

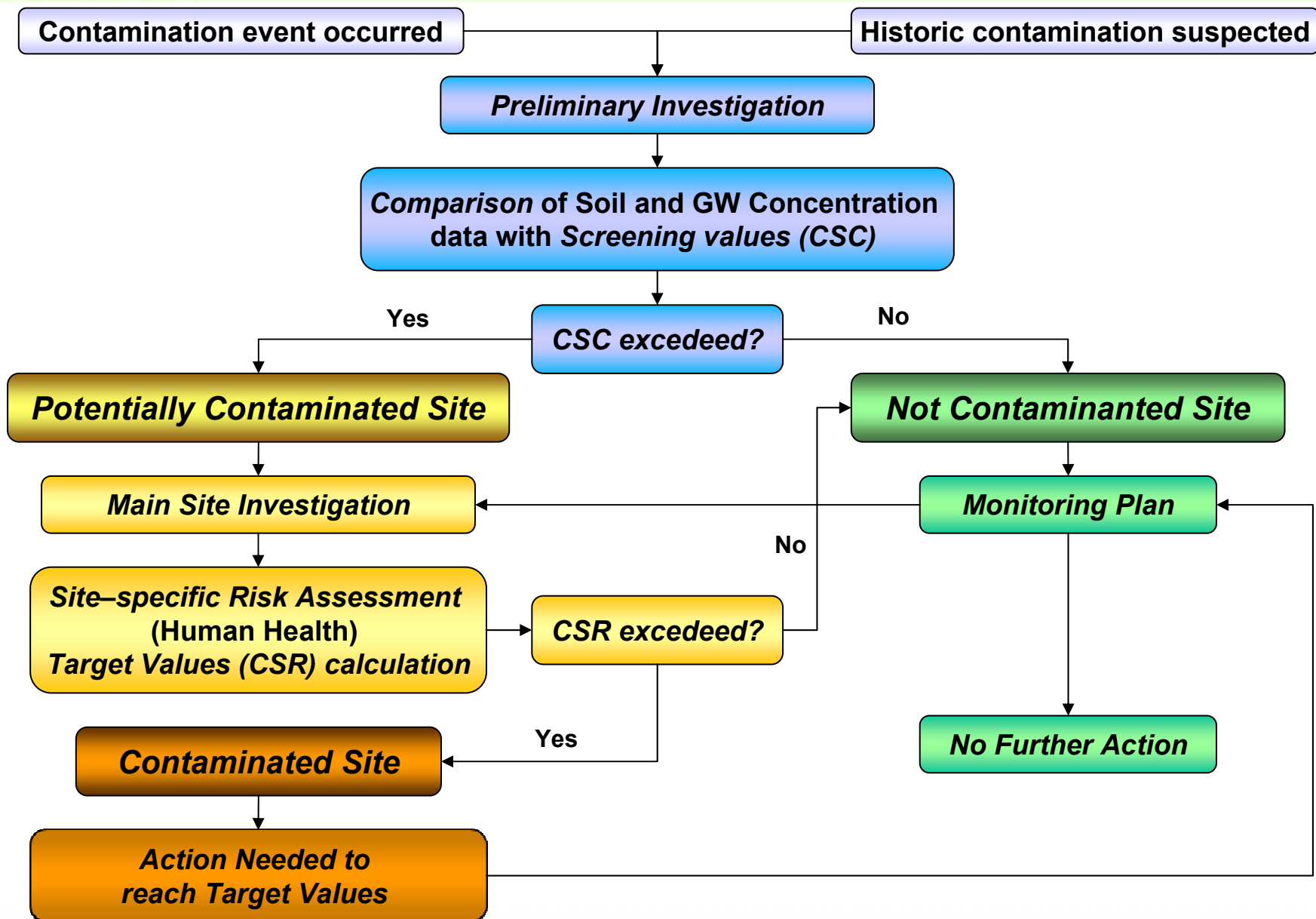
# Application of Human-health Risk Assessment in Italy: Regulatory aspects and technical guidelines

