

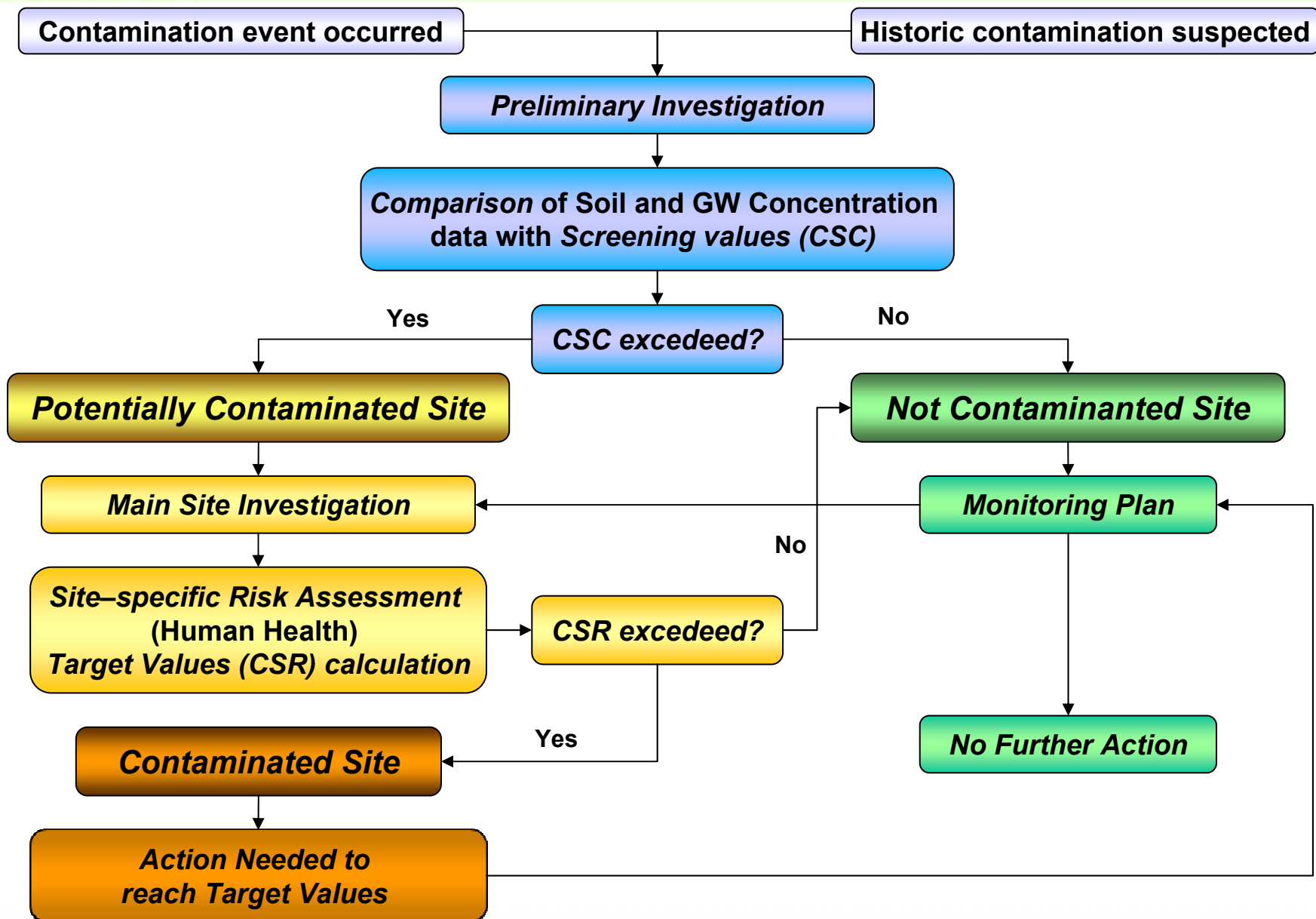
Application of Human-health Risk Assessment in Italy: Regulatory aspects and technical guidelines

