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The Italian Information System on Occupational Exposure to Carcinogens (SIREP): Structure, Contents and Future Perspectives

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Objectives: The Italian information system for recording occupational exposures to carcinogens (SIREP) was set up in 1996 as a result of the implementation of European directives concerning the improvement of workplace safety and health. The aim of this study is to describe the characteristics of this information system designed and developed for monitoring exposure risk at workplace. The main results about exposed workers in Italy are also presented. Moreover, we discuss the choices adopted when setting up the structure and the issues encountered in recording data and introduce future developments of the system.

Methods: The design of the information system made use of the structured analysis technique, and it is based on a relational database. Particular attention has been addressed to the system security to prevent non-authorized accesses and to guarantee data integrity. The core information of the database is in accordance with recommendations of the European work group on the measurements of the exposures in the workplace. Results are reported by economic sector, carcinogenic agent, job task and exposure level.

Results: The professional exposures of ~36 547 employees from 2778 firms were reported to the SIREP database in the period 1996–2005. The three prevalent exposures—hardwood dust, benzene and polycyclic aromatic hydrocarbons—account for >25% of the exposed workers. The main economic activity involved is wood industry and furniture manufacture, while the most frequently observed job is chemical-processing plant operator of petrochemical plants. At the end of 2005, >100 000 different exposure histories were recorded and the number of exposed workers accounts for ~0.2% of the Italian workforce.

Conclusions: The SIREP database has been set up in order to assess, control and reduce the carcinogen risk in the workplace. It may be useful as part of a surveillance and monitoring system to determine the need for intervention strategies and to assess their effectiveness.

Keywords: exposure assessment; occupational database; surveillance system

INTRODUCTION

It is a matter of primary importance to record occupational exposure to carcinogenic substances in developing surveillance systems of risk factors in the workplace (LaMontagne *et al.*, 2002). Integrating surveillance systems with exposure databases makes it possible to improve workplace health and safety. The Italian Institute for Occupational Safety and Prevention (ISPESL) has instituted in 1996, as a result of the Italian Legislative Decree n. 626 of 19 September 1994 and subsequent integrations, an information system for recording the professional exposures to carcinogens, named SIREP, with the aim to promote prevention programmes at the workplace level finalized to eliminate or reduce the number of exposed workers and to decrease the exposure levels to hazard agents. The SIREP database is based on company notifications of the exposed workers and includes quantitative measurements of exposure to airborne carcinogens.

The Italian information system is established in an international framework in which other specific

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databases already exist, e.g. the Finnish Register of Occupational Exposure to Carcinogens (ASA Register: Finnish abbreviation; Kauppinen, 2001). Moreover a lot of databases regarding the exposure to hazardous substances have been set up, such as the ones created in France, Germany and England. In a specific instance, the databank COLCHIC (Occupational Exposure to Chemical Agents Database; Raymond and Jeandel, 2001), instituted in France in 1987, is based on 27 000 surveys in 14 000 different facilities and, up to 1997, counts >400 000 exposure measurements involving 600 chemical agents. The MEGA archive—Chemical Workplace Exposure Database (Stamm, 2001)—is operative since 1972 in Germany and has recorded more than one million data (~31 000 measurements carried out from 4000 companies, up to 1999). In the UK, it is active in the Health and Safety Executive, the National Exposure Database (Burns and Beaumont, 1989), that contains, up to 2000, 100 000 exposure measures covering ~400 different substances. A similar situation exists in the US where the National Occupational Exposure Survey (Seta *et al.*, 1988), carried out by the National Institute for Occupational Safety and Health in the period 1981–1983, provides information on occupational exposures to chemical agents.

Thus, the ISPESL's database becomes part of this scenario by providing the registration of the records related to worker's risk exposure and the possibility to compare, in the future, these data with the information held by other disease-based recording systems, e.g. population-based cancer registers (Kauppinen *et al.*, 2003), mortality archives or hospital discharge forms.

OBJECTIVE

The aim of this study is to illustrate the characteristics of the information system SIREP and the choices that have been adopted for a flexible and integrated management of the acquired data. In particular, it describes the methodology applied in the development of the database structure and the procedures used in order to collect and store the data. The main results about exposed workers in Italy are also presented. Moreover, it discusses issues encountered in recording the data and introduces future developments of the system.

