HPC Group & INOGEN Joint Venture Company

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Inogen
Environmental Alliance

MOA-methodology of Risk Assessment and Exposure on Pollutant Cocktails (Agent Orange & Agent Blue, Dioxins, Pesticides, Chloro-phenols, Arsenic)

Méthodologie MOA des évaluations des expositions aux cocktails de polluants : Agent Orange et Agent Bleu, etc. (Dioxines, Pesticides, Chlorophenols, Arsenic)

Frank P.M. KARG / HPC Group

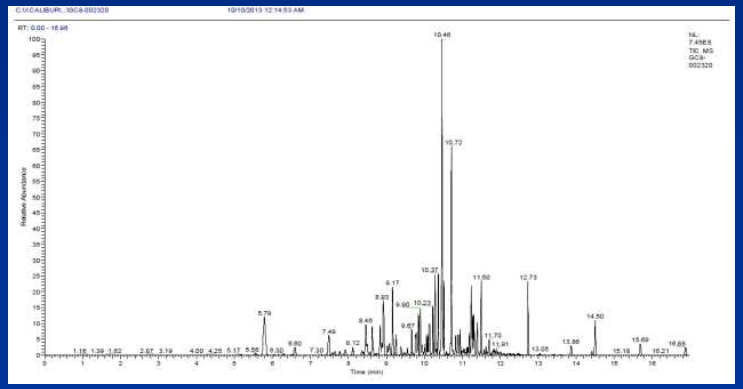
HRA: Health Risk Assessment Methodology Application

Goals:

- **HRA:** Health Risk Assessment for future Site use.
- **Implementation** of Toxicological Exposure Quantification for Industrial Sites, Real Estate & Urbanization Projects, Objects and Products, etc.,
- **Verification of acceptable Risks**.
- **Definition of AC-AR: Acceptable Concentrations for acceptable Risks**: **For ex.: SS-RG: Site specific Remediation Goals, Maximum Product Concentrations,**
- **Transparency of Health Risks concerning Contaminated Sites, Drinking Water, Food Stuff, Cosmetics, Domestic & Professional Objects & Tools, Housing, Transport, etc.**
- **Health, Environment, Legal and financial Budget-Safety.**

Risk Assessments in general

- **First Stage simplified Risk Assessment** (Threshold-Values based on a Generic Health Risk Assessment),
- **Health Risk Assessment** and Definition of Quality Goals for Acceptable Risks (for ex. ICR-Cancer Risk $<10^{-5}$),
- **Certification of Acceptable Toxic Risks and no presence of non-acceptable Risks:**



> Contaminated Sites,
> Drinking Water,
> Surface Water,
> Food Stuff,
> Cosmetics,
> Domestic & Professional Objects & Tools,
> Housing,
> Transport, etc.

HRA: Health Risk Assessment Steps:

1. Identification of all Contaminants, including toxic break down Products, as microbiological Metabolites, etc.,
2. Definition of Site uses & Exposure Scenarios with their specific Exposure Pathways,
3. Calculation of Daily Exposure Doses (mg/kg/day) for Ingestion, Inhalation and dermal Contact
4. Choice of TRD: Toxicological Reference Doses (as RfD, RfC, UR, etc.)

5. Quantification of Risks and Identification of Action Needs and Application of the Additivity Principle per Toxicological Target.
6. Definition of AC-AR: Acceptable Concentrations for acceptable Risks: For ex.: Site specific Remediation Goals.

General Considerations: Risk & Danger :

- **Hazard** of a Pollutant is the posibility of creating toxicolgical (or other) damages.
- **Risk** is the probability of occurrence concerning the toxicological (or other) damages → For example: the Probability of a non-acceptable Toxic Effect.

