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Roadmaps & Guidelines for Health Units

– Action D2 –

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Abbreviations

| | |
|-------|--|
| BoD | : Board of Directors |
| EC | : European Commission |
| ECHA | : European Chemical Agency |
| EEA | : European Economic Area |
| EEE | : Electrical and Electronic Equipment |
| EU | : European Union |
| HU | : Health Units |
| ICT | : Information & Communication Technologies |
| MS | : Member State |
| REACH | : Registration, Evaluation, Authorization and Restriction of Chemicals |
| ROHS | : Restriction of the use of certain Hazardous Substances |
| SVHC | : Substance of Very High Concern |
| WEEE | : Waste Electrical and Electronic Equipment |

Overview

‘Roadmaps and Guidelines for Health Units’ primary scope is to bridge the awareness and information gap between health care sector and the life-cycle of hazardous substances that are present on consumable products and – under certain conditions – are capable of generating negative effects on human health. While Health Units (HUs) are dealing mainly with the curing of patients, this deliverable aims in providing specific guidelines tailored for the health care system for interpreting the symptoms, for assessing and determining the causes and finally for making sound decisions regarding the appropriate and more holistic treatment approaches against health diseases induced by chemicals’ exposure.

Furthermore, this deliverable aims in disseminating MATHER’s objectives by:

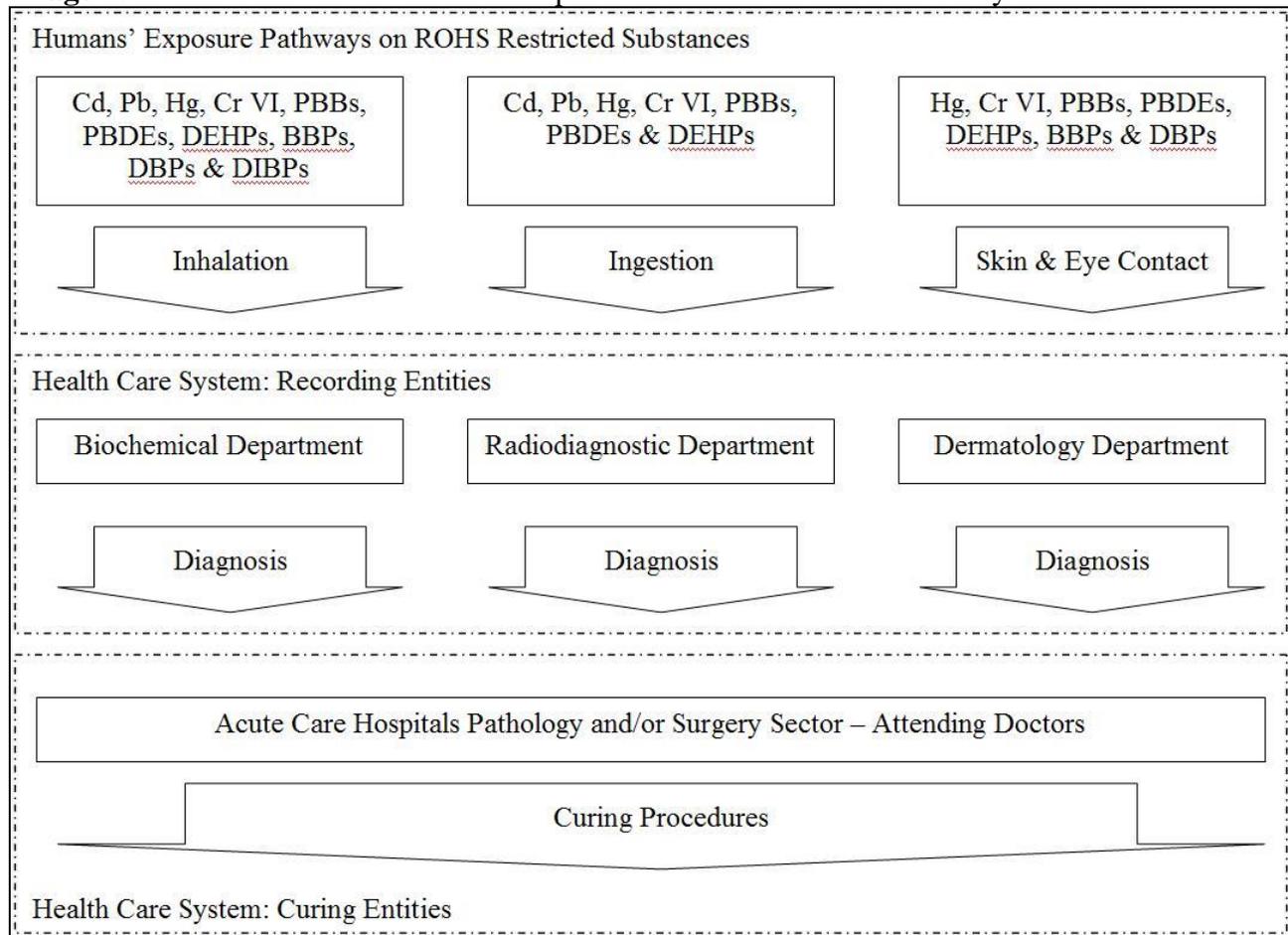
- Cultivating potential synergies among HUs and manufacturers, suppliers and distributors of household appliances and in general distributors of non-edible consumable products in issues related with knowledge sharing in preventing impacts on human health caused by the exposure on hazardous substances.
- Interacting with HU operational entities for information exchange in dealing with incidents related with the exposure of humans to harmful chemicals and hazardous substances.
- Promoting a framework of guidelines capable to be used for decision making regarding the appropriate treatment and curing approaches against health diseases induced by the exposure to chemicals.

