

Ministero della Salute

**DIPARTIMENTO DELLA SANITÀ PUBBLICA
VETERINARIA, DELLA SICUREZZA DEGLI
ALIMENTI E DEGLI ORGANI COLLEGIALI**

**DIREZIONE GENERALE PER LA SICUREZZA E
L'IGIENE DEGLI ALIMENTI– Uff. VII**

***The organizational structure of the Italian
Central Competent Authority
Giovanna Azimonti (dr. Pasquale Cavallaro)***

Sarajevo, 11 March 2015

WHO ARE THEY?



- **26 peoples with the following professional skills :**

Chief Executive Pharmacist

**Director of
the Office**

Executive Chemists (6)
Executive Pharmacists (2)
Assistants for Prevention and Surveillance (5)
Administrative Coordinator (1)
Administrative Operators (4)
IT Technician (1)
External Collaborators (6)

WHAT DO THEY DO? (1/2)



- 1) Authorization for the placing on the market of PPPs;
- 2) Adjustment of authorized products to EU provisions;
- 3) Official Control on marketing and use of PPPs;
- 4) Official Control for pesticides residues on food of vegetal origin
- 5) Maintaining of the National Database on PPPs and publication, on the webpage, of general information about PPPs;
- 6) Focal Contact Point of EU Commission for the overall ruling on PPPs;
- 7) National Coordination with other interested administrations: Ministries of Agriculture, Environment and Industry;
- 8) Risk assessment of pesticides residues and Competent Authority, as Rapporteur Member State, for the assessment of a number of active substances;

WHAT DO THEY DO? (2/2)



- 9) Authorization of production plans of PPPs– DPR 290/2001;
- 10) Authorization of MRL modifications and consequent use variations of PPPs – (EC) Regulation 396/2005;
- 11) Annual Report on the results of the Official Control for pesticides residues in food of vegetal origin;
- 12) Annual Report on the results of the Official Control on marketing and use of PPPs;
- 13) Management of the measures foreseen by the (EC) directive 2009/128;
- 14) Management of the National Advisory Committee on PPPs;
- 15) Contacts with the stakeholders.

HOW ARE THEY ORGANIZED? (1/2)



The Office is organized in **several sections** in relation to the different activity areas:

- **1** – assessment of new active substances and related PPPs – authorization of PPPs containing such substances -National and EU guidance documents;
- **2** – authorization of new PPPs containing known active substance - “me too” authorizations – emergency authorizations- authorization of production plans of PPPs;
- **3** – re-registration, National renewal and technical adjustments of PPPs containing EU Peer Reviewed active substances- mutual recognition of authorizations;
- **4** - Residues – authorization and variation of MRLs – variations of uses of PPPs following modifications of the (EC) Regulation 396/2005;
- **5** - Official Control on marketing and use of PPPs - Official Control for pesticides residues on food of vegetal origin;
- **6** – PPPs containing micro-organisms and natural extracts;

HOW ARE THEY ORGANIZED? (2/2)



- **7** – Technical and administrative variations of the authorizations of PPPs – emergency authorization of use extensions – application of CLP Regulation;
- **8** – Authorization of parallel imports permits;
- **9** – Assessment of active substances for which Italy acts as RMS – contact with EFSA;
- **10** – Contact Point with DG SANTE – LWG meetings, PAI meetings, *ad hoc* expert meetings - SUD;
- **11** – Contact Point for the Zonal and InterZonal Steering Committees for the coordination of zonal authorization activity under the (EC) Regulation 1107/2009;

To achieve part of such activities the Office benefits of the **National Advisory Committee on PPPs (CCPF)**, which is chaired by the Minister of Health or by his deputy.

Since 2010, contracts with different institutions in Italy were established to address registration process.

Authorization is a decisional process which involves several subjects

MINISTRY OF HEALTH

Responsible Body for the placing on the market of PPPs, and of the official control of residues of pesticides in food.

Also responsible of consumer safety and for control on trading and use of PPPs with a particular regard to the working conditions and operator safety.

Finally, responsible for the assessment of GLP compliance of laboratories and facilities performing the studies which are submitted with dossiers on active substances and formulated products.