Hazard / Danger Types	Hazard / Danger (Potential Effect)	
	Effect without Dose-Effect Threshold	Effect with Dose-Effect Threshold
	• Cancergenic, • Mutagenic, • Teratogenic.	• Hepatotoxic, • Nephrotoxic, • Neurotoxic, etc…..
Risk	> or < ICR = 10^{-5}	> or < ADI (etc.)
Gravity	Independent of Dose	Dependent of Dose

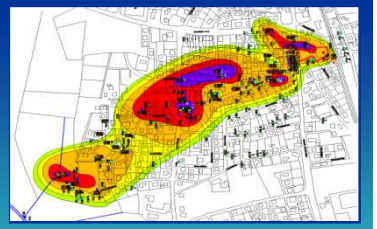
ICR: Individual Cancer Risk ADI: Acceptable Daily Intake (Exposure Dose)

Combined Exposure to multiple Chemicals:

According IPCS & WHO : 2009 etc.(+ lots of other Authors: US-EPA, etc.):

- **Most common Assessment is the Application of Effects Additivity based on Dose Additivity (with dissimilar action), excepted for:**
- **Synergy (interaction) shows Effects greater than Additivity Effects,**
- **Antagonism (interaction) shows Effects less than Additivity Effects.**

  (In this case the slope of the dose-response curve of a Chemical is altered)



Combined Exposure to multiple Chemicals:

According IPCS & WHO : 2009 etc.(+ lots of other Authors: US-EPA, etc.): to be differentiated between:

A. **Aggregate Exposure of a single Chemical via all pathways,**

B. **Cumulative Exposure with combined Risk to multiple Chemicals:**

- **Identification of a Group of Chemicals with the same mechanism of Toxicity (or Target Tissues & Organs) = MOA: Common Toxic Mode of Action**
- **"Dose Addition is assumed for different MOA Subgroups"**

(In this case the slope of the dose-response curve of a Chemical is not altered)

Combined Exposure to multiple Chemicals:

B. Cumulative Exposure with combined Risk to multiple Chemicals:

- Identification of Sub-Groups of Chemicals with the same mechanism of Toxicity (or Target Tissues & Organs) = MOA: Common Toxic Mode of Action

- For ex. Neurotoxicity (including Apopotosis and Necrosis):

  - N1: Inhibition of Cholinesterase,
  - N2: Perturbation of Neurotransmiters,
  - N3: Production of Amyloid Beta 42: Aβ42

Extracellular release of Amyloid β (Aβ) peptides & Increased Production of Aβ42 over Aβ40 and aggregation into oligomers and plaques →
→ Neurodegenerative & Psychiatric disorders : Alzheimer's Disease, Parkinson, etc.

Combined Exposure to multiple Chemicals:

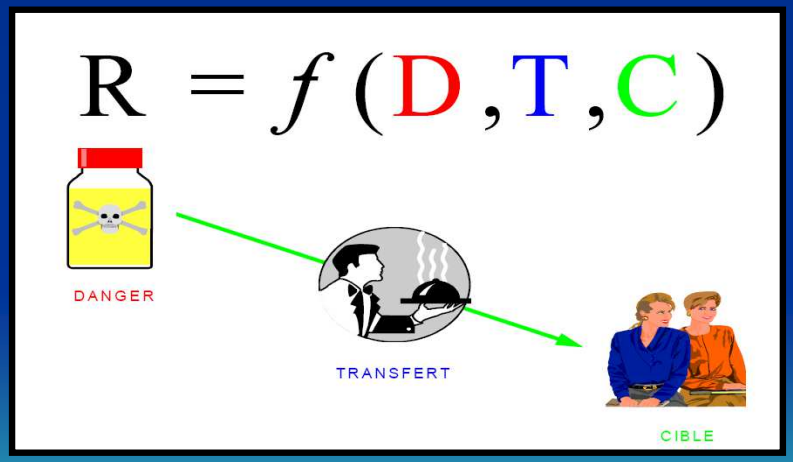
- **Application of Effects Additivity based on Dose Additivity (with dissimilar action):**

  - Addition of Risks from individual Chemicals with the same toxicological mechanism or target:
    - → Risk Index: RI = $Exposure_1/ADI + Exposure_2/ADI + ...$
    - → Individual Cancer Risk: ICR = $Exposure_1 \cdot UR + Exposure_2 \cdot UR + ...$

- **Application of Effects based on Interaction:**
  - Addition of Risks from individual Chemicals with Potency-Correction, for ex. Mixtures with Toxic Equivalent Factors (TEQ), as PCDD/F, PAH, PCB…)
  - Use of Toxicokinetic & toxicodynamic Models (PBTK, ….)

