



the REACh topic: A preliminary investigation among S.It.I. members

The Preventive Health Professions and their knowledge on

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ABSTRACT

Chemical risk is a debated topic in the services of the Italian Prevention Departments, as it is a matter that cuts across many settings. Through a survey jointly promoted by the Task Shifting Working Group and the Healthcare Professions Council of the Italian Society of Hygiene, Preventive Medicine, and Public Health (S.It.I), this study investigates the knowledge and the application level of the REACh issue and discusses the reference regulatory setting with a view to developing and enhancing the skills of healthcare workers who, within their professional activity, deal with this transversal topic daily.

Introduction

Environmental health officers (EHOs) working in the services of local health authorities for prevention, hygiene, and safety in the workplace are involved in the front line in the prevention of accidents and occupational diseases in all the sectors of work subject to controls. Among the issues that are inherent in this line of work, the prevention of chemical risk has taken on increasingly important connotations. In addition to the aforementioned professionals, occupational physicians, chemists, and health visitors (HVs) work synergistically, considering their respective professional profiles and skills, to promote preventive and protective measures while adhering to the topic under investigation [1-3].

REACh, an acronym for "Registration, Evaluation, Authorization, and Restriction of Chemicals", refers to a community regulation that came into force in the EU Member States on 1 June 2007; its primary objective is the improvement of the protection of human health and the environment from the risks that can be generated by the use of chemical substances. In recent years, numerous regulations have followed one another, and they have introduced changes in some articles and various annexes of the same act. This community regulation has been integrated into the sector of classification, labeling, and packaging (CLP) [4,5].

The REACh Regulation is part of a very broad regulatory context aimed at ensuring chemical safety in numerous settings. Chemical substances are used in many sectors, from industry to cosmetics, materials, and objects intended to come into contact with food, as well as everyday consumer products. One of the fundamental objectives of REACh is to ensure that the risks associated with the use of chemical substances are well understood by users and, consequently, managed effectively.

The general population, both as purchasers and consumers, has the right to know and, therefore, to be informed about the nature of the chemical substances with which they come into contact and to which we are, consequently, exposed. In fact, the European Commission recognizes all citizens' right to "access to information on the chemical substances to which they are exposed". Furthermore, it has been established that the information must be "presented in a way that allows anyone to understand the risks associated with use".

These rights are recognized by European and national regulations on chemical substances, particularly by the REACh Regulation, which provides for the

- Information obligations for manufacturers, importers, downstream users, and distributors;
- Communication obligations towards the consumer on substances present in articles;
- Obligations to communicate information along the supply chain;
- Access of workers to information on chemical

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- substances:
- Obligation to keep information on chemical substances at companies.

In many regional contexts, such as in the Apulia Region, the council approved the "Regional Plan of REACh and CLP Control Activities - Year 2024" relating to the general planning of REACh and CLP surveillance, information, and training activities under the responsibility of the local health authorities; this was drawn up according to the tabular format prepared by the Ministry of Health, which is the national competent authority in this matter.

MATERIALS AND METHODS

During the period April-June 2024, a survey with a brief introduction about its objectives was administered to EHOs using dedicated links accessible via the Google Forms platform. The link was sent to 135 EHOs and HVs who joined the 2023 National Congress of the Italian Society of Hygiene, Preventive Medicine, and Public Health (S.It.I.). This survey was promoted jointly by the Task Shifting Working Group and the S.It.I. Health Professions Council. A minimum sample size of at least 101 EHO- and HV-enrolled individuals was required to investigate the selected variables in the surveyed population. The sample was calculated using a sample size calculator based on the reference population of healthcare workers (HCWs) and assuming a response rate of 50%, a 95% confidence level, and a 5% margin of error. With the aim of investigating the awareness regarding the REACh issue among the HCWs joining S.It.I., the survey consisted of 8 questions, both multiple-choice and open-ended.

The survey investigated the following:

- 1. The interviewee's knowledge of REACh;
- 2. The region in which the interviewee works;
- 3. The operating unit in which the EHO carries out its institutional activity;
- 4. Any knowledge of the number of samples carried out in the previous year (2023) with respect

- to the REACh topic by the staff of the specific working groups of the local health authority in which the professional works;
- Any knowledge of the type of matrices sampled by the EHO and, in case of an affirmative answer, the type of matrix samples;
- Any knowledge of the analytical results (compliant or non-compliant) with respect to the limits defined by the REACh Regulation;
- Any knowledge of the safety data sheets examined in the previous year (2023) by the members of the REACh group, belonging to the prevention department;
- Any knowledge of specific projects in the local health authority where the interviewee works that include specific REACh investigations, asking to provide brief details in the case of an affirmative answer.