L. D'Aprile, M. Falconi, [A. Vecchio](#)

*ISPRA - National Institute for Environmental Protection and Research  
Italy*

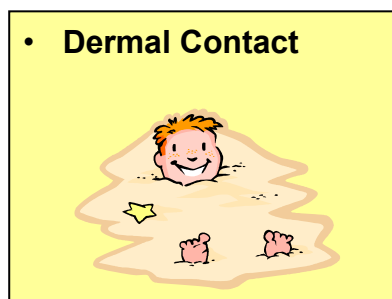
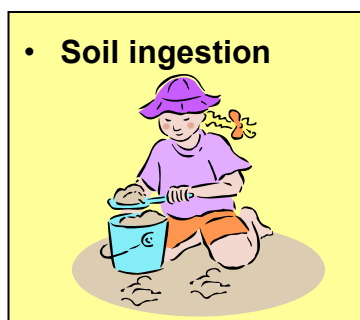
[antonella.vecchio@isprambiente.it](mailto:antonella.vecchio@isprambiente.it)  
[www.isprambiente.it](http://www.isprambiente.it)

- 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/](http://www.apat.gov.it/site/IT/Temi/Siti_contaminati/Analisi_di_rischio/)
- Technical support for users: [criterimetodologici@isprambiente.it](mailto: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 " .**

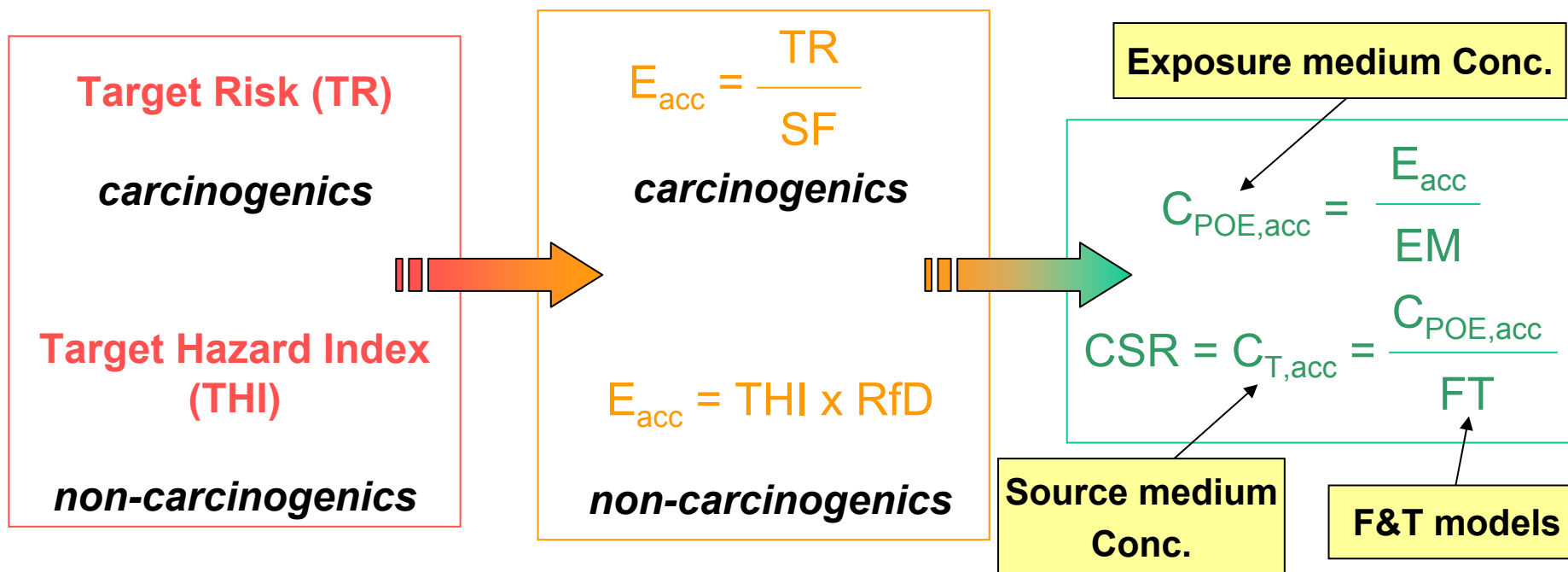
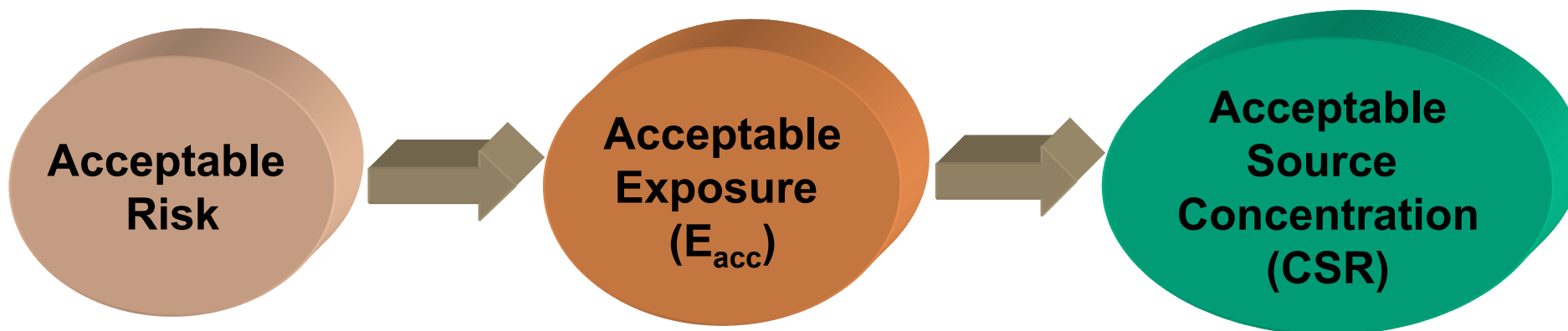