METHODS

Based on a client/server architecture and on a relational database (Atzeni and De Antonellis, 1993) realized in Oracle (ver. 10), the information system SIREP is optimized to collect data about the exposure information notified by companies to ISPESL according to the Italian Legislative Decree n. 626/94. This notification constitutes what we call a company register on exposed workers. Employers are required to report the carcinogens used, data on exposed employees and the exposure levels. These data are collected by employers and regularly sent (every 3 years) to the ISPESL. The companies are responsible for carrying out the necessary analysis and measurements to be sure that they are in compliance with the legislation and rules for work environment. The norm to which companies have to refer for sampling strategies is EN 689:1995 of the European Committee on Standardization (1995) that provides standards and recommendations for exposure measurements in the workplace.

The planning of the database has taken advantage of the structured analysis technique (Yourdon, 1989) in order to obtain a conceptual and organic representation of the elements, procedures and flows that interact with the system. Particular attention has been addressed to system security with regard to the three fundamental properties of Information Technology security: data availability has been guaranteed by using backup and recovery procedures, confidence through the management of multilevel users and passwords, and integrity has been assured by choosing specific computerized tools to prevent non-authorized accesses (Gollmann, 1999).

The information contained in a single register is divided in two subgroups: the first regards information related to the firm, the type of work correlated to the exposure, the carcinogenic substances used and the number of employees; the second is about information on workers, their type of job and the exposure measurement procedures. The core information, in accordance with the recommendations of the European work group on the measurements of exposures in the workplace (Rajan *et al.*, 1997), is as follows: corporate name, territorial location of the firm, economic activity sector [in accordance with the nomenclature générale des activités économiques (NACE) classification of the European Union (EU), (Council Regulation, 1990)] and firm size; last name, first name, sex and date of birth of every worker; and chemical name and chemical abstracts service (CAS) number of the carcinogenic substances, job title and occupation of the worker (in accordance with the CP91 classification of the Italian Statistic Institute (ISTAT, 1991), and the exposure level (intensity, frequency and duration). The CP91 classification codes are in line with the International Standard Classification of Occupations (ISCO-88) of the International Labour Organization. Carcinogen and/or mutagen agents included in the system are an 'open list' since the substances and mixtures considered are those classified from international research agencies as to 'the relative criteria' of Classification 1 and 2 of the EU established from the Directive 67/548/EEC and subsequent integrations (Council Directive, 1967; Commission Directive, 1993) (1, substance known to be carcinogenic and/or mutagenic to man; 2, substances which should be regarded as if they are carcinogenic and/or mutagenic to man). The reference classification for carcinogenic substances is the one created by the EU (carcinogenic Group 1 and 2), then we consider substances classified by the International Agency for Research on Cancer (IARC) in 1 and 2A groups (and not included in the previous classification), by the American Conference of Governmental Industrial Hygienists (ACGIH) in A1 and A2 groups and by the Environmental Protection Agency in A and B1 groups. Substances pertaining to other groups (e.g. IARC 2B group) or classified from other agencies are included in the system when notified by companies.

The acquisition of notified registers is carried out through a service of data entry and through optical acquisition of documents (when they are compiled according to the forms arranged by the ISPESL and available on internet at http://www.ispesl.it/). Every exposure which has been recorded refers to a carcinogenic agent, a worker task and a period of time. On the basis of this recorded information, selection and data analysis procedures have been realized in order to produce aggregate analyses. Statistical analysis has been carried out on the economic sector and the geographic location of the company, on the carcinogenic agent, on the job type and on the exposure level. When more values were available for the exposure measure, the worst-case exposure level was considered, i.e. working under the most conservative hypothesis for the protection of the worker's health. The exposure values pointed out as lower than a detection limit (depending on the agent measured and analytical method used) were assumed to be equal to that limit. When it was not possible to determine the exposure value, we considered the annual quantitative of the carcinogen substance used or produced during the industrial activity, as an indirect measure of the exposure. The data considered for the purposes of this study refer to exposure which occurred in the period 1996–2005.

We finally compared SIREP data with the information about Italian labour force derived from the ISTAT census for the year 2001 of industry and services (ISTAT, 2004), and the findings of the carcinogen exposure (CAREX) study which estimated exposed workers to carcinogens in the period 2000–2003 by an epidemiological point of view (Mirabelli and Kauppinen, 2005).