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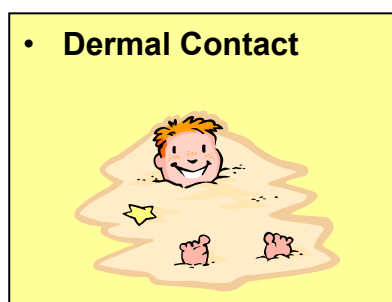
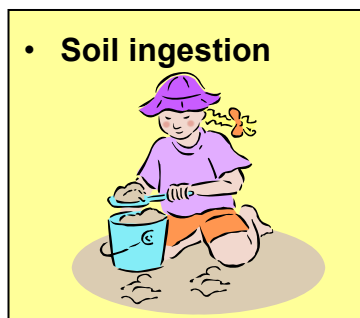
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- Risk Assessment within the new Italian Legislation on Contaminated Sites management (D.Lgs 152/06 - D.Lgs 04/09)
- Criteria for site-specific Human Health Risk Assessment: overview
- Remediation targets evaluation taking into account single and multiple exposure pathways
- Minimum requirements for site-specific input data for Risk Assessment
- Simplified Risk Assessment procedure for Gasoline Stations
- Conclusive Remarks



- With respect to the former Legislation on Contaminated Sites, Risk Assessment is the decision-making criterion for Contaminated Site definition:
 - **Before...** D.M. 471/99 \Rightarrow **'Table comparison'** approach
 - **Now...** D. Lgs. 152/06 – 04/08 \Rightarrow **'Risk Assessment'** approach
- The new Legislation includes a specific Annex I with criteria for Site-specific Human Health Risk Assessment, including:
 - **Acceptable risk criteria:**
 - **Acceptable Carcinogenic Risk (D. Lgs. 04/08):**
 - $R < 1E-6$ for single carcinogenic substance
 - $R < 1E-5$ cumulative value for more carcinogenics
 - **Acceptable Hazard Index (D. Lgs. 152/06 – 04/08):**
 - $HI < 1$ for single non-carcinogenic substance
 - $HI < 1$ cumulative value for more non-carcinogenics
 - **Exposure pathways** to be analysed for **Conceptual Site Model** (following **ASTM RBCA Standards**)
 - **Definitions (D. Lgs. 04/08):**
 - **Compliance Point** for GW assessment
 - **Assessment of 'Risks' for GW resources**

- Legislation is focused on **Human Health protection**, Ecological criteria are not considered.
- **Screening values** (Contamination Threshold Values – CSC) for Soil (industrial/commercial and residential/green use) and GW **are only partly risk-based** for all listed substances (about 100).
- Screening values for **GW** are **tap water drinking standards**
- **Target Values** (Risk Threshold Values – CSR), in many cases, **may be not coherent** with **Screening values** (CSC).
- Many important technical aspects are still missing in Annex 1:
 - How to evaluate effects of **more Exposure Pathways** on the same Target Receptor (**Additive Risks**)



- How to evaluate effects of **more Contaminants** on the same Target Receptor (**Cumulative Risks**)
- **Physical/Chemical** and **Toxicological Parameters** of listed substances and **Fate & Transport** models to be adopted

- In 2005 a Working Group, with the leading role of ISPRA (former National Environmental Protection Agency – APAT), was created for developing harmonized technical criteria for Human Health Risk Assessment in Italy.
- The Working Group includes: ISPRA (former APAT), National Health Institute (ISS), National Institute for Prevention and Safety at Work (ISPESL), 19 (over 20) Regional Environmental Protection Agencies (ARPA/APPA) and 5 Regions. In 2008 National Institute for Energy and Environment (ENEA) joined the WG.



- Human Health Risk Assessment procedure developed according to Tier II ASTM-RBCA Standards.
- Comparison of Fate and Transport models adopted in main Reference Documents and Softwares and selection of the most conservative ones
- Criteria for Site-specific monitoring to validate selected F&T conservative assumptions and revise Risk Assessment results with monitoring data (e.g. vapor intrusion assessment)
- Default values of Exposure parameters on the basis of US EPA documents
- The Manual “Methodological Criteria for Risk Assessment application to Contaminated Sites” was published on June 2005 (rev.0) and updated on July 2006 (rev.1) and March 2008 (rev.2)
- Available (in Italian) on ISPRA website: http://www.apat.gov.it/site/IT/Temi/Siti_contaminati/Analisi_di_rischio/
- Technical support for users: criterimetodologici@isprambiente.it



ASTM E-1739 (USA 1995)
**"Standard guide for Risk Based
Corrective Action Applied at
Petroleum Release Sites-RBCA" .**