Authorization is a decisional process which involves several subjects

MINISTRY OF AGRICULTURE

Responsible Body to ensure that crops are adequately protected.

Ensures the assessment of the efficacy of PPP.

Responsible of the phytosanitary measures to be taken to protect crops and food of vegetal origin from potentially dangerous parasites and toxins.

Responsible for the control of the correct phytosanitary use of PPPs by growers.

In cooperation with Ministry of Health, responsible for assessing the GLP compliance of facilities performing efficacy testing on PPPs.

Authorization is a decisional process which involves several subjects


MINISTRY OF ENVIRONMENT

Ensures that environment and non target species are not damaged by PPP use.

Ensures the assessment of environmental and ecotoxicological properties of both active substances and formulated products.

Responsible of the monitoring programs aimed to check whether, in spite of authorization assessment, undesirable content of pesticides is present in the environment (ground and surface waters, soil and air).

Defines the so called “vulnerable areas” in Italy.



Authorization is a decisional process which involves several subjects

MINISTRY OF INDUSTRY

Ensures that all companies (the big ones as well the small ones) are guaranteed.

Works to legally define a compensation procedure for data sharing to solve the problems arising from data protection.

Authorization is a decisional process which involves several subjects

SUPERIOR INSTITUTE OF HEALTH (ISS)

Essentially a research Institute, depending on the Ministry of Health.

Involved in toxicological, environmental, ecotoxicological and chemical assessment, development of scientific guidance and evaluation criteria.

Responsible for the coordination of all the control activities related to the food and drug safety, from the practical and scientific point of view. It is the National Reference Laboratory for these purposes.




Authorization is a decisional process which involves several subjects

SUPERIOR INSTITUTE ON WORKER'S HEALTH AND SAFETY (ISPESL)

A research and control Institute, depending on the Ministry of Health.

Involved in developing guidance document for the assessment of worker safety, and involved in the control of these aspects when authorizing a plant which produces PPPs.



Authorization is a decisional process which involves several subjects

INSTITUTE FOR VEGETAL PATHOLOGY

Essentially a research Institute, depending on the Ministry of Agriculture.

Involved in research for methods to protect crops and vegetals.

Responsible for coordinating, on the practical and scientific point of view, all the control activities related to the crop quality and the correct use of PPPs in field.

It is the National Reference Laboratory for the aspects related to plant protection.

Advisory Committee on PPPs (CCPF)



CCPF

It is chaired by....

**Minister of Health
or his deputy**

It is composed by....

**Experts from
Academic world**

ISS Experts

INAIL Experts

**Delegates from
Ministry of Agriculture**

**Delegates from
Ministry of Environment**

**Delegates from
Ministry of Industry**

It meets....

Indicatively every 2 months

Advisory Committee on PPPs (CCPF)

Consultancy activity – scientific technical opinion
on the following aspects:

Efficacy

*Physico-
chemical
properties*

*Toxicology
(mutagenicity,
carcinogenicity,
teratogenicity)*

*Operator
exposure*

Residues

Ecotoxicology

E-fate

CCPF composition

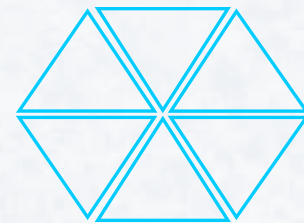
- **Minister of Health or delegate as President**
- **4 Representatives for the Ministries involved**
 - **1 representative for Ministry of Health**
 - **1 for Ministry of Environment**
 - **1 for Ministry of Agriculture**
 - **1 for Ministry of Industry**
- **20 experts**

CCPF composition

20 experts

- **5** appointed by the Minister of Health, for health and toxicological aspects.
- **5** appointed by Minister of Agriculture, for the aspects related to crop protection.
- **5** appointed by Minister of Environment, for the environmental and ecotoxicological aspects.
- **3** from Superior Institute of Health, for chemical, biochemical and toxicological aspects.
- **2** from Superior Institute for Worker's Health and Safety, for the aspects related to hygiene and work medicine.