Major scope of this report is including also the promotion of the MATHER Demo Platform by triggering representatives of the health care sector towards active participation in exchanging information about the whole life cycle of substances covered by the REACH Regulation and the currently amended ROHS Directive.

Furthermore, the formation of guidelines that are proposed to be adopted by HUs in terms of assessing certain incidents caused by the exposure of humans to chemicals requires primarily the mapping of HU structure and how this structure is mobilized in dealing with incidents derived by the negative effects of these substances to human health. To this end and as the target audience of the dissemination activities, the roadmapping procedure addresses those HUs’ operational entities where their role – among others – is the implementation of certain processes for the assessment of incidents that may be caused by the exposure on harmful chemicals and/or hazardous substances. In addition, these substances which are already covered by the REACH Regulation and the currently amended ROHS Directive are assessed as for their most commonly found physical state, their concentration on consumable products as well as the exact nature of their negative impacts on human health.

In this framework, the formation of guidelines requires firstly the capacity building on how these HUs entities (labs, units, departments and divisions) are operating in relation with these incidents and secondly what is the level of awareness of the respective representatives in exchanging information with other stakeholders concerning impacts and effects of harmful chemicals and/or hazardous substances to human health.

Image 1: Health Units' Involvement in Impacts on Human Health Derived by Chemicals



The combination and analysis of the abovementioned and gained data will form a set of proposed guidelines that are suggested to be followed in order to highlight or at least, to inform these representatives towards the prevention of impacts and the facilitation in handling incidents caused by the exposure of humans on hazardous chemicals.

The awareness tools that were utilized towards for developing guidelines tailored for HUs, were:

- E-mail address of the project for enabling the communication with targeted stakeholders (lifematherproject@gmail.com);
- Structured questionnaires with multiple choices for the collection of information that will set the framework for the development of guidelines;
- Communication skills of the working group as a mean of extracting necessary data through interviews.

Besides the collection of information through literature sources and involving and interacting with targeted stakeholders, the basic means for achieving this scope were the distribution of structured questionnaires tailored for HUs' representatives accompanied by personalized interviews.

Due to the different and fragmented scenario of health systems across Europe, the health units to get in touch with for Action D2 purpose have been identified within the Greek Health System.

Roadmapping for Health Units

Besides the curing of diseases, HUs are standing as the entities which are dealing with the curing of incidents related with the exposure of humans to harmful chemicals and other hazardous substances. Although that the respective procedures for counterbalancing these effects are complicated, there are certain departments which are more familiarized in identifying symptoms and providing – or at least proposing upon initial diagnosis – the curing procedure. To this end, the roadmapping for HUs in dealing with this type of incidents requires the exact identification of certain departments that are considered as critical in performing curing procedures.