In the response form, to express informed consent, it was stated that the answers provided would be aggregated and would not be attributable to the interviewees, as they would be used exclusively as a proposal for the improvement of solutions for territorial operations.

The investigation was performed in accordance with the World Medical Association's Declaration of Helsinki and did not include any experiments involving human or biological samples, nor did it involve research on identifiable human data. The study protocol was approved by the S.It.I. Health Professions Council with the ID CPS_SItI_29032024.

RESULTS

Of 135 professionals enrolled, 103 responded to the survey and provided complete answers. This number allowed was adequate to make the sample representative. Figure 1 represents the regions in which the respondents carried out their work activity, while Figure 2 indicates the services to which they belonged.

Region of working activity

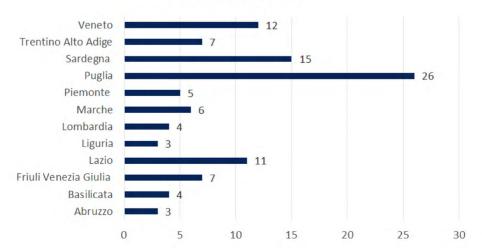


Figure 1. Region of working activity.

Prevention and Protection Service (outside the Prevention Department)

Prevention, Hygiene and Safety in the Workplace Service

Surveillance and Prophylaxis of Infectious Diseases

I am not working in the Prevention Department

Ministry of Health (outside the Prevention Department) Health Management (outside the Prevention Department)

Food Hygiene and Nutrition Service Hygiene and Public Health Service

Health Promotion Service

Screening Operations Center



Figure 2. Operating units in which respondents carry out their activity.

Services of the Prevention Department where the working activity is carried out

In all, 60 interviewees (58.25%) knew what REACh is. No statistically significant difference was found between knowledge of REACh and the distinction of responses from different Italian regions. Only 15 out of 103 respondents (14.56%) knew the number of matrix samples intended for the analysis required by REACh; the professionals who affirmatively answered carried out their activity in the Service for Prevention, Hygiene, and Safety in the Workplace and in the Hygiene and Public Health Service. These affirmative answers allowed us to delve deeper into the types of matrices sampled in 2023, and the following answers were obtained: e-cigarette liquid (3 out of 15), tattoo ink (4 out of 15), and cement (8 out of 15).

However, none of the respondents were aware of the laboratory results and, therefore, of whether or not the samples complied with the analysis. No positive answers to the question regarding the knowledge of the outcomes and details of the safety data sheet control emerged, nor were there any regarding targeted objective projects.

DISCUSSION

From the answers provided, it is clear that the technical details of the REACh topic are still largely unknown within prevention departments; in fact, none of the respondents were aware of the number of samples examined, the related results, or the checks carried out on safety data sheets. According to the analysis of these results, the need to promote the investigated topic as a priority arises, in addition to considering the potential impacts on the health of the population, creating specific groups coordinated by the Service for Prevention, Hygiene, and Safety in the Workplace and by the Hygiene and Public Health Services, preliminarily implementing specific training for operators, and consequently guaranteeing

improvements arranged by sectoral legislation.

The REACh Regulation requires member states to implement measures to ensure its application and establish an adequate system of controls on the safety of chemical substances. In the event of non-compliance with the obligations of the regulation, specific sanctions apply. At the European level, the regulation requires companies to identify and manage the risks associated with the chemical substances they produce and sell in member states; companies must, therefore, register substances with the European Chemicals Agency (ECHA) by providing detailed information on their properties, risks, and methods of use. The ECHA evaluates this information to establish whether the chemical substances pose risks to human health or the environment. Furthermore, Regulation (EC) No. 1907/2006 established the Forum for Exchange of Information on Enforcement coordinated by the ECHA. This is a network of authorities responsible for control activities that have, among other things, the following tasks:

- Disseminating best practices;
- Proposing, coordinating, and evaluating harmonized projects for control activities;
- Proposing and implementing training courses for inspectors;
- Coordinating the exchange of information between inspectors and developing working methods and tools for inspectors.

The forum, through the adoption of Reach-en-Force (REF) projects, annually establishes a work program that aims to ensure the complete, coordinated, and harmonized application of the REACh and CLP Regulations in each EU member state through the control system. REF projects are carried out by inspectors of the national authorities of each participating member state. With these projects, inspectors acquire a common and shared control methodology; the results of the controls are collected by each state and

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subsequently sent to the forum. On the basis of the information collected, a European report is drawn up, which is then made available to the public. The forum can also propose small-scale pilot projects in order to identify the best control methodology for specific provisions of the REACh and CLP Regulations.

