testing. Due to similar features of some manufacturing material, some of them have been grouped in macro-categories, i.e.: for Spectacles - Metal alloys, Polymers (Plastics), Varnishes/Inks, Textile, Leather, Others; for Sunlenses - Polymers (Plastics), Primer for Hard Coatings, Functional coatings, In-Mass dyes, Tinting dyes, Various tinting method, Polarizing Wafer/Film, Auxiliaries, Vacuum Applications; Cases – Metals, Polymers (Plastics), Textile, Leather, Others.

The third section is titled "Restricted substances, limits and methods" and it lists the ANFAO requirements (limits) for the most important markets, test methods and various information for each restricted substance (Table 1 and Table 2). The Market Limit is based on the cautionary and restrictive requirements of the most important PRSL's of various luxury brands and non-governmental authorities. If the substance is not regulated, but has a "Market Limit", is considered as a part of a voluntary requirement. Materials are listed according to macro-categories: Metal Components, Plastic Components, Textile, Leather, Sunlenses. The same limits have been applied both for eyewear and cases. Within this section, data are reported that summarise: the CAS number (a numerical identifier that uniquely identifies a chemical) of the substance, the test method to be used based on international standards.

On Table 1 and Table 2, a comparison between the PRSL of ANFAO (ANFAO) and the PRSL of an International brand (Brand X) has been reported in order to highlight the differences. In the first one (ANFAO), the limits of the considered elements are reported based on ANFAO requirements (fixed by the Technical Committee) and international markets and they were defined just for the eyewear materials, while in the second one (Brand X), a list of limits are reported considering all the categories of products managed by the brand (Fashion, Leather Goods and Watches, etc.), without a focus on spectacles and sunlenses. This comparison provides valuable insights into the strengths of the PRSL of ANFAO, or rather a document has been developed *ad hoc* for a specific industrial sector which accounts of different regulatory frameworks on the basis of the materials and components of the eyewear sector.

Table 1: Restricted substances table for spectacles and sunlenses. In this case, the detail for “METAL COMPONENTS” (Heavy Metals, Total content) has been reported as an illustrative example in order to show the methods and limits of ANFAO and the comparison with limitations imposed by European Union and North American countries. The table shows the limits for three elements: Lead, Cadmium and Mercury.

ANFAO					
METAL COMPONENTS					
Heavy Metals (TOTAL CONTENT)					
CAS	SUBSTANCES	METHOD	ANFAO LIMIT (mg/kg) ppm	European Union	North American Countries
7439-92-1	Lead	CPSC-CHE1001-08.3	Adult <150	≤ 0.05% by weight	
			Child <100	≤ 500 ppm	
7440-43-9	Cadmium	CPSC-CH-E1001-08.3	Adult <100	≤ 0.01% by weight	Only children requirements
			Child <100	≤ 100 ppm	
7439-97-6	Mercury	CPSC-CH-E1001-08.3	<1	≤ 0.01% by weight	≤ 0.01% by weight

Table 2: Restricted substances table for spectacles and sunlenses. In this case, the detail for “METAL COMPONENTS” (Heavy Metals, Total content) has been reported as an illustrative example in order to compare ANFAO limits and those reported in a PRSL of an International brand (Brand X). The table shows the limits for three elements: Lead (Pb), Cadmium (Cd) and Mercury (Hg).

METAL COMPONENTS					
Heavy Metals (TOTAL CONTENT)					
SUBSTANCES	ANFAO LIMIT (mg/kg) ppm	European Union	North American Countries	Brand X	
Pb	Adult <150	≤ 0.05% by weight		Substrate: Strictest law: USA RTW and Fancy Jewelry (<200 ppm) All other product categories (<300ppm) However, for REACH: < 500 ppm for all categories Surface coating (only for US Market: <90 mg/kg)	
	Child <100	≤ 500 ppm		Substrate: Strictest law: USA <40 mg/kg Surface coating Strictest law: USA <40 mg/kg USA However, for REACH: < 500 ppm for all categories	
Cd	Adult <100	≤ 0.01% by weight	Only children requirements	substrate <100 mg/kg US REACH: <100 ppm (only for plastic polymers, copolymers and paints)	
	Child <100	≤ 100 ppm		<75 mg/kg	
Hg	<1	≤ 0.01% by weight	≤ 0.01% by weight	metal substrate <1000 mg/kg	<1 mg/kg

Furthermore, within the third section, there is a part that resume where there is a requirement for the substance based on the material/matrix considered, as reported in Table 3.