According to their certain role, Greek HUs are generally divided in five (5) types as follows:

- Acute Care Hospitals.
- District Care Hospitals.
- Specialized Care Hospitals.
- Teaching Hospitals.
- Clinics.

Furthermore, according to their legal type, Greek hospitals may be classified into four (4) categories as follows:

- Public law entities which are autonomous self-governing and self-managed organizations under the jurisdiction of the national Ministry of Health.
- Private law entities which are built by charitable foundations and operating under the supervision of the Ministry of Health mostly as non-profit-making institutions.
- Private clinics which are profit-making organizations, usually in the form of limited liability companies, with doctors usually being the shareholders.
- Hospitals with special status which are including military hospitals operating under the supervision of the Ministry of Defense.

Given the fact that the incidents related with the exposure of humans to hazardous chemicals and substances are required acute and specialized care as for the curing procedure, the types of HUs that were reached in order to obtain information as for the prevention of the respective impacts, where located at the most populated cities of the Attica region (Athens, Piraeus and Eleusis which are covering approximately 35% of the Greek population in total, based on census data).

The organizational structure of HUs in Greece follows a certain pattern which is common among different types of hospitals. This pattern is having as a core the three main pillars of any health care operational system, namely, the diagnosis of a disease, the curing procedure and the rehabilitation of the patient.

In order to identify HU's Divisions, Sectors and Departments which are involved in incidents related with the exposure of humans to chemicals and hazardous substances that covered by ROHS Directives, there must be summarized the types of incidents which are caused by the exposure itself, or alternatively, the pathways where a human can be potentially harmed by these substances.

The following Table correlates ROHS restricted substances with exposure pathways and furthermore, it links the negative effects with exact HUs' Departments which are responsible for the tracing of these substances to human health in terms of factors which are causing certain diseases. To this end, the Departments which are prioritized concerning harmful chemicals effects which are responsible for certain incidents, are those that involved in the diagnosis procedure.

Table 1: ROHS Restricted Substances in Relation with the Exposure Pathways and the Health Units Departments that are Responsible for Tracing and Identification of the Substances

| ROHS Restricted Substances | Exposure Pathways | HUs Departments Responsible for Tracing and Identification of the ROHS Restricted Substances |
|--|--------------------------------|--|
| Cadmium (Cd) | Ingestion | Biochemical Department / Laboratory Sector / Medical Division |
| | Inhalation | Radiodiagnostics Department / Laboratory Sector / Medical Division |
| Lead (Pb) | Ingestion | Biochemical Department / Laboratory Sector / Medical Division |
| | Inhalation | Radiodiagnostics Department / Laboratory Sector / Medical Division |
| Mercury (Hg) | Ingestion | Biochemical Department / Laboratory Sector / Medical Division |
| | Inhalation | Radiodiagnostics Department / Laboratory Sector / Medical Division |
| | Skin Contact | Dermatology Department / Pathology Sector / Medical Division |
| Hexavalent Chromium (Cr VI) | Ingestion | Biochemical Department / Laboratory Sector / Medical Division |
| | Inhalation | Radiodiagnostics Department / Laboratory Sector / Medical Division |
| | Eye & Skin Contact | Dermatology Department / Pathology Sector / Medical Division |
| Polybrominated Biphenyls (PBBs) | Ingestion | Biochemical Department / Laboratory Sector / Medical Division |
| | Inhalation of Dioxins & Furans | Radiodiagnostics Department / Laboratory Sector / Medical Division |
| | Skin Contact | Dermatology Department / Pathology Sector / Medical Division |
| Polybrominated Diphenyl Ethers (PBDEs) | Ingestion | Biochemical Department / Laboratory Sector / Medical Division |
| | Inhalation of Dioxins & Furans | Radiodiagnostics Department / Laboratory Sector / Medical Division |
| | Skin Contact | Dermatology Department / Pathology Sector / Medical Division |
| Bis(2-Ethylhexyl) Phthalates (DEHPs) | Ingestion | Biochemical Department / Laboratory Sector / Medical Division |
| | Inhalation | Radiodiagnostics Department / Laboratory Sector / Medical Division |
| | Skin Contact | Dermatology Department / Pathology Sector / Medical Division |
| Benzyl Butyl Phthalates (BBPs) | Inhalation | Radiodiagnostics Department / Laboratory Sector / Medical Division |
| | Eye Contact | Dermatology Department / Pathology Sector / Medical Division |