RESULTS

The architecture of the information system SIREP is represented in Fig. 1. The database includes ∼20 tables linked through primary keys, each one containing, in average and excluding look-up tables, at least 12 fields in order to record data. The database structure is outlined in Fig. 2. The currently recorded information in the database regards 2778 different companies and refers to exposures that happened in

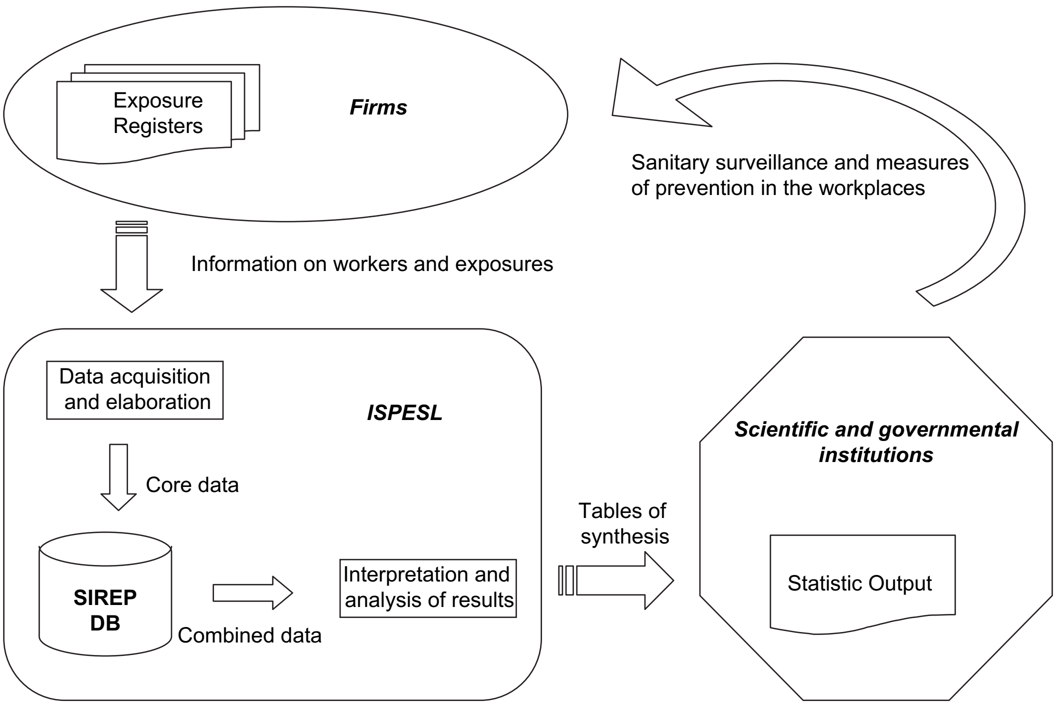

Fig. 1. Structure of the information system SIREP.

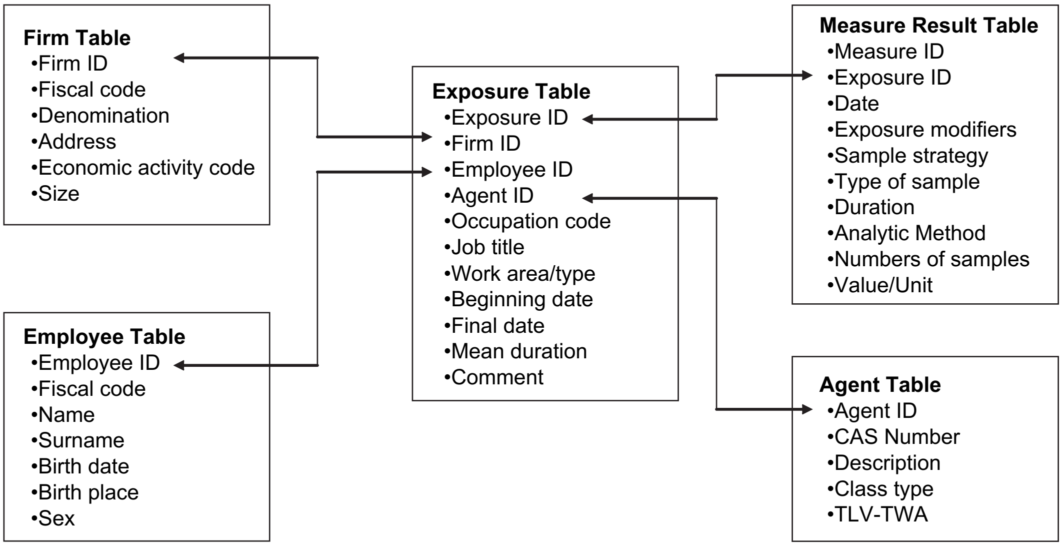

Fig. 2. Structure of the main database tables.

