

Review Article

Legislative and preventive measures related to contact dermatitis*

CAROLA LIDÉN

Occupational and Environmental Dermatology, Department of Medicine, Karolinska Institutet and Stockholm County Council, Stockholm, Sweden

Legislation can be a useful tool in the prevention of contact dermatitis. This is particularly true for dermatitis due to exposure to the many contact allergens that are chemical substances in products. A brief review is given of the most important European legislation – the EU Nickel Directive, the Cosmetics Directive, the Hazardous Substances Directive and the Hazardous Preparations Directive – and of some national regulations and standardization projects. It is concluded that it is essential that experts on contact dermatitis support, with their expert knowledge, national and European authorities.

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Recent years have seen increasing awareness – among physicians, scientists, legislators and industry and the general population – that it is possible to prevent many allergies and allergy-related diseases. Legislation can be an effective tool in the prevention of contact dermatitis. This is particularly true for many of the contact allergens that are chemical substances in various types of product. Examples of such legislation are given in Tables 1, 2. Occupational safety has a long tradition of setting different types of rule and limitation to prevent hazardous exposure, and some focus on hazardous skin exposure. Specific occupational hazards will not, however, be dealt with below.

The Nickel Directive

The Nickel Directive (1), aiming at primary and secondary prevention of nickel allergy, limits nickel in some types of product. A brief summary of the

3 points of the Nickel Directive is presented in Table 3. The Directive was adopted by the European Parliament and Council in 1994. All member

Table 1. European legislation relevant to the prevention of contact dermatitis (examples)

EU Directive	Ref.
Nickel Directive (94/27/EEC)	(1)
Cosmetics Directive (76/768/EEC), and amendments	(2)
Dangerous Substances Directive (67/548/EEC), and amendments	(3)
Dangerous Preparations Directive (88/379/EEC), and amendments	(4)

Table 2. National legislation aiming specifically at the prevention of contact dermatitis (examples)

Country	Area of concern	Ref.
Denmark	nickel in certain products (nickel release)	(5)
Sweden	nickel in ear-piercing materials (nickel content)	(6)
Sweden	chromate in cement	(7)
Finland	formaldehyde in clothes	(8)
Germany	wet work in workplaces	(9)

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Table 3. Brief summary of the EU Nickel Directive (1) and of the reference test methods for demonstrating compliance with the Directive

Point	Limitation	Reference test method (ref.)
1	posts (rings or other items) used during epithelialization after piercing shall not <i>contain</i> more than 0.05% nickel	nickel content by atomic absorption spectrometry (11)
2	objects intended to be used in direct and prolonged contact with the skin shall not <i>release</i> more than 0.5 μg nickel/cm ² /week; the Directive lists examples of such items, including jewellery, watches, buttons and zips	nickel release in artificial sweat (12)
3	items covered by point 2 shall fulfil the requirements for <i>2 years of normal use</i>	wear and corrosion procedure (13) and nickel release (12)

Table 4. European and international standardization projects and standards for the prevention of contact dermatitis (examples)

Standardization project	Published standard (ref.)
precious metals – applications in jewellery and associated products/health and safety aspects – with special reference to nickel allergy (CEN/TC 283/WG 4)	body-piercing post assemblies – reference test method for determination of nickel content by flame atomic absorption spectrometry, EN 1810 (11); reference test method for release of nickel from products intended to come into direct and prolonged contact with the skin, EN 1811 (12); method for the simulation of wear and corrosion for the detection of nickel release from coated items, EN 12472 (13); screening tests for nickel release from alloys and coatings in items that come into direct and prolonged contact with the skin, prEN 12471 (14);
non-active medical devices – medical gloves (CEN/TC 205/WG 3)	medical gloves for single use – requirements and testing for biological evaluation, EN 455–3 (15)
biological evaluation of medical devices – irritation, sensitization (ISO/TC 194/WG 8)	
horology – allergenic materials (ISO/TC 114/WG 2)	

states should have adapted their legislation to the Directive by January 2000, and there is then step-wise introduction. From July 2000 importers and manufacturers may not place on the market products that fail to comply with the Nickel Directive. From July 2001 such products cannot be sold or made available to the final consumer.