| ROHS Restricted Substances | Exposure Pathways | HUs Departments Responsible for Tracing and Identification of the ROHS Restricted Substances |
|-------------------------------|-------------------|--|
| | | Division |
| Dibutyl Phthalates (DBPs) | Inhalation | Radiodiagnostics Department / Laboratory Sector / Medical Division |
| | Skin Contact | Dermatology Department / Pathology Sector / Medical Division |
| Diisobutyl Phthalates (DIBPs) | Inhalation | Radiodiagnostics Department / Laboratory Sector / Medical Division |

Based on the above Table, the main pathways for the exposure of humans to ROHS restricted substances are through inhalation and ingestion. In addition, the Departments which are responsible for medical examinations where their results will correlate the incident as being caused by exposure to harmful chemicals are Radiodiagnostics and Biochemical Departments respectively. For the cases where the exposure pathway is referring to eye and/or skin contact, the effects are visible and the responsible Department for the diagnosis is the Dermatology Department (at some cases is entitled Allergy Department). To this end, these Departments are considered critical for retrieving information that can join the respective representatives with the usage of IT tools that are informing all stakeholders in issues related with quantitative and qualitative characteristics of chemicals which are consisting non-edible consumable products.

In addition and in order to have a more comprehensive view of the procedures where a HU is operating in relation with the scopes of this study, there were reached representatives from other Departments of HUs, namely:

- Procurement Departments / Financial Sector / Administrative Division. Representatives from these Departments were reached in order to retrieve information concerning the environmentally sound criteria where electromechanical equipment for medical purposes is selected. For example, when a HU is applying ‘green public procurement’ principles it means that the heads of these Departments are fully aware as for hazardous substances found on electrical and electronic equipment.
- Department of Quality Control / Independent Department / Director’s Office. Quality control Departments are indirectly related with procurement procedures as they are responsible for ensuring that any chemical that is inserted to the HU either as part of equipment, either as a consumable for medical purpose is fulfilling required quality standards based on protocols. These Departments are also related with the smooth implementation of REACH Regulation principles for substances which are used for medical purposes.
- Department of Research and Development / Independent Department / Director’s Office. R&D Departments are considered as key players in exploiting the potential of the MATHER Demo Platform as a knowledge base that will enrich information for incidents related with the exposure of humans to harmful chemicals.

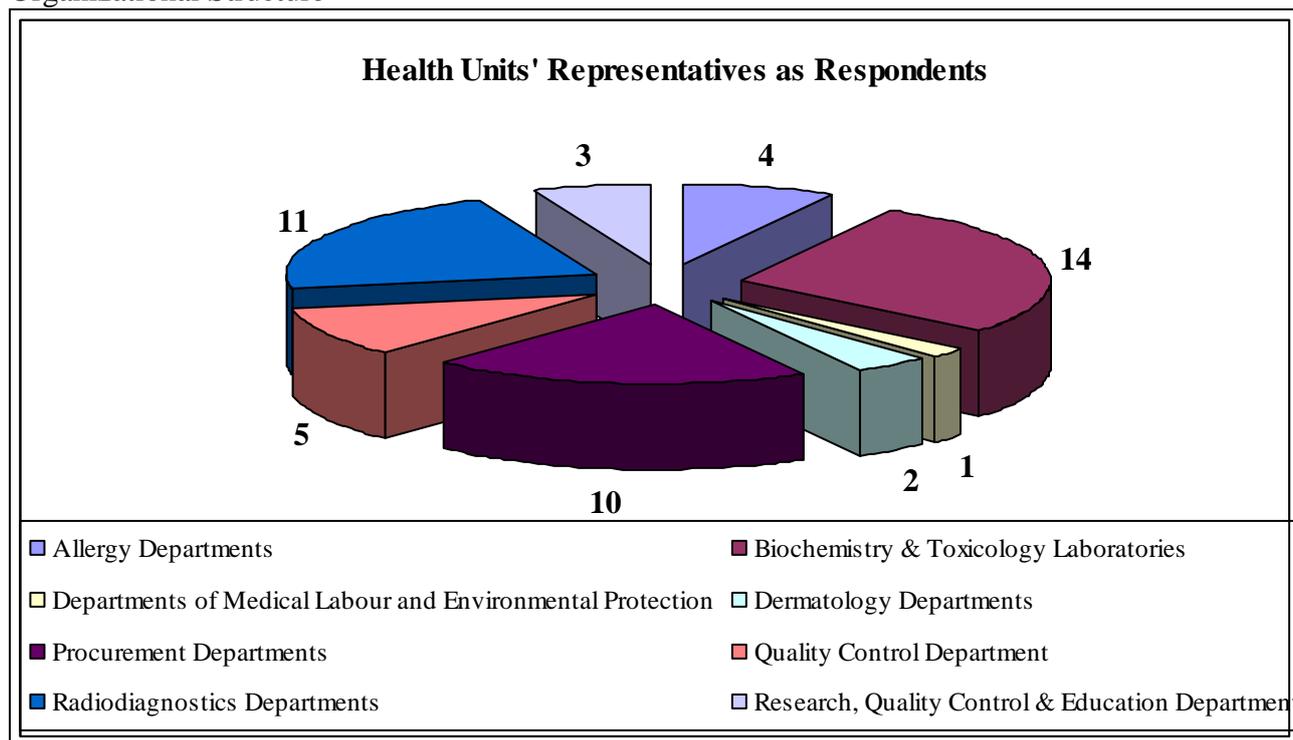
In the above mentioned framework, twelve (12) Greek HUs have been reached and informed about MATHER’s objectives through an engagement message. The engagement message and structured questionnaires tailored for HUs representatives were sent to a total of 50 Departments of which:

- 4 were Allergy Departments (Pathology Sector / Medical Division);
- 14 were Biochemistry & Toxicology Laboratories (Laboratory Sector / Medical Division);
- 1 was Department of Medical Labour and Environmental Protection (Public Health Sector / Medical Division);

- 2 were Dermatology Departments (Pathology Sector / Medical Division);
- 10 were Procurement Departments (Financial Sector / Administrative Division);
- 5 were Quality Control Department (Administrative Division);
- 11 were Radiodiagnostics Departments (Laboratory Sector / Medical Division);
- 3 were Research, Quality Control & Education Departments (Administrative Division).

Questionnaire tailored for Health Unit Representatives is still available in the following address:
[State-of-Play Questionnaire for Health Units](#)

Image 2: Health Units' Representatives as Respondents According to their Position at Organizational Structure



Main Results

The answers received from HU representatives, as respondents of structured questionnaires, are supporting a twofold scope, namely, an insight view from stakeholders as for the impacts derived from the use of hazardous substances on humans as well as, the optimization and adoption of web-based tools for exchanging information on these impacts among HU and other relevant stakeholders.

From this perspective, explanation of questionnaires results and the consequent guidelines that have been elaborated can be divided in:

- capacity building for developing new synergies and sharing knowledge across different sectors;
- awareness to maximize communication and impact among all stakeholders.

Capacity Building Results

The answers received from HU's representatives as respondents and after the elaboration of the results in order to match with questionnaires' content in relation with capacity building are summarized as follows:

- HU's Department where incidents are firstly recorder are depending on the acuteness nature of the incident. In particular, concerning incidents that are requiring acute care, these are firstly recorded at outpatient departments while incidents related with long term diseases can be correlated with the exposure on chemicals during initial diagnosis which is made by rediodiagnostics departments, by biochemistry labs and dermatology departments. These entities are also providing adequate information as experimental test results to outpatient departments in relation with the acuteness of the incident.
- The responsibility of imposing curing procedures belongs to patients' attending doctors where, according to the acuteness and severity of the incident, it involves the pathology and/or surgical sector. For acute care cases, attending doctors are in-house personnel of the HU while for cases with low severity, attending doctors may be not personnel of the HU were the incident was firstly recorded.
- Due to internal's HU regulation and because of confidentiality restrictions, it is hardly clear to estimate the annual number of incidents which are directly related with the exposure of human to chemicals and even more, with substances covered by ROHS Directive in relation with household appliances. However, this information can be obtained upon authorization by each HU's scientific council.
- The most common effect derived by the exposure of human to chemicals are related either with poisoning caused by inhalation of liquid substances, either with lungs irritation caused by inhalation of tiny airborne solid particles and/or toxic gases, either with skin irritation caused by contact with acidic liquids. Concerning effects on the respiratory system, inhalation of toxic gases is related with the generation of toxic gases derived by the accidental burning of certain substances (e.g. phalates).
- The traceability of chemicals and in addition, of substances related with ROHS Directive is possible for incidents where acute healthcare is needed. In addition, it is rather difficult to quantify the impact of a certain substance in cases of chronic diseases.
- According to their physical state, chemicals and/or other hazardous substances are negatively affecting human health in the form of liquids, dusts and/or gases while, the most common effects derived from inhalation of toxic gases, ingestion of liquid state chemicals and skin irritation from improper use of acidic substances.
- Incidents of exposure to chemicals in relation with EEE usage are not correlated with substances themselves but are related either with improper use of the device, either with impacts derived from the dismantling of the device at workplaces (e.g. at a recycling facility).
- There is no direct communication channel among HU representatives and other stakeholders involved in manufacturing and/or supplying not edible products.