Examples

based on the Additivity Approach per MOA-Group

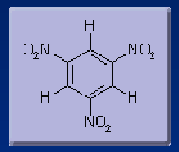


Cancer & genotoxic Effects

Product Safety & Toxicological Mechanisms

Effects without Dose Threshold

Effects with Dose Threshold



CSA
CSR

Cancerous Compound

Genotoxic

Epigenetic

Aneugenic

Clastogenic

Mutagenic

Modification of Chromosome numbers

Modifications of Chromosome Structures

Induction & up-rizing of Mutation Frequency (permanent DNA-modification)

Promotion of Tumeurs without action on DNA

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Acceptable / Unacceptable Risks:

- **Individual Cancer Risk : ICR ≤ 10^{-5}**

  -

ICR = DED • UR

Daily Exposure Dose (mg/kg/d) • Unit Risk or Slope Factor $(mg/kg/d)^{-1}$

- **Non-Cancer-Risk: Risk Index: RI ≤ 1**

RI = DED / TRD

Daily Exposure Dose (mg/kg/d) / Toxic Reference Dose or ADI (mg/kg/d) per toxicological target Organ

HRA: Health Risk Assessment Methodology Application

Acceptable Risks (for ex.: ICR Individual Cancer Risk):

- **WHO:** WHO: World Health Organisation, M. Younes: International Symposium "Exposure and Risk Assessment with Respect to Contaminated Soil", Munich from February 28 & 29/1996: Acceptable Individual Cancer Risk: **ICR = 10^{-5}** (= 1 additional Cancer per 100 000 Persons),
- **Austria:** UBA_{AT}: Umweltbundesamt (2011): Acceptable Cancer Risk: **ICR = 10^{-5},**
- **UK:** DEFRA: Department for Environment, Food and Rural Affairs (2002): Report CLR9TOX1-10: Acceptable Cancer Risk: **ICR = 10^{-5},**
- **Canada:** According HEALTH CANADA (2002) : "Atlantic Provinces" (NS, NB, PEI, and Nfld./Lab.): Acceptable Cancer Risk: **ICR = 10^{-5},**
- **France:** MEDD: Circular from February 08/2007: Acceptable Cancer Risk: **ICR = 10^{-5},**
- **Germany:** Bundesanzeiger BA 161a from August 28/1999 : Toxicological Screening Level (PW) for Acceptable Cancer-Risk: **ICR = 10^{-5}**, Proved intervention level: ICR = $5 \bullet 10^{-5}$
- **Italy:** Décreto 52/2006 from 2006: Acceptable Cancer Risk: **ICR = 10^{-5},**
- **Netherlands:** RIVM (2001): Document 711701 025 Re-Evaluation of Human-Toxicological Maximum Permissible Risk levels: Acceptable Cancer Risk: **ICR = 10^{-5},**
- **Switzerland:** Anhang 1 der Altlastenverordnung (AltlV): BAFU: 31/03/2009 & Art. 2 Verordnung über Belastungen des Bodens (VBBo) SR 814.12 from 01/07/1998 (State 01/07/2008), in Art. 12 of Verordnung über die Sanierung von belasteten Standorten AltlV. from 26/08/98, State 01/08/2011: Acceptable Cancer Risk: **ICR = 10^{-5},**
- **USA:** DOH: Acceptable Cancer Risk: **ICR = 10^{-6} - 10^{-4}**. In the most cases and States an Acceptable Cancer Risk of **ICR = 10^{-5}** is used.
- **Australia, Hong-Kong, Denmark, Japan, New Zeeland, Norway, Sweden: ICR = 10^{-5}** is used.