**RBCA TOOLKIT ver. 2.0**  
**Groudwater Seirvice Inc. (GSI)**  
**(USA 2008)**

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

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

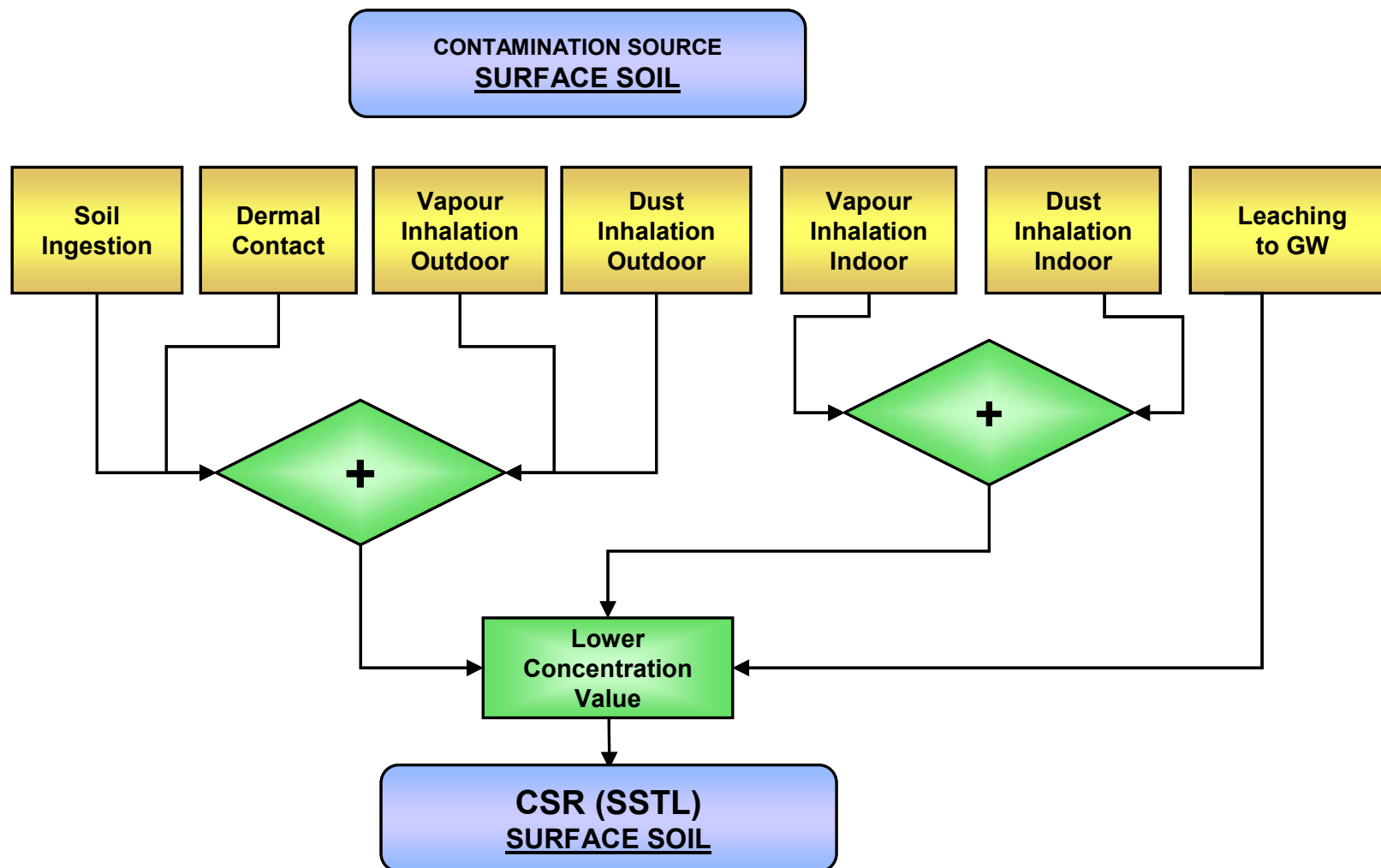
**GIUDITTA ver. 3.1**  
**Provincia di Milano (IT 2006)**