Table 3: An extract of the table of PRSL's ANFAO to resume where there is a requirement (geographical area, country) for a substance of the PRSL reporting, divided for each category of macro-material. The table reports the information for three elements: Lead (Pb), Cadmium (Cd) and Mercury (Hg).

Substance	Metals		Polymers			Inks	Textile			Leather			Lense
	Metal Components	Plastic Components	Rubber, PU	PVC	Varnishes	Textile	Coated Textile	Textiles Anti-Rain	Natural leather	Coated leather	Leather Anti-Rain	Lenses	
Key Code	CAS	MET	PLAS	RUB	PVC	PLAS	T&L	T&L	T&L	T&L	T&L	T&L	LENS
Pb	7439-92-1	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA
Cd	7440-43-9	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA	EU/US/CHINA
Hg	7439-97-6	EU	EU	EU	EU	EU	EU	EU	EU	EU	EU	EU	EU

In the section four are reported the regulated chemicals for the main countries. Substances, which are grouped in the following categories: Heavy Metals, Alkyl-Phenols & Alkyl-Phenols Ethoxylates (APs & APEOs), Azo Dyes, Allergenic & Carcinogenic Dyes, Bisphenols, Chlorinated Paraffins, Chlorinated Phenols and Ortho-Phenylphenols, Chlorinated Carriers (Chlorobenzene and Chlorotoluenes), Biocides & Preserving Agents, Formaldehyde, Nitrosamines, Organotin Compounds, Perfluorinated & Polyfluorinated Chemicals (PFCs), Phthalates, Polycyclic Aromatic Hydrocarbons, Quinoline, Solvent Residuals, UV Stabilizers, Volatile Organic Compounds (VOCs) and Chlorinated Solvents (CSs).

PRSL of ANFAO includes an annex titled "Annex 11 - Guidance for end-user risk analysis of contact dermatitis (irritative or allergic) with finished spectacle frames". The Annex 11 of PRSL has been designed in 2010, based on a project of the scientific board on allergens of ANFAO Technical Committee, in order to provide the eyewear manufacturers a straightforward tool to access medical information relevant their own production cycles. The information to provide are to be specifically related to potential irritative or allergic issues reported in the scientific literature, with single substances or group of chemical molecules contained in the eyeglasses frame in contact with the customer's skin at the very end of the production process. Gradually this process has been extended to the eyeglass's envelopes. The Annex 11 has been written and is reviewed on a yearly basis by a dermatologist, member of the scientific Board on Allergens of the Technical Committee of ANFAO, in the eyewear production cycle: moreover, the list of relevant substances is continuously integrated based on the inputs offered by the manufacturers, consistent with the development of their industrial processes. The document implements two parts: 1) a thorough analytic report of data of the scientific literature relevant to single substances or group of chemicals potentially implied in the eyewear production cycle, based upon PubMed and PubChem citations for biomedical literature from MEDLINE and the respective publisher websites; 2) a tailored "risk assessment tool" offering the eyewear manufacturers an analog scale of evaluation of the potential statistical risk of an irritative contact dermatitis and of allergic contact dermatitis, caused by a given substance or family of chemicals, based on codes H315 (causes skin irritation) and H317 (may cause an allergic skin reaction) respectively, as provided by ECHA.

In addition, the Annex 11 is a useful tool also for monitoring the post-market surveillance to assess any complaints or reports received from users, as defined by the European Medical Device Regulation 2017/745.

4. Conclusions

The *Associazione Nazionale Fabbricanti Articoli Ottici* (ANFAO), through its Technical Committee, has developed a list of materials used by frames, lenses and cases manufacturers matching substances and their risk level, to comply European and international regulations. Therefore an *ad hoc* Product Restricted Substance List (PRSL) has been drafted to establish specific Market Limits for each considered substance with its related test methods, that take into account the main international regulations and the restricted substances lists of the

most important fashion retailers and brands. So, eyewear companies are not forced to follow parameters and limits from other sectors, the relationship between customers and suppliers is simplified, potential dermatological problems are prevented, safety of consumers and employees of the whole eyewear sector will be increased. The PRSL of ANFAO has been divided into two documents, one for spectacles and lenses, and one for cases. The PRSL is annually revised in order to be compliant with the evolving international regulations and to be in line with irritative or allergic issues reported in the scientific literature. This innovative document is unique and can be used as an example for others industrial sectors.

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