EPA (USA 1994)
**"Technical Background Document
for Soil Screening Guidance"**

ASTM PS-104 (USA 1998)
**"Standard provisional guide for
Risk-Based Corrective Action"**

EPA (USA 1996)
**"Soil Screening Guidance: Fact
Sheet".**

UNICHIM
**"Manuale n. 196/1 "Suoli e falde
contaminati, analisi di rischio sito-
specifica, criteri e parametri".**

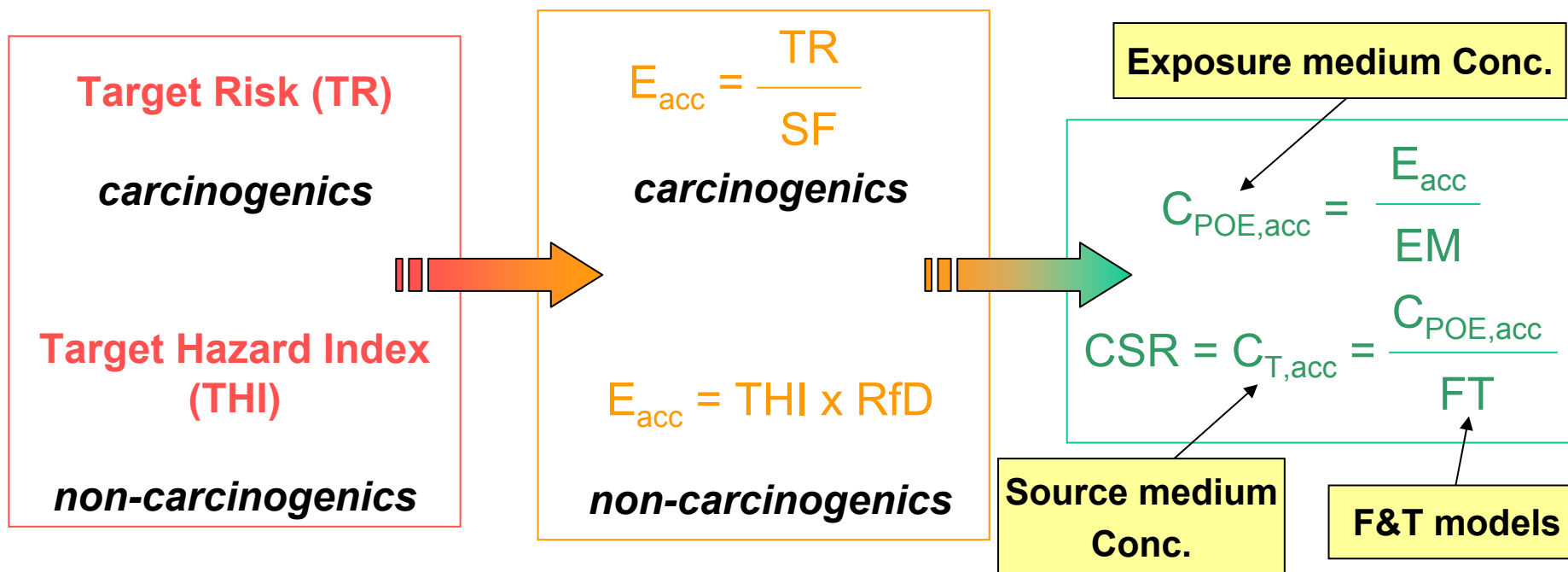
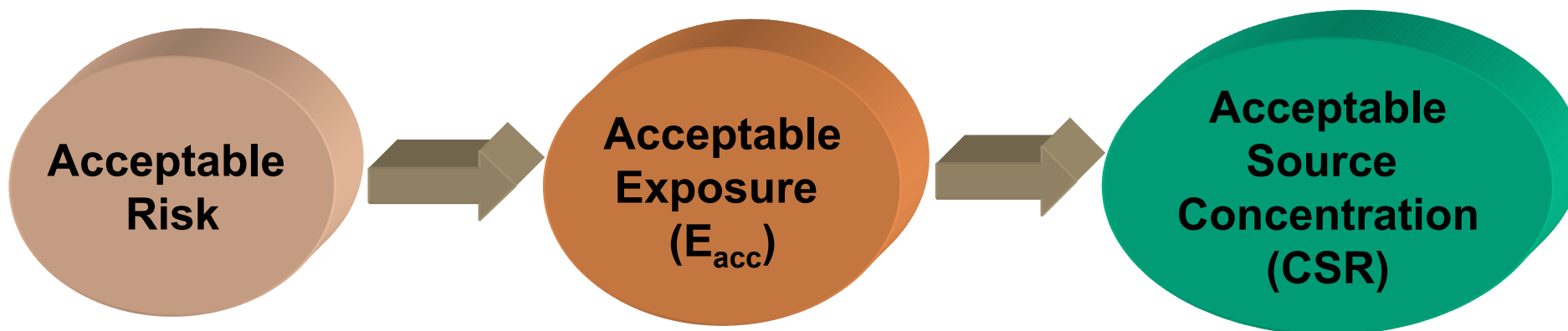
CONCAWE
**"Report 3/03: european oil
industry guideline for risk based
assessment of contaminated
sites ".**