HRA: Health Risk Assessment Methodology
Application: Steps 2 & 3 : Exposure Pathways & Doses

Analyzing or Modeling of Exposure Milieu Concentrations for Determination of Daily Exposure Doses:

- **HPC created a specific Model Conglomerate, based on:**

→ EC-Modeling recommendations (1994),
→ C-Soil (1999) with modifications to 2007,
→ US-EPA RBCA (2000 - 2015) with modifications,
→ HESP (2001) with modifications to 2007,
→ RISC Workbench 4 & 5 (2004, 2011) with modifications,
→ Johnson & Ettinger (1995 - 2005): Ambient Air,
→ US-EPA (2004) : Skin Contact
→ US-EPA (2005) & UBA-Ger. (2004), AFSSET (2010), UBA-Aut. (2011): Cancer: Kids, ITVA (2015),
+ GW-Modeling (Modflow, Feflow, UMSTD4, etc.)

Model using as Black Box is dangerous !!!
Best Model-Modules must be combined !!!
Transparent Modell Approach is needed. A Model “Monopol” must be avoid !!!

HRA: MOA - Health Risk Assessment Methodology

Example Bien Hoa Air Base:

- **MOA- HRA:**
  Health Risk Assessment
- **Remediation technical-economic Feasibility Study and Cost estimate.**
- **Application of Remediation Technologies:**
  In-situ chemical Dehalogenation & Microbiological Degradation of Dioxins (PCDD/F)

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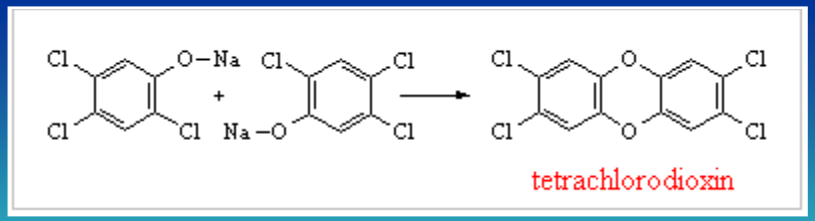
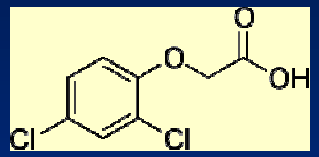
HRA: MOA - Health Risk Assessment Methodology

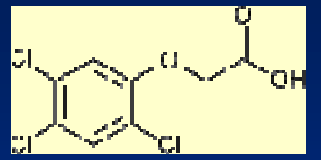
- **Historical Survey**: **Example:** Contaminated Sites by Ranch Hand Mission (U.S.-AF):
- **During the Vietnam War, the U.S.-Air Force sprayed up to 72 million liters of herbicides** over the vegetation, the homes, and the people of Vietnam ("Operation Ranch Hand": 1961 - 1971),
- **Agent Orange was a 50/50 mixture** of two herbicides; **2,4-D and 2,4,5-T**. Orange stripe across the barrels, contains 2,3,7,8-TCCD (tetrachloro-dibenzo-para-dioxine).
- **TCCD-Impurity in Agent Orange Mixtures** from 2,4,5-Trichloro-sodium phenolate use for the 2,4,5-T-Production.
-



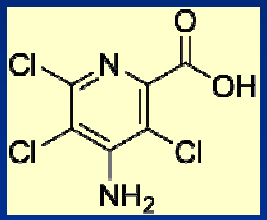
Historical Survey & Pollutant Definition:

- **Agent Orange: 30 x 10^6 liters,**



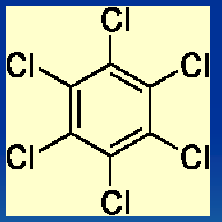


→ 1/1 mixture of 2,4-D (2,4-dichlorophenoxyacetic acid) and 2,4,5-T (2,4,5-trichlorophenoxyacetic acid).