the period 1996–2005. The system includes information on >2500 chemical substances and ∼550 of them are linked to exposure measures. The most frequently notified substances are, in order: hardwood dust, benzene and polycyclic aromatic hydrocarbons. The number of exposed workers reported in the period 1996–2005 and 'on duty' at the end of 2005 is 36 547 (11% of them women) while the professional exposure histories recorded in the databank are ∼100 000 and refer to 39 561 workers (on or off duty). Those firms that sent the register belong, for the most part, to the wood industry sector (25%), furniture manufacture (25%), treatment and coating of metals (6%) and retail sale of automotive fuel (5%), while talking about the number of exposed workers, the major sector is manufacture of chemicals and chemical products (20%), then wood industry (18%), furniture manufacture (15%) and treatment and coating of metals (4%). The most frequently observed job is chemical-processing plant operator in the petrochemical industry (10%); carpenter in the manufacture of wood and furniture (5%); and laboratory assistant in the collection, purification and distribution of water (3%). The majority of the recorded companies are located in the north-east of Italy (∼43%) while only 7% come from firms located in the south and the islands. Currently, the annual average of the notifications is ∼1500. Table 1 shows, by economic branch, the number of firms and exposed workers recorded in the SIREP database, Italian firms and workers derived from the ISTAT census of industry and services and the findings of the epidemiological project CAREX. Table 2 reports the number of exposure histories, the typical occupation (job title) of the workers, the mean level of exposure and 5–95 percentiles for the most common carcinogens recorded in SIREP. Referring to the ISTAT 2001 census of industry and services, the number of exposed workers resulting from the SIREP database adds up to 0.2% of the Italian workforce.

DISCUSSION

The need to establish a reliable recording system of occupational exposures to hazardous chemical agents is, by now, widely accepted by the scientific community, industry and the trade union organizations. This kind of system is useful in order to integrate information of medical and epidemiological surveillance systems with monitoring for occupational risk factors (Ruttenber *et al.*, 2001). The epidemiological approaches to find out the correlation between environmental conditions in the workplaces and the workers' health status need a specific and punctual characterization of the personal exposure. The lack of information and the insufficient standardization of the applied methodologies in quantitative measure of the exposure are, generally, the major difficulties (Tielemans *et al.*, 2002). Databases constructed on information obtained from the exposure registries, which document workplace exposures changes over time, can reduce or eliminate this limitation.

The industries which notified the register to ISPESL belong mainly to the wood and furniture sector, the petrochemical branch (in particular those linked to the chlorine industry) and the galvanic sector (mainly correlated to exposure to chromium VI compounds). For the services sector, registers are mainly from the trade and retail sale of automotive fuel. Making reference to the ACGIH (2004) threshold limit

Table 1. Number of firms and workers as results from the 2001 ISTAT census, firms and exposed workers as results from the SIREP database (1996–2005) and exposed workers as results from the CAREX database (2000-2003), by economic branch