RBCA TOOLKIT ver. 2.0
Groudwater Seirvice Inc. (GSI)
(USA 2008)

BP-RISC ver. 4.0
BP Amoco Oil (UK)

ROME ver. 2.1
Agenzia Nazionale per la
Protezione Ambientale (IT)

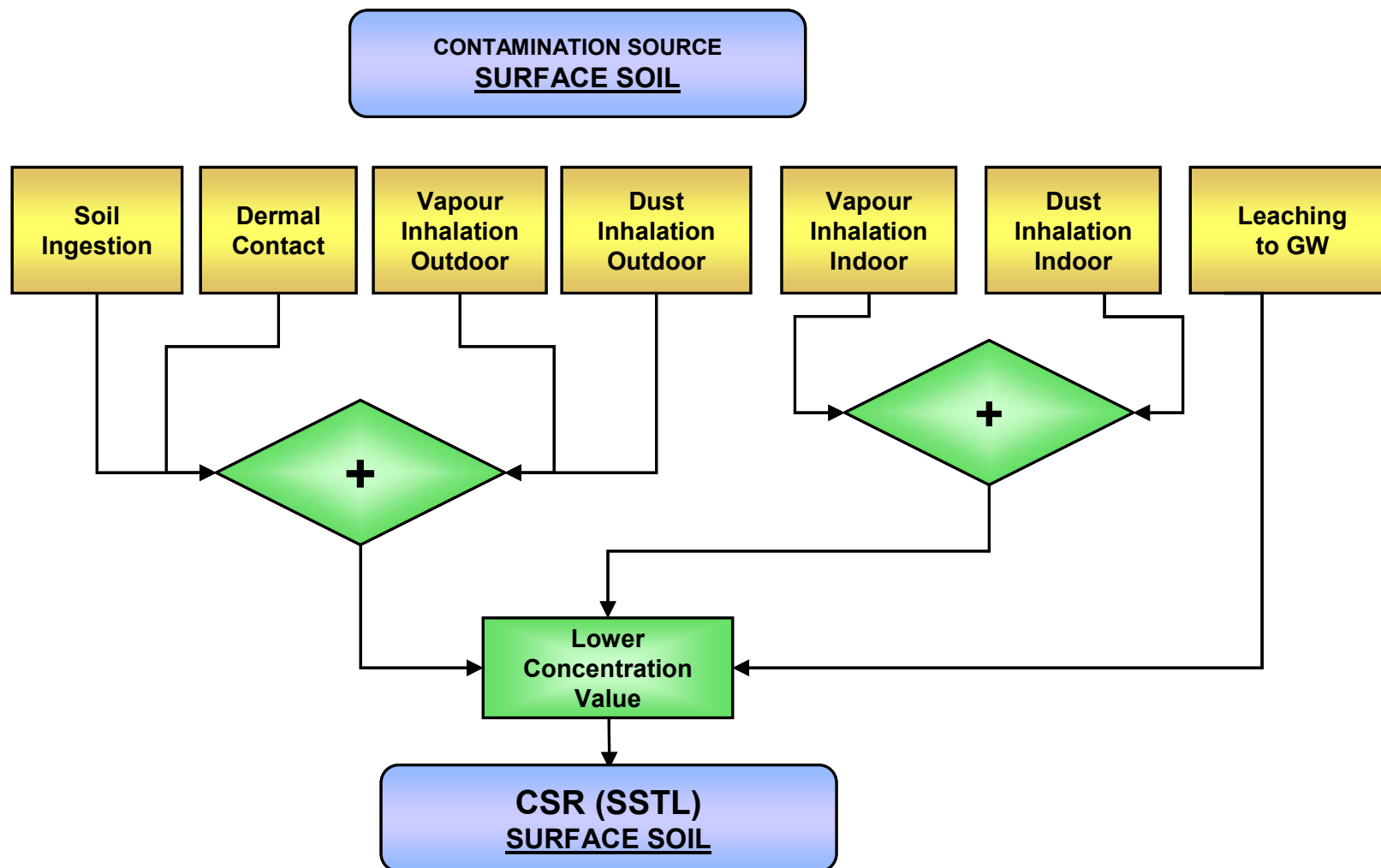
GIUDITTA ver. 3.1
Provincia di Milano (IT 2006)