Awareness Results

The answers received from HUs' representatives as respondents and after the elaboration of the results in order to match with questionnaires' content in relation with awareness assessment are summarized as follows:

- HUs’ representatives are fully aware as for the negative impacts on human health caused by the exposure on hazardous substances, including those that are covered by ROHS Directive, based on their practical experience.
- In general, HUs as public sector entities are incorporating green principles during public procurement tenders especially for items that related with healthcare consumables.
- HUs’ representatives are fully aware as for the limits of hazardous substances concentration where they are expecting to have negative impact on human health since their expertise is related with such type of knowledge and practical cases.
- In general, sharing data on non-edible consumable products with manufacturers will be useful but this is expected to upgrade readiness level in curing certain incidents only in cases of newly entered and/or innovative substances where there is a lack of recording incidents.
- HUs’ representatives are eager in sharing information with manufacturers of non-edible consumable products where they consider themselves as knowledge providers.
- On the contrary, they are not permitted to share quantified data on incidents mostly because of internal regulatory and confidentiality restrictions of their units.
- Concerning the most preferable communication channels for retrieving and/or exchanging information by other stakeholders, HUs’ representatives assume that data exchange platforms will be useful as well as more traditional pathways such as scientific journals.

Guidelines for Health Units

The formation of guidelines tailored for HU regarding the development of a more holistic approach in dealing with incidents related with the exposure of humans to harmful chemicals and hazardous substances – especially for those covered by REACH Regulation and ROHS Directive – is based on the cultivation of interactions and synergies among HU and all potential stakeholders including policy makers, manufacturers, suppliers and distributors regarding the appropriate treatment and curing approaches against health diseases induced by the exposure to chemicals.

Capacity Building Guidelines

The proposed **guidelines in relation with the upgrading of HUs’ readiness level** in dealing with incidents caused by the exposure of humans to chemicals and other harmful substances are including:

- **Development of a database which will include a practical guide for the correlation of exposure incidents** with certain chemicals and the biosphere. This database should include all the chemicals which are characterized as harmful for human health in accordance with their presence on domestic, working and wider environment and even more, according to their most common physical state. On the other hand, the effects on human health which had been identified to be caused by certain chemicals should be correlated with recorded incidents which had been faced up by HUs in real time during the past. The extensive experience of HUs needs to be utilized more so as to involve the whole life-cycle of a substance on the basis of its impact on human health, including its derivatives during improper use (e.g. generation of toxic gaseous compounds produced through heating and/or accidental burning).

- **Development of an annual published report supervised by the national Ministry of Health** in which all incidents related with the exposure of humans to chemicals will be reported and categorized. All national HUs are suggested to contribute in realizing this report by listing all recorded incidents in correlation with the exact chemicals and/or mixture of substances that were responsible for certain effects on human health. This report must secure and protect confidentiality data by providing only information that is needed by other involved stakeholders.
- **Development of an organizational structure responsible for the direct correlation of incidents with environmental parameters.** Since this structure's occupation will not be based on incidents but with the correlation of incidents with cases of environmental degradation, it can be hosted by Research and Development Department of HUs. The scope of this structure should be the quantification of environmental impacts on human health and their correlation with certain effects.