Economic branch	ISTAT census		SIREP database		CAREX database
	Firms	Workers	Firms	Exposed workers	Exposed workers[a]
Agriculture, hunting and forestry and fishing	35 913	118 567	8	64	42 600
Mining and quarrying	5430	37 214	15	458	32 602
Manufacture of food products, beverages and tobacco	74 001	452 483	6	15	31 416
Manufacture of textiles and textile products	78 362	607 776	7	54	29 902
Manufacture of leather and leather products	24 195	206 035	4	9	69 901
Manufacture of wood and wood products	50 255	179 366	822	8360	122 375
Manufacture of pulp, paper and paper products and publishing and printing	34 457	259 405	13	92	19 716
Manufacture of coke, refined petroleum products and nuclear fuel	913	24 537	20	1324	6835
Manufacture of chemicals, chemical products and man-made fibres	7728	206 076	133	9430	49 975
Manufacture of rubber and plastic products	15 115	216 876	24	317	62 401
Manufacture of other non-metallic mineral products	31 189	253 788	27	177	155 748
Manufacture of basic metals and fabricated metal products	106 279	840 271	227	2608	324 995
Manufacture of machinery and equipment n.e.c.	46 492	598 873	73	738	167 289
Manufacture of electrical and optical equipment	57 921	464 573	22	371	80 732
Manufacture of transport equipment	7210	281 165	78	1505	46 371
Manufacturing n.e.c. (furniture, recycling etc.)	56 656	315 091	830	7045	181 527
Electricity, gas and water supply	6178	134 333	28	500	19 319
Construction	529 830	1 530 917	89	1137	549 614
Trade	1 603 959	4 015 659	214	908	66 687
Transport, storage and communication	189 157	1 193 027	15	120	219 092
Financing, insurance, real estate and business activities	1 000 460	2 871 650	53	670	—
Public administration, defence; compulsory social security	27 686	947 830	24	220	31 000
Community, social and personal services	766 250	3 655 044	46	424	371 710
Total	4 755 636	19 410 556	2778	36 547	2 681 807

[a]Excluding exposure to solar radiation and tobacco smoke (environmental) not included in SIREP database.
n.e.c., not elsewhere classified.

values (TLV) Table 2 shows that the mean exposure values are generally lower than the threshold values except for some agents such as the hardwood dust. It must be considered that Italian law fixes, for some agents, the Occupational Exposure Limit (OEL) higher than the TLV proposed by the ACGIH (e.g. hardwood dust OEL = 5 mg m^{-3}, TLV = 1 mg m^{-3}).

The reported results underestimate the number of workers exposed to carcinogens in Italy, as evidenced from the previous epidemiological assessment of CAREX. Table 2 shows the gap between the CAREX estimate and the SIREP data. This is mainly due to the lack of normative reference elements for the procedures of register arrangement (official forms) and for the data transmission. In many cases, in fact, the activity of encoding and standardizing the information contained in the registers required time and resources. Often different systems of classification were used and the description of the worker task is not always assignable to a unique code. This activity of encoding is fundamental in constructing the Job Exposure Matrix, in contributing to the running of epidemiological studies and to measure the portion of attributable risk to exposure in occupational pathologies (Barone-Adesi *et al.*, 2005). Another reason for which SIREP data underestimate the number of exposed workers may be the difficulty in determining whether a worker is occupationally exposed to carcinogens particularly when the exposure level is low or the amount of the carcinogen used is small. In a former study on occupational exposure to carcinogens in Finland, Heikkila and Kauppinen (1992) partially ascribed to this reason the difference found between reported and estimated figures. In some economic sectors, the discrepancy between CAREX and SIREP data seems to be smaller (e.g. chemical and wood industry) than in others (e.g. construction, rubber industry). One possible reason is that, when the

Table 2. Most common carcinogen agents and exposure histories recorded in SIREP (1996–2005)

CAS No.	Carcinogen agent	Number of exposures	Typical occupation	Mean level of exposure	5–95 percentiles	TLV–TWA[a]	Measure unit
—	Hardwood dust	15 189	Carpenter	1.629	0.160–4.800	1.00	mg m^{-3}
71-43-2	Benzene	12 053	Chemical-processing plant operator	0.098	0.010–0.480	0.50	p.p.m.
—	Polycyclic aromatic hydrocarbons	11 002	Asphalt worker	—	—	—	—
106-99-0	1,3-Butadiene	8992	Chemical-processing plant operator	0.152	0.001–0.777	2.00	p.p.m.
107-13-1	Acrylonitrile	7096	Chemical-processing plant operator	0.121	0.001–0.400	2.00	p.p.m.
107-06-2	1,2-Dichloroethane	6126	Chemical-processing plant operator	0.424	0.001–1.343	10.00	p.p.m.
—	Chromium VI compounds	5480	Welder, painter and metal plater	0.156[b]	0.001–0.700	0.05	mg m^{-3}
75-01-4	Vinyl chloride (VCM)	3238	Chemical-processing plant operator	0.514	0.003–2.370	1.00	p.p.m.
75-21-8	Ethylene oxide	2309	Chemical-processing plant operator	0.146	0.006–1.000	1.00	p.p.m.
75-56-9	Propylene oxide	2065	Chemical-processing plant operator	0.643	0.003–3.083	2.00	p.p.m.
79-06-1	Acrylamide	1640	Laboratory assistant	0.009	0.002–0.012	0.03	mg m^{-3}

p.p.m., parts per million; TWA, time-weighted average; VCM, vinyl chloride monomer
[a]Referred to the ACGIH's TLV, up to 2004.
[b]Measured as chromium VI oxide.