**TECHNICAL COMMITTEE FOR NUTRITION AND ANIMAL HEALTH
(DPR 44 /2013) INCLUDED ADVISORY COMMITTEE FOR PPP)**



Committee

Chaired by:

**Minister of Health
or his deputy**

Composed by:....

**Experts from
Academic world**

**ISS
Experts**

**INAIL
Experts**

**Representative
of Regions and of
Nation/regions
conference**

**Delegates from
Ministry
of Agriculture**

**Delegates from
Ministry
of Environment**

**Delegates from
Ministry
of Industry**

**Delegates from
Producers and
growers**

**Delegates from
Carabinieri
corp**

**Delegates from
Custom agencies**

MUTUAL RECOGNITION

- **Applications for MR relate to PPPs which did not fall under (EC) Regulation 1107/2009.**
- **However, agreed that it can be acceptable if the PPP has been assessed under Uniform Principles in the MS of origin.**
- **Increasing number of applications.**

MUTUAL RECOGNITION: OPEN POINTS

- **Different rules, requirements, and procedures applied by Member States.**
- **Request for MR of a PPP which got a “me too” authorization in the MS of origin.**
- **Capacity of MSs to respond promptly to the request of another MS for the RR or Re-RR.**
- **Capacity to grant the MR in the timeframe foreseen by the Regulation.**

MUTUAL RECOGNITION IN ITALY

- **Only if the RR or the Re-RR of the MS of origin is available in English, it can be accepted.**
- **RR accepted even if submitted by the applicant.**
- **A copy of the full dossier is required for consultation.**
- **Consultation of National Advisory Committee on PPPs (CCPF) is necessary.**
- **A sworn translation of the label in the MS of origin is necessary.**

Home page Ministry of Health

www.ministerosalute.it

TOOLS AND SERVICES

- Access to **DATA BASE** of authorized PPPs
- Information on Authorizations of PPPs
- Authorization of production plans of PPPs
- Fees
- Guidance to the submission of applications



NEWS

DOCUMENTS

LINKS

LEGISLATION

Data Base

It may be an useful tool for Control Authorities and for the interested parties

For each product it is available:

- **Registration number**
- **Trade name**
- **Date of authorization**
- **Expiry date of the authorization**
- **Hazard indications**
- **Activity**
- **Formulation type**
- **Active substance/s**
- **Content of active substance/s**
- **Parallel imports (IP)**
- **Amateurs products (PPO)**
- **Administrative status of the product**
- **Informazion about the eventual withdrawal**
- **Authorized label**

The database, on-line since 2007, contains records on about 13.000 PPPs accounting the ones authorized, withdrawn, suspended, re-registered or provisionally authorized