Since 2011, our country has been participating in the harmonized control projects and pilot projects proposed by the ECHA forum. Verification of compliance with specific provisions addressed to a defined target of companies and to certain areas (such as the obligation to register substances, compliance with the limits set by the restrictions of substances in products, and verification of the quality and correctness of safety data sheets) is ensured at the national level and on an annual basis through the national control plans. In Italy, the control system is carried out in synergy among state administrations, regions, and autonomous provinces. The Agreement between the State, Regions, and Autonomous Provinces of 29 October 2009 established the national organization for control activities in the area of REACh and involves the Ministry of Health (General Directorate of Health Prevention), the Regions and Autonomous Provinces with the support of the Anti-Adulteration and Carabinieri Health Unit (NAS), the Customs and Monopolies Agency, and the Maritime, Air, and Border Health Offices (USMAF) [6].

The subsequent State, Regions, and Autonomous Provinces Agreement of 7 May 2015 then established that the regions and autonomous provinces, within their own organizations and legislation, identified the authorized laboratories for carrying out the analyses of samples taken during control activities [7]. The laboratories are identified on the basis of the indications coming from the national and regional control plans and operate according to a "network model" for the fulfillment of certain analytical needs thanks to the coordination of the National Center for Chemical Substances, Cosmetic Products, and Consumer Protection of the Italian National Institute of Health (CNSC-ISS).

The Italian Ministry of Health—DG Health Prevention, as the national competent authority for REACh and CLP, ensures the operation of a control system in order to verify the complete implementation of the requirements by all parties in the supply chain, from the manufacture/import of substances and their use to their placement on the market as such, in mixtures, or in articles.

The REACh Regulation also establishes that each member state of the European Union adopts the provisions relating to the sanctions to be applied in cases of violation of the obligations set out in the regulation. In Italy, the sanction system was established with Legislative Decree 14 September 2009 n. 133. Some of the violations of the obligations provided for by the decree concern the registration and notification of substances, the information to be

communicated in relation to the tonnage band, the chemical safety report and the risk reduction measures adopted, the sharing of data, the provisions aimed at reducing testing on vertebrate animals, and the information within the supply chain.

Every year, the Italian Ministry of Health drafts a national plan that reports the programming of control activities. The annual national plan is drawn up while taking the following aspects into account:

- Indications from the ECHA Forum and the European Commission;
- Indications from the results of control activities in previous years;
- Epidemiological knowledge and analysis of the territorial and environmental context based on the regional information system;
- The need to carry out joint inspection programs between two or more member states of the European Union;
- Indications from the poison control centers (CAV).

REACh inspectors, when carrying out territorial activities, carry out sampling on mixtures or articles to verify their compliance with the legislation using accredited laboratories. In Italy, the network is made up of the laboratories of the Regional Agencies for Environmental Protection (ARPA) and the laboratories of the ISS. In the event that the sample analysis reveals the presence of non-permitted chemical substances or substances in quantities exceeding the permitted limits, the authority that carried out the check activates the RAPEX System (Rapid Alert System for Dangerous Non-Food Products), a rapid alert system established by the European Union to report dangerous non-food products, including those containing chemical substances, that represent a risk to the health or safety of consumers. The system is managed by the European Commission, which coordinates the reports between the various member states by activating actions to withdraw and recall dangerous products, thus protecting the health and safety of the community, similarly to the Rapid Alert System for Food and Feed (RASFF) system.

REACh-CLP obligations, with particular reference to the related control activity, represent a mandatory obligation. Indeed, the Ministerial Decree of 12.01.2017 on the "Definition and updating of the essential levels of assistance referred to in art. 1, paragraph 7, of Legislative Decree 30.12.1992 n. 502" places the health protection services against risks for the population deriving from the use of chemical substances, mixtures, and articles among the Essential Assistance Levels (LEA) and, specifically, in the level "Collective prevention and public health"-Intervention Area B "Protection of health and safety of open and confined environments" [8]. The programs included in Intervention Area B and the related services are provided in an integrated manner between the health system and ARPA agencies in accordance with the regional regulatory indications and in com-

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pliance with art. 7 quinques of Legislative Decree no. 502/1992. The "New Guarantee System for monitoring health care" is referred to in the Decree of the Ministry of Health of 03.12.2019. Furthermore, Annex I relating to the indicators approved for monitoring the provision of LEA has included the indicator P08Z relating to "Safety of chemical products, controls during the production, import, placing on the market, use and distribution phases (REACh and CLP Regulations)" as further confirmation that this activity represents an essential obligation on the part of the local health authorities themselves.