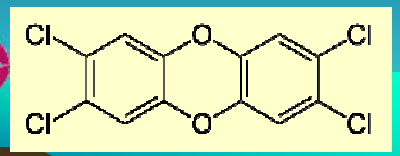
- **Agent White: 17 x 10^6 liters,**

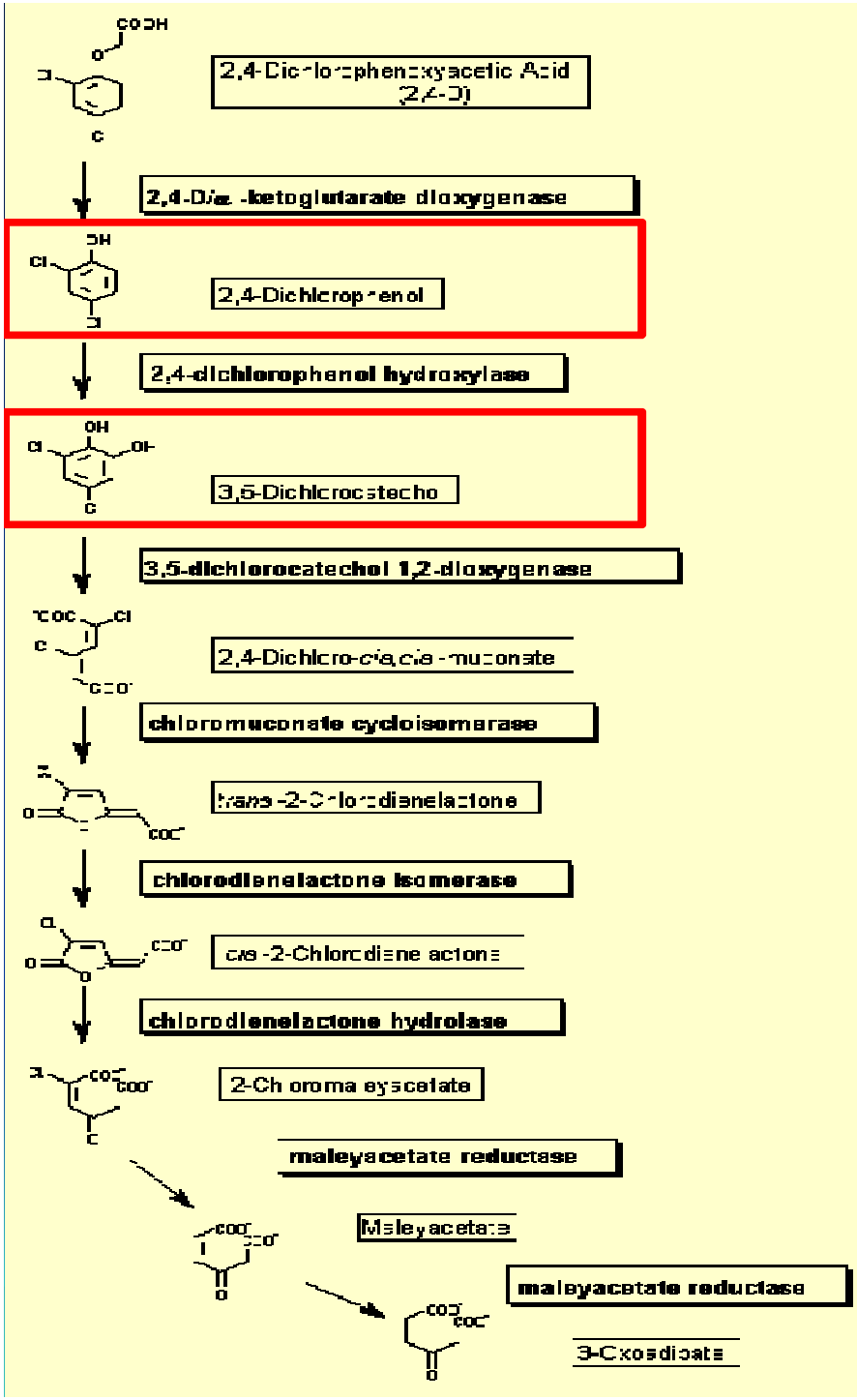
→ Tordon 101 =: 4/1 mixture of 2,4-D and Picloram (4-amino-3,5,6-trichloro-picolinic acid) or tri-isopropanolamine salt of P.(+ about 200 ppm HCB: Hexa-chloro-benzene)