Awareness Guidelines

Concerning the results from the implementation of awareness tools, the guidelines where HUs can potentially follow regarding their collaborative contribution to other stakeholders towards the prevention – or at least minimization – of incidents caused by the exposure of humans to chemicals and other harmful substances are including:

- **Interaction with ECHA related entities by participating on the recently released portal for poison centres.** The ECHA Submission portal¹ is an online tool that allows industry to prepare and submit a dossier for a Poison Centre Notification (PCN)². Concerning the use of substances of very high concern, HUs can contribute to the technical dossier submitted by obliged companies by means of providing additional information on issues regarding with acute care of incidents related with the exposure of humans to hazardous chemicals.
- **Interaction with OSHA by providing information on incidents related with the exposure of humans to dangerous substances** through OSHA's 'Dangerous Substances e-tool'³. This tool is an interactive web-based guide that provides employers with the support and advice needed in terms of effectively manage dangerous substances in the workplace. Furthermore, HUs can exchange information on the way they are handling incidents towards the content upgrading of 'Health Effects' section of the 'Practical tools and guidance on dangerous substances' platform that has been released by OSHA⁴. On this section, HUs' representatives can provide valuable feedback in relation with acute care principles as for the incidents that may occur accidentally at workplaces.
- **Interaction with policy makers and manufacturers through the provision of consultation on substances of very high concern acceptable concentrations** at non-edible consumable products. Based on HUs' knowledge and experience in dealing with incidents related with inhalation, ingestion and skin contact effects derived from the exposure to harmful chemicals, they can provide positive feedback on both policy makers and manufacturers in relation with quantified limits of certain substances on non-edible consumable products. This can be accomplished through a common shared web-based tool

¹ <https://poisoncentres.echa.europa.eu/echa-submission-portal> [Accessed 02-06-2020]

² European Chemical Agency, (2020), 'Poison Centre Notifications: A Practical Guide', May 2020

³ <https://osha.europa.eu/en/tools-and-resources/e-guides/dangerous-substances-e-tool> [Accessed 02-06-2020]

⁴ <https://osha.europa.eu/en/themes/dangerous-substances/practical-tools-dangerous-substances> [Accessed 02-06-2020].

where policy makers and manufacturers can get advices by HUs representatives on the effects derived by certain substances on human health.

Concluding Remarks

The involvement of HUs in issues related with safe use of chemicals and other substances of very high concern – which are legislatively restricted – is present when incidents caused by the exposure of humans to these substances are occur. To this end, HUs are involved indirectly with information that is regulating the use of chemicals at both domestic and working environments. From this perspective, HUs cannot act as policy makers and even more, they are having limited interaction with stakeholders involved throughout the whole life-cycle of chemicals.

Despite the above mentioned facts and through this study, it is obvious that the knowledge and experience which HUs are possessing in terms of dealing with exposure incidents, is crucial as it is a proof about real time effects of chemicals to human health. It should be mentioned that for several substances, their hazardousness has been previously documented partially based on animal testing and not on real incidents related with humans. From this point of view, the exploitation of qualitative and quantitative data on chemicals' exposure incidents will have a reverse impact on Regulations and Decisions concerning certain uses of a wide variety of substances. In other words, the utilization of HUs experience will enhance a more holistic approach as for the safe, environmental friendly and sustainable management of chemicals throughout their whole life-cycle, based on scientific results of practical experience which are quantifying the impacts on human health. However, during the past two years, EU Agencies and especially, ECHA (through the initiation of Poison Centre Notification) and OHSA (through the development of 'Practical Tools and Guidance on Dangerous Substances' webpage) have been incorporating interactive web-based platforms for the correlation of certain chemicals – primarily those which characterized as substances of very high concern – with impacts and effects on human health. It is clear that the optimization of this trend requires the active involvement of HUs either in the form of individual hospitals, either in the form of the entire healthcare system. In this framework and taking under consideration the role of HUs' scientific councils as for the publishing and distribution of such information, it is essential for ECHA and OHSA related competent authorities at national level to develop, maintain and upgrade all available communication channels in obtaining data of exposure on chemicals' incidents.

Finally, towards the cultivation of a more integrated approach in proper management of chemicals throughout their whole life-cycle, HUs are suggested to take under consideration possible and/or potential correlation and/or interaction among certain incidents of exposure with cases on environmental degradation.