With particular reference to the Veneto Region, in order to ensure compliance at the regional level with the requirements of the aforementioned regulations and the above-mentioned agreement at the Permanent Conference for Relations between the State, the Regions, and the Autonomous Provinces of Trento and Bolzano of 29.10.2009, with D.G.R. Veneto n. 523 of 02.03.2010, the Regional Council identified the "Competent Regional Authority for REACh" in the Regional Prevention Directorate, which is currently named the Prevention, Food Safety, and Veterinary Directorate. This also defines the territorial organizational structures to support the authority itself, as well as the institutional, functional, and organizational system, which is aimed at ensuring the implementation of Regulation (EC) n. 1907/2006 in the region [9]. Among these latter regional structures, in particular, following the establishment of Azienda Zero with Regional Law n. 19 of 25.10.2016, the U.O.C. Screening by Azienda Zero has been entrusted with the coordination, monitoring, and annual reporting of the control activities carried out by the local health authorities in the application of the RE-ACh and CLP Regulations.

Since 2011 the Prevention, Food Safety, and Veterinary Directorate, as the competent regional REACh authority in Veneto Region, transmits the national plan of control activities on chemical products for the current year to the prevention departments of the local health authorities after approval and simultaneously requests to propose the program of each health authority relating to the new REACh and CLP surveillance areas for the year in order to proceed with the regional planning of controls. On the basis of the programming proposals transmitted by the local health authorities, the assessments of the regional experts, and the PD-NEA users developed in the preparatory meetings at the regional level, the Prevention, Food Safety, and Veterinary Directorate draws up the "REACh Regional Control Plan", which also takes into account the emerging problems in the regional territory in terms of chemical safety. The regional plan contains a summary table of the number and type of controls to be carried out in the current year and provides that, in addition to the control activity indicated in the national plan, controls deriving from any further reports received by the competent regional Authority or from particular

situations emerging at the local level must be carried out in the regional territory.

From the examination of the topic discussed, it emerges that surveillance activity involves different types of controls in relation to the specific needs (also local) deriving from the production system and the complexity of the REACh and CLP regulations, which require, on the part of the competent institutional bodies, specific obligations to be respected. The performance of surveillance activity is guaranteed through the use of expert personnel from the local health authorities, who are usually in possession of the qualification of judicial police officer (UPG) and, following a defined training and education path, are identified by the Director of the Prevention Department as a "REACh Inspector". This person is assisted, with regard to the performance of laboratory analytical activities, by personnel from ARPA or other laboratories belonging to the National Network of Laboratories established and coordinated by the ISS.

Each Local Health Authority plans its own activity while taking into account the regional control plan and a parameter linked to the available resources in terms of the number of inspectors and related hours of work dedicated (equivalent operators). For each year, the local health authorities must report their activity to the superior regional body, which, once the annual activity report has been drawn up, sends this report to the regional prevention directorate (competent regional REACh authority) for subsequent forwarding to the nationally competent REACh authority, which, in turn, transmits the data flow to the ECHA.

For 2021, 19 authorities for REACh and CLP controls of the regions and public administrations reported 3320 product controls carried out on 1031 companies. In detail, 2671 were documentary product controls and 649 were analytical product controls that were carried out using the potential of the laboratory network. Among these, following the agreement between the Ministry of Health and ADM regarding border control cooperation, 51 documentary product controls and 77 analytical product controls were finalized. The scheduled-type product controls (documentary and analytical) were 3133 in total. The reactive-type product controls (documentary and analytical) were 187 in total. In addition to these data, 14 analytical controls were carried out by seven USMAFs on 14 imported articles [10].

To the best of our knowledge, this is the first pilot study to assess the knowledge of the REACh issue among the members of an Italian scientific society. However, this investigation has some limitations. Although the survey was extended to a national level, a small number of respondents emerged; furthermore, there was potential for self-selection bias related to the responses received only from S.It.I. members who deal with chemical risk in their daily professional activity.

CONCLUSIONS

REACh is a significant step forward in the regulation of chemicals at a global level. Through an approach based on industry responsibility and transparency, this regulation aims to create a balance between the protection of human health, the environment, and the competitiveness of the chemical industry in Europe.

Soon, HCWs in the prevention area, particularly hygienists, occupational physicians, EHOs, and HVs, will have to continue to interact synergistically through their specific skills to broaden the scope of the investigation and to promote the numerous activities underlying REACh, in addition to the execution of sampling envisaged in specific plans. In particular, EHOs, considered the suitable professionals in the matter investigated, assume a significant role,

in compliance with the specific professional profile established by the Italian Ministerial Decree n. 58/1997 [11].

In the near future, it will be necessary to promote a raise awareness, especially among HCWs not directly involved in the REACh field. Communication, both internal and external, together with targeted on-site training for all prevention actors, will be able to favorably support the dissemination of knowledge which, as highlighted, appears to have ample room for improvement.

The safety of our future in the use of these substances depends, above all, on greater sensitivity among all actors involved in this field, who must contribute to spreading the culture of REACh towards the areas delegated to supervision while continuing to act to ensure adequate levels of prevention and protection.

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