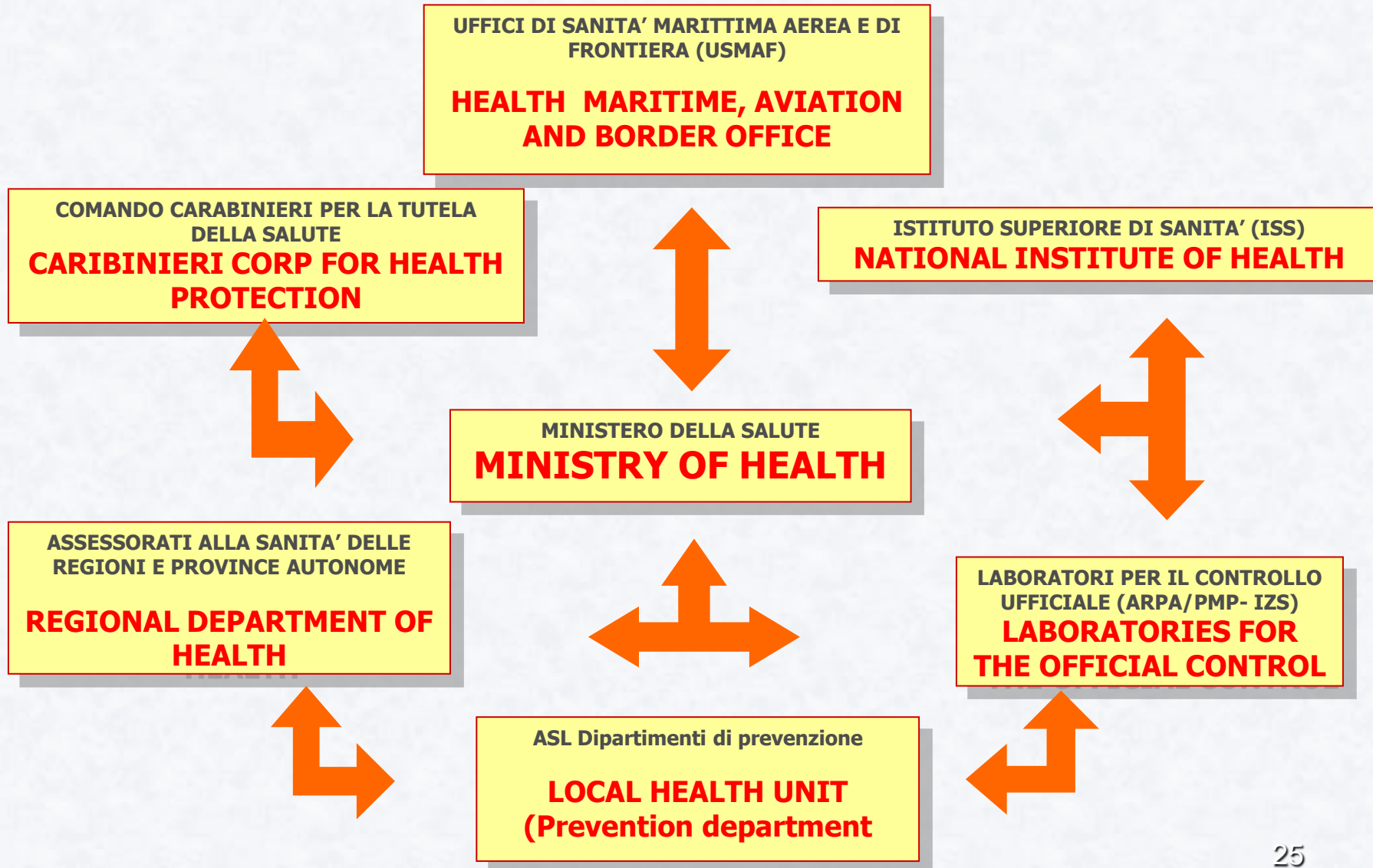
**Control food operators
(first responsible
of food safety):
respect national
and EU rules**