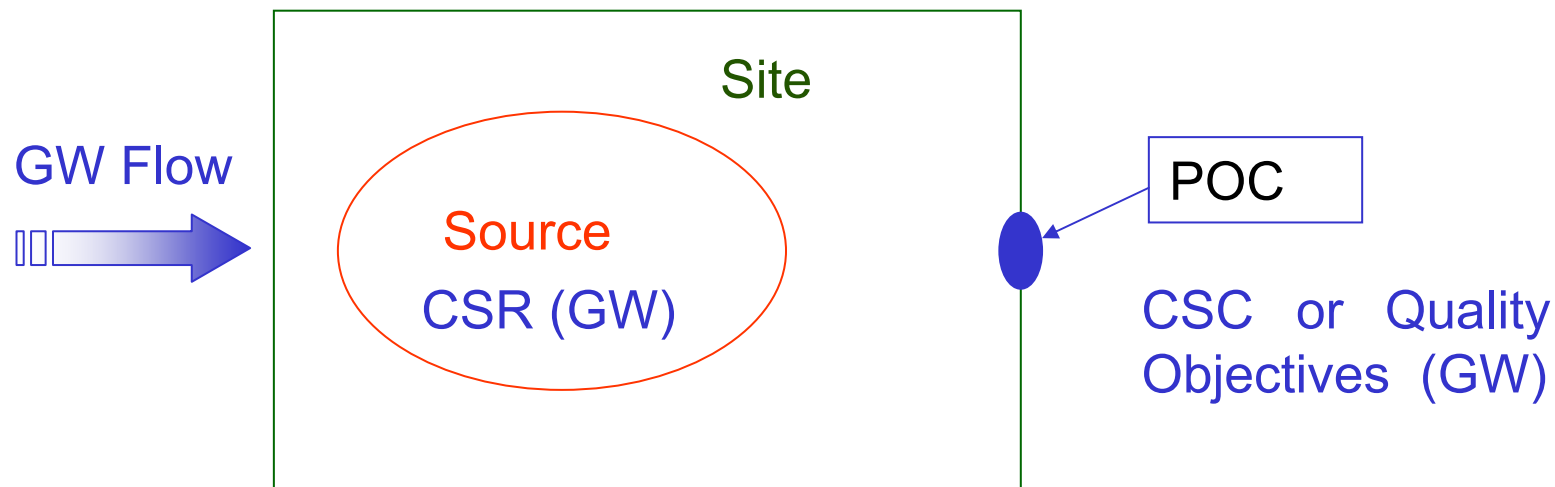
ENVIRONMENTAL MEDIUM SOURCE OF CONTAMINATION	EXPOSURE PATHWAY
<p align="center">SURFACE SOIL (0-1 m from ground level)</p>	<ul style="list-style-type: none"> • Dermal Contact • Ingestion • Outdoor/Indoor Vapour Inhalation • Outdoor/Indoor Dust Inhalation • Leaching to GW - Compliance with quality objectives
<p align="center">SUB-SURFACE SOIL (-1m to water table level)</p>	<ul style="list-style-type: none"> • Outdoor/Indoor Vapour Inhalation • Leaching to GW - Compliance with quality objectives
<p align="center">GROUNDWATER</p>	<ul style="list-style-type: none"> • Outdoor/Indoor Vapour Inhalation • Compliance with quality objectives for GW

- Exposure Concentration (at Point of Exposure–POE) and Source Concentration (CSR) are evaluated for all Exposure pathways included in the Conceptual Site Model;
- The “ingestion of vegetables” pathway is still not included in the Manual, since an integrated procedure for residential/agricultural soil use has not been agreed;