legislation became effective (Legislative Decree n. 626/94), the substances involved were only those classified as 'known' or 'probable' human carcinogen by the EU, and thus some substances, such as crystalline silica and glass wool were not included. Subsequently, with the introduction of the Italian Legislative Decree n. 66 of 25 February 2000, this list has been widened becoming an open list, and now includes also those substances classified as 'known' or 'probable' human carcinogen by other international research agencies such as IARC and ACGIH. Moreover, the absence yet of a complete legislative process (that establishes the procedures by which firms should manage the register, compile and send the forms) has encouraged widespread disregard of the obligation to notify occupational exposures to the ISPESL.

The information reported by companies on forms is not always complete. Some kinds of error or missing values are easy to correct (e.g. the code of a classification from the title), but for others it has been necessary to contact companies to enable completion of the forms. Generally, there are no data about the type of sampling used, the analytical method applied in implementing the measurement or about the kind of monitoring which has been carried out (personal or environmental). In some cases the time-weighted averages are not specified (TWA or short term exposure limit) and the measure units are not always homogeneous, requiring a conversion of data (e.g. mg m^{-3} versus parts per million). The measurements performed are seldom followed by information on weather conditions and environment characteristics present at the moment of the survey.

Using the annual quantity of the carcinogen used as an alternative measure of exposure can lead to distortions or misclassification of exposure in any data analysis. Other issues can influence data quality. The exposure measurements, e.g. are collected for a purpose (compliance) different from that of epidemiological research (Rushton and Betts, 2001). The hypothesis of assuming as a measure of the exposure level the value originating from 'the worst-case exposure level' can be questionable since this value is not representative of the exposure concentration, as argued by Kromhout (2002). Moreover, it is necessary to keep in mind that a worker may have been exposed to one or more agents at the same time for the same job task.

The structure of SIREP generates a modular and distributed design, supporting the integration between units (Ceri and Pelagatti, 1984). The modularity of the system facilitates updates and integrations, and the 'distribution' characteristic improves the data transparency and the database migration features. In recording workers' personal information, particular attention in the design of the architecture of the databank has been given to the requirement of privacy protection in line with Italian legislation (Italian Law n. 675 of 31 December 1996 and subsequent integrations). This information can be useful in reconstructing a complete work history and in linking occupational data with medical files. The result of exposure data analysis will be distributed to regulatory organizations, legislative institutions and sanitary surveillance services in order to plan prevention programme, to improve workplace safety and to evaluate intervention measures.

In the future, it should be possible to integrate the SIREP database via the World Wide Web, allowing each firm to complete the exposure register forms online. This new system would have to incorporate tools for the automatic search of codified information (e.g. the standard classification of the industrial sectors, the job title, the CAS number of carcinogens etc.) and have control procedures to increase the data quality and to avoid usual errors in data entry (e.g. the wrong typing of an identification number, date, classification code etc.). This will improve accessibility to occupational exposure data for those involved in worker health and safety issues.

CONCLUSIONS

The purpose of the SIREP database is to enable the identification, the monitoring and the prevention of exposures to carcinogens in the workplace. Characteristics of the carcinogens used in industrial settings and the measurements of exposure levels are helpful to predict high-risk occupations and to identify specific tasks which involve exposure near or above the OELs that may need additional exposure reduction or other methods of worker protection. The systematic identification of workers exposed to carcinogens facilitates the analysis of occupational health data in epidemiologic studies and may document the effectiveness of many preventive interventions (i.e. programmes and policies). Moreover, we look forward to a definitive approval of the Italian legislation, which will fix the procedures by which firms should manage the register of exposed workers, and to the promotion of information campaigns on the necessity of recording occupational exposures.

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