**Health priority to
guarantee
high level of
consumer protection**

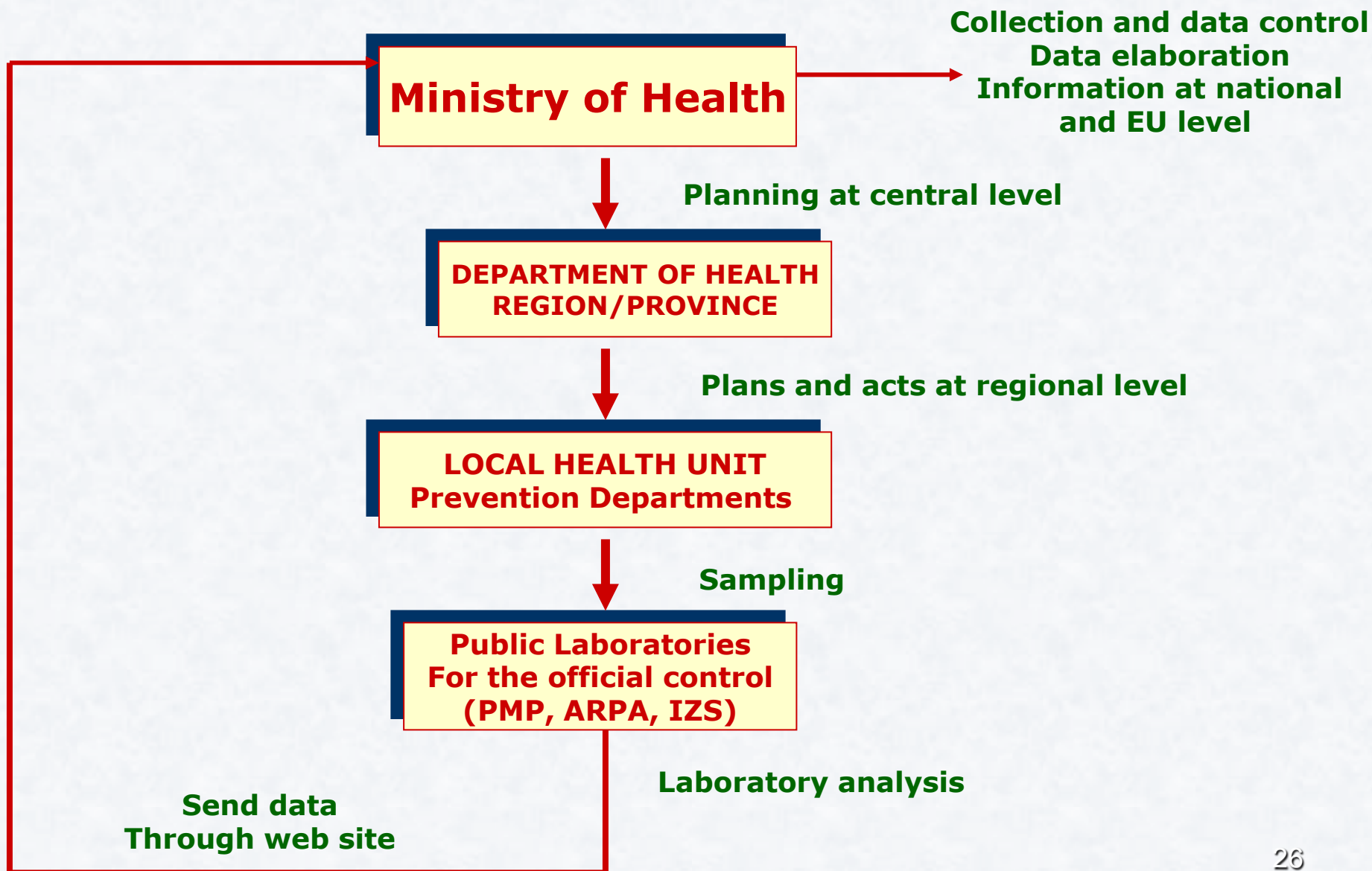
**OFFICIAL CONTROL
ON FOOD PRODUCTS**

**AIM: to verify and guarantee conformity
of food products to disposals act to prevent
public health risks, to protect consumers'
interests and to guarantee transparency
in commercial actions**

Health organisation of the official control system for food products in Italy. PPP area



Planning of the official control – PPP residues



International Centre for Pesticides and Health Risk Prevention



Centro Internazionale per gli Antiparassitari e la
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Dipartimento di Medicina del Lavoro



Ospedale Luigi Sacco
Azienda Ospedaliera
Polo Universitario

HISTORY



Founded in 1990 by the Region of Lombardy on WHO proposal, in co-operation with the University of Milan and in agreement with the Italian Ministry of Health

Mainly funded by the Health Directorate of the Region of Lombardy



28



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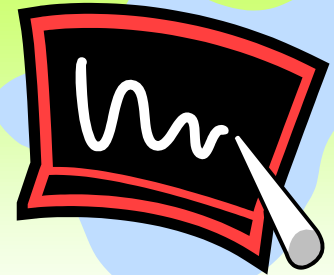
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MISSION



To provide scientific support to preventive and safety programmes in the field of pesticides, both in Europe and other regions of the World

Main area of interest

- **Human and environmental risk assessment of pesticides**
- **Public Health and Prevention**
- **ICPS staff includes biologists, chemists, physicists, toxicologists, occupational health physicians and information specialists**

29



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COLLABORATIONS

The International Programme
on Chemical Safety (IPCS)