- **Agent Green: 5 x 10^6 liters.**

→ 2,4,5-T (2,4,5-trichlorophenoxyacetic acid) + traces of 2,3,7,8-tetrachloro para dibenzo dioxine (2,3,7,8-TCDD),





Eva C. Young

- **Historical Survey & Pollutant Definition:**

Degradation of 2,4-D:

http://umbbd.msi.umn.edu/2,4-d/2,4-d_map.html

Identification of toxic degradation products (metabolites)

+ 2,4-DCP

+ 3,5-DC-Catechol

- **Historical Survey & Pollutant Definition:**

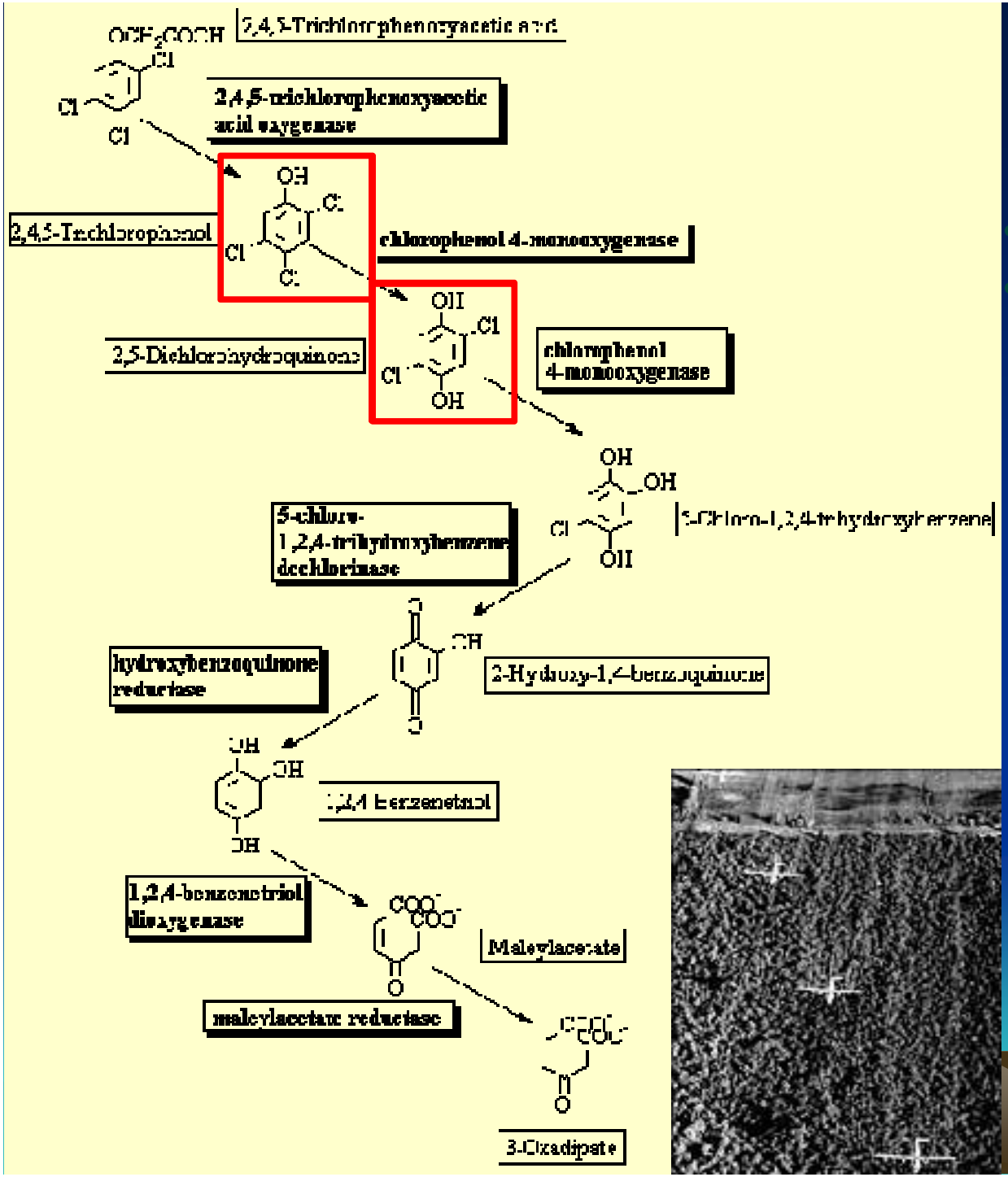
Degradation of 2,4-D:

http://umbbd.msi.umn.edu/2,4-d/2,4-d_map.html

Identification of toxic degradation products (metabolites)