The Nickel Directive was put forward by EU DG III (the present DG Enterprise) due to national regulations in some countries (Table 2), and to work done by the Dermatology Society, and was also based on the attempts to develop relevant analytical methods for nickel in jewellery, etc. Denmark decided in 1989 on a limitation of nickel release from objects in contact with the skin (5), similar to point 2 of the Nickel Directive. Sweden decided in 1989 on a limitation of the nickel content in ear-piercing materials (6), close to point 1 of the Nickel Directive. In 1991 a European Standardization project on nickel allergy and relevant analytical methods, CEN/TC 283/WG 4, started within a precious metals jewellery project (Table 4) (10). The work has, from the start, been convened by Sweden, and it was later mandated by the EU to develop reference test methods for the planned Nickel Directive (16). 3 reference test methods have

been produced (11–13) – for nickel content, for nickel release, and for wear and corrosion. The screening test based on the use of dimethylglyoxime (DMG) has been developed further to increase its sensitivity and specificity (14). Thus initiatives at national level and in European standardization have proved to be an important path to European legislation.

A study was conducted of the Swedish market before the Nickel Directive came into force (17). 725 products on the market, items with metal parts that come into direct and prolonged contact with the skin, were tested with the simple screening test, using DMG and ammonia. Of the products, 25% were DMG-test-positive, which means that they will most likely not comply with the requirements of the Nickel Directive. 15 piercing posts were analysed for nickel content and 9 of them contained more than 0.05% nickel. Some also released nickel when tested with the DMG test. Non-nickel piercing posts were made of titanium, gold, niobium or plastic. This study provides a baseline, and it will be repeated within some years to estimate exposure changes due to the introduction of the Nickel Directive.

The nickel regulations in Sweden, Denmark and

Europe have already had some positive effects. The survey of the Swedish market (17) showed that some adaptation had been made to the requirements of the Nickel Directive's point 2 – nickel release from items in prolonged contact with the skin. Many of the major suppliers have included nickel in their quality control programme and they are trying to follow the forthcoming regulation. There has been limited control, however, of the nickel content in piercing materials and practically no adaptation of the market to what has been the requirement in Sweden for 10 years (6). Strong indications of a decrease in the sensitization rate to nickel among the youngest age groups in Denmark were reported in a study of dermatitis patients (18). In Europe, much lobbying was done by some areas of industry before the Nickel Directive was adopted and during the development of the analytical methods, and is still continuing now as the Directive is coming into force. Those parts of industry that have participated in the standardization work have, however, been very constructive (16).

The Cosmetics Directive

Contact dermatitis caused by cosmetics and hygiene products is widespread. Contact allergy to fragrances is increasing, and the pattern of allergy to preservatives is always changing. Several other cosmetic ingredients may also cause dermatitis due to contact allergy or skin irritation.

The Cosmetics Directive (2) with several amendments covers cosmetics and hygiene products, and parts of the Directive focus on the prevention of contact dermatitis. The Cosmetics Directive lists substances that are allowed (Annex I), not allowed (Annex II), or restricted (Annex III). A well-known example of a restriction due to risk of sensitization is methylchloroisothiazolinone/methylisothiazolinone (MCI/MI or Kathon[®] CG), which is not allowed above 15 ppm. The Cosmetics Directive requires full ingredient labelling (ingredient identification) according to the uniform INCI nomenclature. Fragrances, however, are not listed in detail but by the word "parfum". The listing of ingredients is helpful in many ways. The value of the information may however be limited by the fact that the phrase "may contain" is used to list colorants, e.g., in mascara and lipstick, which may not be present in the product but rather in similar products. The phrase may not be used for other types of ingredient. According to the Cosmetics Directive, there will probably be severe restrictions on testing ingredients in experiment animals in the future. As in vitro methods have so far proved of limited value for the prediction of sensitizing potential, the test animal will then be man.

The Scientific Committee for Cosmetic Products and Non-food Products intended for Consumers (SCCNFP), including a number of dermatology experts, has an important role in further development of the Cosmetics Directive. SCCNFP recently published a list of 36 perfumery materials suggested not to be allowed in cosmetic products. The work of SCCNFP can be followed on the Internet (<http://europa.eu.int/comm/food/fs/sc/sccp/index>).