- For Risks and Remediation Targets (CSR) calculation:
 - to integrate the effects of **more exposure pathways** (e.g. ingestion, dermal contact, inhalation):
 - Risks from the same source medium (surface and subsurface soil, GW) may be added up (**Additive Risks**) and the relative CSRs may be harmonically added up; alternatively
 - may be considered the exposure pathway (**Critical Pathway**) with the higher Risks and, consequently, the lower CSR;
 - to integrate the effects of **more contaminants**:
 - Risks of more chemicals from the same source medium may be added up (**Cumulative Risks**) and the relative CSRs may be calculated; alternatively
 - may be considered the contaminant (**Critical Contaminant**) which cause the highest Risks and, consequently the lowest CSR
- Main reference documents and softwares use different procedure for the integration of exposure pathways and of the effects of more contaminants



- According to:
 - **Current Legislation** on Contaminated Sites Management (D.Lgs 04/08);
 - **Recent adoption** into Italian Legislation of the **Directives 2000/60 EC** and **2006/118 EC**;
- at **Point of Compliance** (i.e. site boundary downgradient GW flow) the **quality objectives** for specific groundwater body have to be respected.
- If, for specific water bodies the quality objectives have not yet been fixed, the most sensitive use (**drinking water use**) is considered and the **GW Screening Levels (CSC)** have to be respected at POC



- **Database of Physico-chemical and Toxicological Properties**
- **Reference Document for the Identification and Validation of Site-specific Parameters:**
 - minimum set of input parameters for Risk Assessment to be evaluated on the basis of site-specific measurement;
 - the minimum set of site-specific input parameters has been evaluated through a “sensitivity analysis”.
- **Appendix V: “Application of Risk Assessment at Gasoline stations”:**
 - Gasoline stations are the [principal typology of contaminated sites in Italy](#);
 - Simplified procedures needed for small sites as the majority of Gasoline stations
 - Complex exposure assessment since many Gasoline stations are located in urban areas.
 - In the technical discussion also private stakeholders (Italian Union of Oil Companies) have been involved

Off-site receptors (other than workers):

- Need to evaluate off-site contamination in soil and GW if:
 - GW plume may have passed site boundary;
 - Presence of free product near site boundary downgradient;
 - Potential source of contamination (CSC exceeded) in soil near site boundary
 - Source of spills (underground storage tanks, pipelines, etc.) near site boundary.
- Need to evaluate risks for off-site receptors if potential contamination have been registered off-site.

Simplified procedures:

- Short list of Chemical of Concern for soil and GW (always: BTEXS, TPH, MTBE; in specific cases: PAH, Lead, Tetraethyl Lead, ETBE, Chlorinated Hydrocarbons)
- Exclusion of indoor/outdoor inhalation pathway on the basis of soil-gas monitoring data.
- Screening values proposed for soil-gas concentrations.
- Screening values for TPH concentrations in the unsaturated zone to evaluate the potential presence of free product.
- Exclusion of soil-leaching to GW pathway on the basis of GW monitoring data.



TPH Compounds	Screening values for NAPL presence [mg/kg _{dw}]			
	<i>Coarse gravel</i>	<i>Gravel and coarse sand</i>	<i>Sand</i>	<i>Silt and clay</i>
GRO	1000	1700	3400	10000
DRO	2000	3900	7700	22800
HO	2000	3900	7700	22800
MO	5000	8700	17400	51400

Note: TPH = Total Petroleum Hydrocarbons; DRO = Diesel range organics; GRO = Gasoline range organics; HO = Heavy oil range organics; MO = Mineral oil.

When measured soil concentrations exceed screening values:

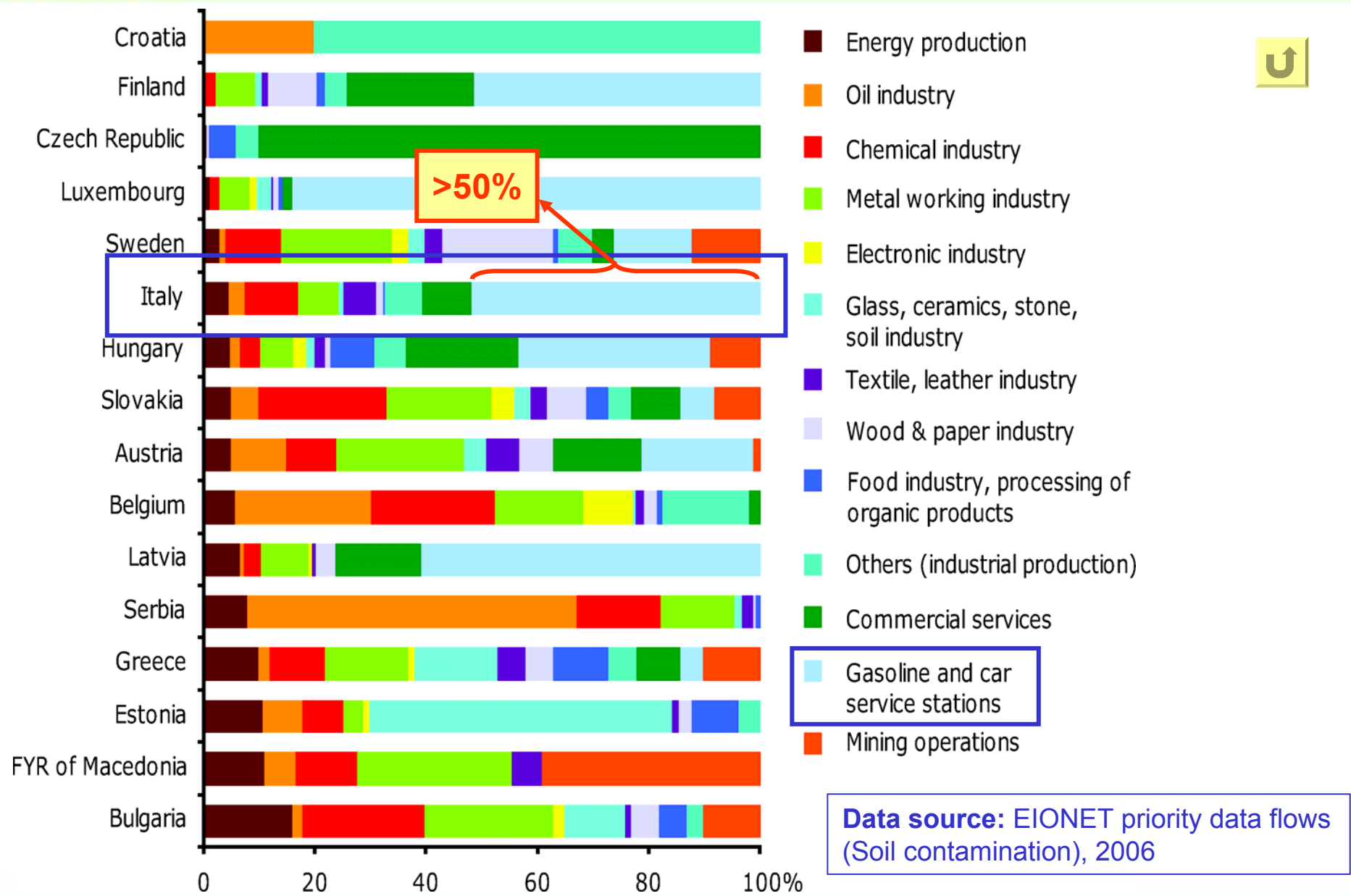
- verify if the free product has reached the water table, and/or
- verify that, if present, the free product has not reached the (smear zone) and/or
- verify if in the proximity of the investigated area, GW values are near the water solubility of specific TPH compounds.

- The Manual “Methodological Criteria” developed by the Italian Working Group on Risk Assessment proposes technical procedures and solutions for many aspects not included in the national technical legislation.
- The cooperation between National research institutes and the Regional environmental authorities (ARPA/APPA) represents an added value in integrating national and local perspectives in contaminated sites management.
- The raising awareness in the application of the Risk Assessment procedure will require more flexibility in the proposed criteria, taking into account site specific peculiarities.
- The Manual is in continuous upgrade, following application experiences and the development of National and European legislation.
- The cooperation with private stakeholders, as in Appendix V on Application of Risk Assessment at Gasoline stations, is envisaged also for the future upgrades of the Manual.
- The work carried out at National level on Human-health Risk Assessment, will contribute to the discussion on the Soil Framework Directive, currently pending approval.

Thank you for your attention!

Questions???





Data source: EIONET priority data flows (Soil contamination), 2006