Food and Agriculture
Organization of the
United Nations

Sistema Sanitario



Regione
Lombardia



World Health
Organization



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European Food Safety Authority
Committed to ensuring that Europe's food is safe



MINISTERO DELL'AMBIENTE
E DELLA TUTELA DEL TERRITORIO E DEL MARE



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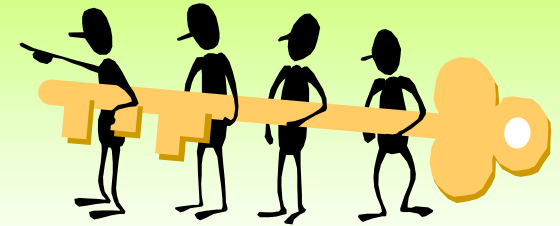


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KEY ACTIVITIES



- 1. advisory and consultation services for the Region of Lombardy and for national Authorities**
- 2. information and documentation**
- 3. research**
- 4. training (EU Master in Risk Assessment & Risk Analysis)**
- 5. organization of conferences and meetings on relevant topics**

31



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COLLABORATION WITH NATIONAL AUTHORITIES (1)



- Contracted by the Italian Ministry of Health to prepare DAR, RAR, DRAR, evaluation report, confirmatory data, equivalence report.... and to follow their discussions at EU level
- Contracted by the Italian Ministry of Health to prepare dRR for zonal registration, technical modifications, extension of uses.... and to follow their discussions at EU level
- Contracted by the Italian Ministry of Health to prepare dRR for national registration

32



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COLLABORATION WITH NATIONAL AUTHORITIES 2



- ICPS experts are members of the National Advisory Committee on Pesticide Products of the Ministry of Health
- Contracted by the Italian Ministry of Environment on specific projects linked to environmental risk assessment and management
- ICPS experts were involved in the definition of the NAP for Directive 128 (Sustainable Use)

COLLABORATION WITH THE REGIONAL AUTHORITY



PESTIDOC (from 1999) –

- ✗ **Implementation and maintenance of a database based on a collection of pesticides (historical value: old and new ones, actual and dismissed products) and ancillary data regarding compounds; crops; chemical and physical characteristics; pesticide producers; data on toxicology, environmental fate, and ecotoxicology; classification; regulatory status, labels.**
- ✗ **Aim: to support the Regional institutional activities.**



COLLABORATION WITH THE REGIONAL AUTHORITY



Fitoweb290 (from 2004)

- ✕ Implementation and maintenance of a web-based database for data collection of pesticides sales in the Region of Lombardy on yearly basis.

Aim: to get estimates of how much each PPP has been used on the territory, and to use these data for the implementation of integrated plans of prevention, and for monitoring.



COLLABORATION WITH THE REGIONAL AUTHORITY



ASTERisk –

- ✗ **Creation of a decision support system (SSD) providing indicators useful to assess risk deriving from pesticide residues in groundwater, food, and working environment.**
 - ✗ **It feeds on data from Fitoweb290, PESTIDOC, and other public EU certified databases.**
- Aim:** to help the Authority to address monitoring and surveillance campaigns.



COLLABORATION WITH THE REGIONAL AUTHORITY



SUSaP (Supplying Sustainable Agriculture Production) Network, 2008-2014 –

- **✕ Collaboration in the realization of a web (on-line) system which provides an yearly updated picture on the real use of plant protection products on the regional territory.**
- **✕ It suggests the best pesticide defence to use on farmer land, according to soil and crop characteristics, to the diffusion and distribution of pests, to agricultural adopted techniques, taking into consideration treatment efficacy, and assessing the global impact on the environment.**
- **✕ It feeds on PESTIDOC.**
- **Aim: to help farmers in the choice of sustainable strategies for use of plant protection products, and to provide the Authority with a detailed register of treatments.**



COLLABORATION WITH THE REGIONAL AUTHORITY



Regional action plan 2014-2015

- ✕ Contribution to the implementation of action plan for SUD at regional level. Recently adopted, First Region in Italy. Mandatory also for EU funding in agriculture

AIM: identify measurements for the sustainable use of PPP, reduction of contamination, education and training.....



Thank you for your attention