The Directive on Dangerous Substances

Many chemical products are used in workplaces and in homes, while generally very little information concerning their ingredients is available to users or consumers. To limit hazards, the Directive on Dangerous Substances (3) and the Directive on Dangerous Preparations (4) require classification of dangerous substances and labelling of chemical products. Around 2,500 substances are listed in Annex I of the Dangerous Substances Directive. Of such substances, 360 are classified as skin sensitizers and 60 as respiratory allergens. The general concentration limit for classification as a skin sensitizer is 1%. Specific concentration limits have been set for more than 20 substances classified as skin sensitizers, e.g., formaldehyde 0.2%, glutaraldehyde 0.5%, acrylates 0.5–0.2%, and isocyanates 0.5–0.1%. The Commission working group on classification of dangerous substances recently agreed to the specific concentration limit for Kathon[®] CG (MCI/MI=3/1) being 15 ppm.

A chemical product containing a classified skin sensitizer at a concentration above 1%, or above a specific concentration limit, has to be labelled with the risk phrase "R 43 – May cause sensitization by skin contact" and a symbol (St. Andrew's cross). Other risk phrases in relation to skin exposure declare harmful (R 21), toxic (R 24/27), burning (R 34/35) and defatting (R 313) properties of substances. The labelling is a system of information for users, not a limitation of contents. Sensitization and elicitation of contact allergic reactions may, however, be the result of exposure to allergens in products far below the 1% level or the specific concentration levels. It would be useful if the names of all ingredients classified as sensitizers had to be printed on chemical products. Sensitive people would thus get an opportunity to avoid exposure to allergens. The ideal, however, would possibly be full ingredient identification as required by the Cosmetics Directive.

Industry sometimes makes great efforts to introduce changes in existing or proposed classifications. Recent examples are colophonium (rosin) and Kathon[®] CG. The colophonium-producing industry has tried to convince the Commission

working group that colophonium should not, as it is now, be classified as a skin sensitizer. The Kathon[®] CG-producing industry has endeavoured to have a higher classification limit than the recently agreed 15 ppm. A change in the use of Kathon[®] CG (MCI/MI=3:1) and its 2 ingredients has started, partly as a result of the classification and labelling system. Industry is now able to produce MI separately, while previously the 2 components were produced simultaneously. Industry is now introducing MI on the market – without MCI, together with MCI in different proportions, or in combination with other preservatives. MI is less potent than MCI as a skin sensitizer and as a biocide. Studies are in progress to establish the sensitizing potential of MI, and the results will provide an important basis for an adequate classification limit.

Some National Regulations

National regulations concerning contact allergens (Table 2) may sometimes support the development of European legislation, as shown by the Nickel Directive. Some other examples of national regulations should also be mentioned. Cement contains hexavalent chromium and the level varies in different parts of the world. By adding iron sulfate the level can be reduced significantly. For more than 10 years, Sweden and other Nordic countries have had legislation limiting hexavalent chromium in cement to below 2 ppm (7). Formaldehyde in clothes is limited in Finland (8). Other European countries refer to the limit, although it has not been introduced in their legislation. New German legislation limits exposure to wet work in workplaces (9), and Germany is trying to introduce limitations on some dyes in textiles. Para-phenylenediamine had not been allowed in hair dyes in Sweden for many years. When Sweden joined the EU, however, the ban on para-phenylenediamine in hair dyes had to be dropped, as para-phenylenediamine is allowed by the Cosmetics Directive. The many national regulations concerning occupational exposure to hazardous chemicals, some of which are contact allergens, are also important but not covered by the present review.

Standardization

The European Committee for Standardization (CEN) and the International Organization for Standardization (ISO) produce standards, which in some cases aim at the prevention of dermatitis. Standardization may support legislation, but standardization is not the same as legislation. A number of standardisation projects and standards are listed

in Table 4. Sweden is now preparing a proposal for a new CEN project on clinically relevant methods for analysis of allergens.

Participation by Contact Dermatitis Experts

Legislation has sometimes proved to be a powerful tool for the prevention of hazardous skin exposure and contact dermatitis. It is, however, necessary that experts on contact dermatitis – dermatologists, immunologists, toxicologists and chemists – participate in such work, on different levels. It is essential that well-designed scientific studies be performed and published as a solid and scientific basis for these forms of legislation and standardization. The major health problems have to be identified and relevant preventive measures suggested. Experts on contact dermatitis generally understand better than other specialists the role of skin sensitizers, skin exposure, bioavailability and skin absorption. National and European authorities should be provided with this expert knowledge.

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Address:

Carola Lidén
Department of Occupational and Environmental Dermatology
Norrbacka
SE-171 76 Stockholm
Sweden