

## The activity of the Istituto Superiore di Sanità in the field of existing chemicals

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**Summary.** - The Istituto Superiore di Sanità (Italian National Health Institute, ISS) is one of the main Italian research institutes and a scientific body of the Italian National Health Service. At present, the ISS includes twenty laboratories, six technical services, an administrative division for personnel affairs and a library. The staff includes about 1400 people, plus over 600 external collaborators. The ISS international activities in the field of existing chemicals includes the participation in a wide number of programmes of the World Health Organization, the European Union, the International Agency for Research on Cancer, the Organisation for Economic Co-operation and Development and other organizations. At a national level, the ISS is particularly active in the field of risks connected with chemicals in the environment and in food, and constantly provides advice to the Ministry of Health and often to other ministries in the definition of laws and regulations which include technical-scientific aspects related to the existing chemicals. The ISS research activity in the field of chemical substances represents a significant part of the Environment research project, which includes more than one hundred research lines, and also of other research projects.

**Key words:** Italian National Health Institute, existing chemicals.

**Riassunto** (*L'attività dell'Istituto Superiore di Sanità nel settore delle sostanze chimiche esistenti*). - L'Istituto Superiore di Sanità (ISS) è uno dei principali istituti di ricerca italiani ed è organo scientifico del Servizio Sanitario Nazionale. L'ISS è formato da venti laboratori e sei servizi tecnici, da servizi amministrativi e del personale e da una biblioteca. L'organico include oggi circa 1400 unità, a cui si aggiungono più di 600 collaboratori esterni. L'attività internazionale dell'ISS nel campo delle sostanze chimiche esistenti include la partecipazione ad un vasto numero di programmi dell'Organizzazione Mondiale della Sanità, dell'Unione Europea, dell'Agenzia Internazionale per la Ricerca sul Cancro, dell'Organizzazione per la Cooperazione e lo Sviluppo Economico ed altri enti. A livello nazionale, l'ISS è particolarmente attivo nel campo dei rischi correlati con la presenza di sostanze chimiche nell'ambiente e negli alimenti, ed effettua regolarmente attività di consulenza al Ministero della Sanità, e spesso anche ad altri ministeri, in relazione alla definizione di leggi e normative che includono aspetti tecnico-scientifici connessi con le sostanze chimiche esistenti. L'attività di ricerca dell'ISS in materia di sostanze chimiche è in larga misura inserita nel progetto Ambiente, che comprende più di cento diverse linee di ricerca, ed anche in altri progetti.

**Parole chiave:** Istituto Superiore di Sanità, sostanze chimiche esistenti.

### Introduction

The Istituto Superiore di Sanità (ISS, Italian National Health Institute) was founded in 1934. It is one of the main Italian research institutes and a scientific body of the National Health Service. The role of ISS within the national health system is protection of health through scientific research, surveys, controls, testing and measurements. ISS also provides scientific advising and expertise to the national government through the Ministry of Health and other ministries. Moreover, ISS regularly cooperates with the major international organizations dealing with health protection, which include the European Union (EU), the World Health Organization (WHO), the International Agency for Research on Cancer (IARC), the Food and Agriculture Organization (FAO),

the International Labour Office (ILO), the International Radiation Protection Association (IRPA), the Organisation for Economic Co-operation and Development (OECD), the United Nations Environment Programme (UNEP), the International Programme on Chemicals Safety (IPCS), the International Register of Potentially Toxic Chemicals (IRPTC) and the Committee on the Challenge of Modern Society of the North Atlantic Treaty Organization (CCMS-NATO) projects. Within this framework, ISS has major responsibilities in the prevention of toxic risk and of environmental pollution, in the safety assessment of chemicals and of their use and in programming and carrying out experimental measurements and monitoring surveys of human and ecosystem exposure to dangerous chemicals, as well as controlling their quality. In this field, the Institute

participates in programmes, studies and commissions of EU and of the other international organizations mentioned above.

### **The structure of ISS**

The structure of ISS includes twenty laboratories, six technical services, a scientific library and an administrative division for personnel affairs. The permanent staff includes more than 1400 people, plus over 600 fellows, external collaborators and undergraduate and graduate students.

The ISS laboratories of Applied Toxicology, Comparative Toxicology and Ecotoxicology, Environmental Hygiene, Pharmaceutical Chemistry and Pharmacology are regularly involved in research, control and institutional activities concerning various aspects of risk and safety assessment of existing chemicals. These activities represent a major part of the scientific-technical work carried out by these laboratories. Other laboratories (Clinical Biochemistry, Epidemiology and Biostatistics, Food, Veterinary Medicine) are also involved in this matter, while the remaining laboratories provide sporadic contributions. A significant role in this field is played by the Documentation Service, which is connected to the major data banks and databases concerning information on chemicals and chemical risk. The Library of ISS contains about 150,000 volumes and 3,500 current periodicals; it is considered one of the most exhaustive national libraries in the field of public health, and, specifically, in the field of existing chemicals.

However, it is important to notice that the ISS activity in the field of the existing chemicals is typically carried out in cooperative programmes to which many laboratories, laboratory sections and services contribute.

### **The international activities of ISS in the field of existing chemicals**

At an international level, ISS participates in many scientific-technical activities of EU in the field of chemical risk assessment, management and control.