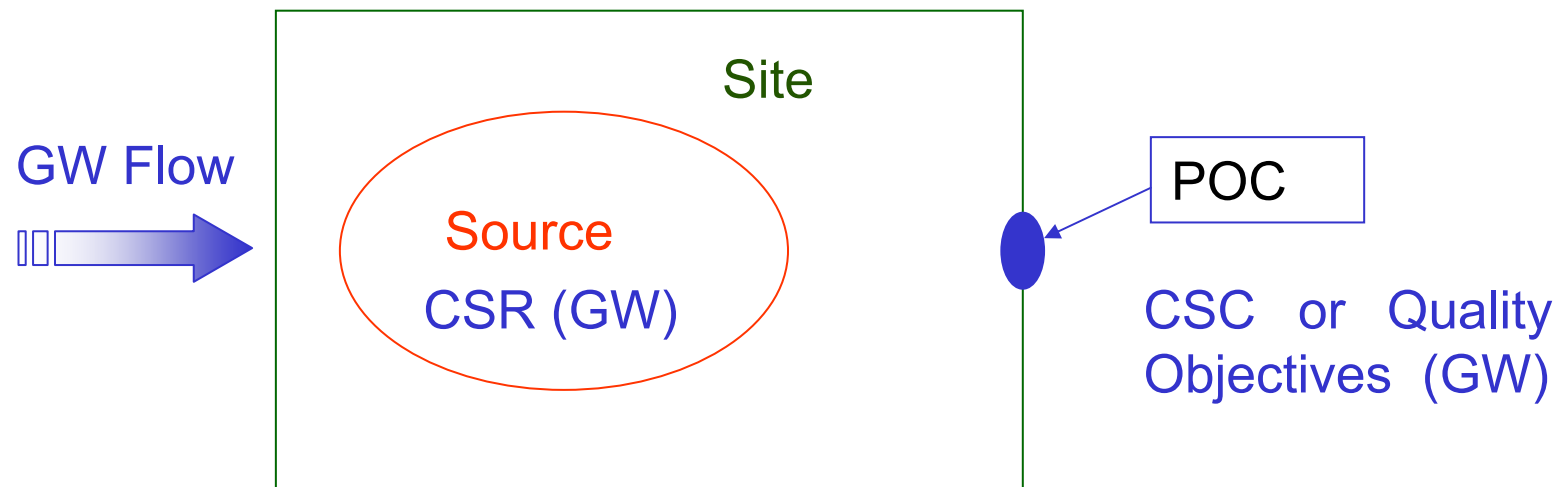
ENVIRONMENTAL MEDIUM SOURCE OF CONTAMINATION	EXPOSURE PATHWAY
<p align="center"><b>SURFACE SOIL</b> (0-1 m from ground level)</p>	<ul style="list-style-type: none"> <li>• Dermal Contact</li> <li>• Ingestion</li> <li>• Outdoor/Indoor Vapour Inhalation</li> <li>• Outdoor/Indoor Dust Inhalation</li> <li>•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

- 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 <sub>dw</sub> ]			
	<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???