Since many years ISS regularly participates in EU scientific commissions concerning the classification and risk assessment procedures. In particular, the Institute is the competent authority for activities concerning "new chemicals", and, in cooperation with the Ministry of Health, will assume this role also for "existing chemicals" in a near future.

It is also important to underline that ISS regularly provides experts to EU commissions concerning the classification of chemical substances and of their health and environmental risks, as well as the preparation of test guidelines.

Moreover, the ISS data bank on chemical hazards and risks of existing and new substances (the National Inventory of Chemical Substances - *Inventario nazionale delle sostanze chimiche*, INSC) is operating both at national and EU level and includes all the data collected, elaborated and evaluated in Italy in this field (a specific description of this structure is given elsewhere in this issue).

In ISS operates one of the four Community reference laboratories of EU for residues in food and environmental matrices, according to a recent Commission decision.

ISS is responsible at a national level for EU activities connected with the directive on pesticides (agricultural pesticide homologation), dealing with the revision and risk assessment of such chemicals.

ISS also has specific competences in OECD activities concerning new and existing chemicals; it is responsible, among others, for the national coordination of the Test guidelines programme.

ISS hosts the national focal point for the International Register of Potentially Toxic Chemicals (IRPTC) of the United Nations Environment Programme (UNEP).

Moreover, the Institute is involved in the quality control of food analytical measurements (within FAO-WHO activities and programmes).

ISS is also a WHO Collaborating centre for the chemical emergencies. Moreover, ISS experts regularly participate, as temporary advisors, in WHO groups concerning chemical pollution of the environment, environmental toxicology, chemical hazard identification and risk assessment, as well as epidemiology of chemical risk. Furthermore, ISS constantly cooperates with the WHO Centre for environment and health of Rome.

In particular in the field of epidemiology, ISS has participated and participates in IARC programmes.

Lastly, ISS regularly participates in UNEP, IPCS and NATO-CCMS activities and programmes.

This brief survey shows that ISS has dedicated and is still dedicating a significant amount of its work to international activities in strict cooperation with international organizations and other countries, in agreement with the principle that this is the best way for carrying out good scientific studies, for verifying the value of scientific-technical production through an open and clear comparison of ideas, methods and criteria, and for improving the efficiency and quality of experimental data and theoretical work produced.

### **The national role of ISS in the field of existing chemicals**

At a national level and within the National Health Service, ISS is particularly active in the field of risks connected with chemicals in the environment, in drinking

water and in food, as well as in the field of chemical emergencies. Moreover, the Institute constantly provides advice to the Ministry of Health, and often to other ministries, in the definition of regulations and laws which include technical-scientific aspects connected with chemical pollution, chemical residues, chemical risk assessment and prevention.

The National Advisory Toxicological Committee (Commissione consultiva tossicologica nazionale, CCTN) regularly meets at ISS, and its inception has been coordinated by an ISS scientist; moreover, this Committee includes a large number of ISS experts as members or temporary advisors. This Committee presents proposals to the Ministry of Health for the carcinogenic, mutagenic and toxicological classification of hazardous factors, for the definition of environmental standards, exposure limits, and other risk parameters at a national level, and for the management of chemical risks in the national territory.

In accordance with national laws and regulations, ISS regularly cooperates with the regional and local bodies of public health, often with coordination responsibilities, in the fields of environmental epidemiology, environmental pollution monitoring, control and prevention, in food safety assessment and in other related areas. Moreover, ISS is often requested to provide advice, information and data to these bodies. In the case of chemical emergencies at national level, ISS is regularly involved.

ISS has also coordination responsibilities in the fields of quality control of testing and measurements and of good laboratory practice.

ISS has an intense training activity for national public health bodies; in the field of chemical substances, the number of courses organized yearly often exceeds twenty.

### **The research activity of ISS in the field of existing chemicals**

The research activity of ISS in the field of chemical substances and of the risk that they pose to human health and the environment, is mainly included in the ISS Environment research project [1]. The subprojects of this programme are:

1. Pesticides and dangerous substances
2. Bioelements and environment
3. Mineral fibers and dust
4. Models and methods for the assessment of the genotoxic risk
5. Models and methods for the assessment of the toxicological risk
6. Existing chemical substances: priority selection through mathematical models and tests of toxicological screening

7. Ecotoxicity and environmental fate
8. Airborne processes and air quality
9. Water quality
10. Soil quality and wastes
11. Prediction models for chemical substance impacts on health and environment
12. Environmental epidemiology
13. Ionizing radiation
14. Non-ionizing radiation
15. Environmental radioactivity
16. Structure of the matter (special project).

More than one hundred single research lines are included in the subprojects of the Environment project.

The activities of this project are in part connected with EU, WHO, IARC, NATO-CCMS projects, as well as, at a national level, with research projects of the National Research Council (Consiglio Nazionale delle Ricerche, CNR), of universities and other national institutions. A significant part of the research is also partly economically supported by national and international organizations. The number of scientific publications produced by this project in the last five years exceeds 650, and a major part deals with chemical substances.

Moreover, other ISS research projects focus at different levels on chemical substances; among these, it is worth mentioning the Food safety and pharmaceutical drug projects [2].

### **Conclusions**

For brevity reasons, the above description has been limited to the main aspects and many details have not been reported. However, it is important to point out that ISS considers itself as a scientific body whose research and institutional activities are mainly aimed at offering people an effective contribution towards the improvement of health in different fields, including the prevention of risk induced by chemicals, with strict reference to the national and international reality and needs.

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