+ 4-CP

+ 4C-Catechol



- **Historical Survey &**
- **Pollutant Definition:**

Degradation of 2,4,5-T

http://umbbd.msi.umn.edu/2,4,5-t/2,4,5-t_map.html

Identification of toxic degradation products (metabolites)

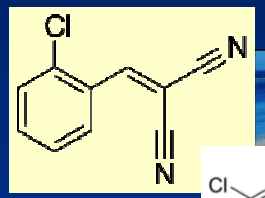
+ 2,4,5-TCP

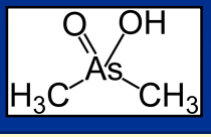
+ 2,5-DC-Hydroquinone

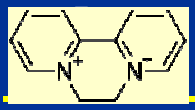
HRA: MOA - Health Risk Assessment Methodology

Other Agents: Used by the US-AirForce in Vietnam

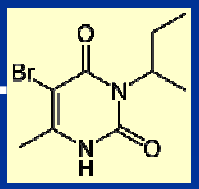
- **Agent Orange: 2,4-D and 2,4,5-T;** used between January 1965 and April 1970.
- **Agent Orange II (Super Orange);** 2,4-D and 2,4,5-T; used in 1968 & 1969.
- **Agent Purple: 2,4-D and 2,4,5-T;** used between January 1962 and 1964.
- **Agent Pink: 2,4,5-T;** used between 1962 and 1964.
- **Agent Green: 2,4,5-T;** used between 1962 and 1964.
- **CS: 2-chlorobenz almalono nitrile (CWA!):** 9 million litres ?
- **Agent White (AW): Picloram and 2,4-D.**
- **Agent Blue: contained Cacodylic acid (arsenic).** 4.74 million litres
- **Dinoxol: 2,4-D- and 2,4,5-T-butoxyethylester;** used 1962-1964.
- **Trinoxol: 2,4,5-T;** used between 1962 and 1964.



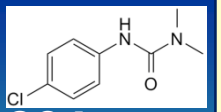


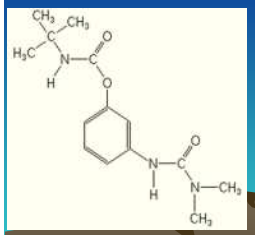


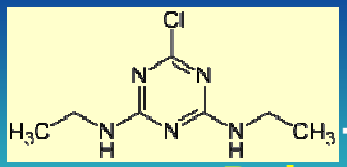
Diquat: used between 1962 and 1964.



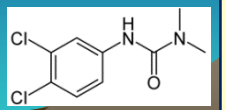
- **Bromacil: Used between 1962 and 1964.**
- **Tandex (simazine and Karbutilate 2:1) : 1962 -1964.**

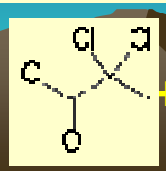






- **Monuron: 1962 - 1964.**
- **Diuron: 1962 - 1964.**
- **Dalapon: 1962 - 1964.**





+ Toxic Metabolites & Impurities……

Diseases:

- Acute and Subacute Transient Peripheral Neuropathy
- AL Amyloidosis
- Chloracne
- Chronic Lymphocytic Leukemia
- Hodgkin's Disease
- Multiple Myeloma
- Non-Hodgkin's Lymphoma
- Porphyria Cutanea Tarda
- Prostate Cancer
- Respiratory Cancers
- Soft Tissue Sarcoma
- Type 2 Diabetes Mellitus

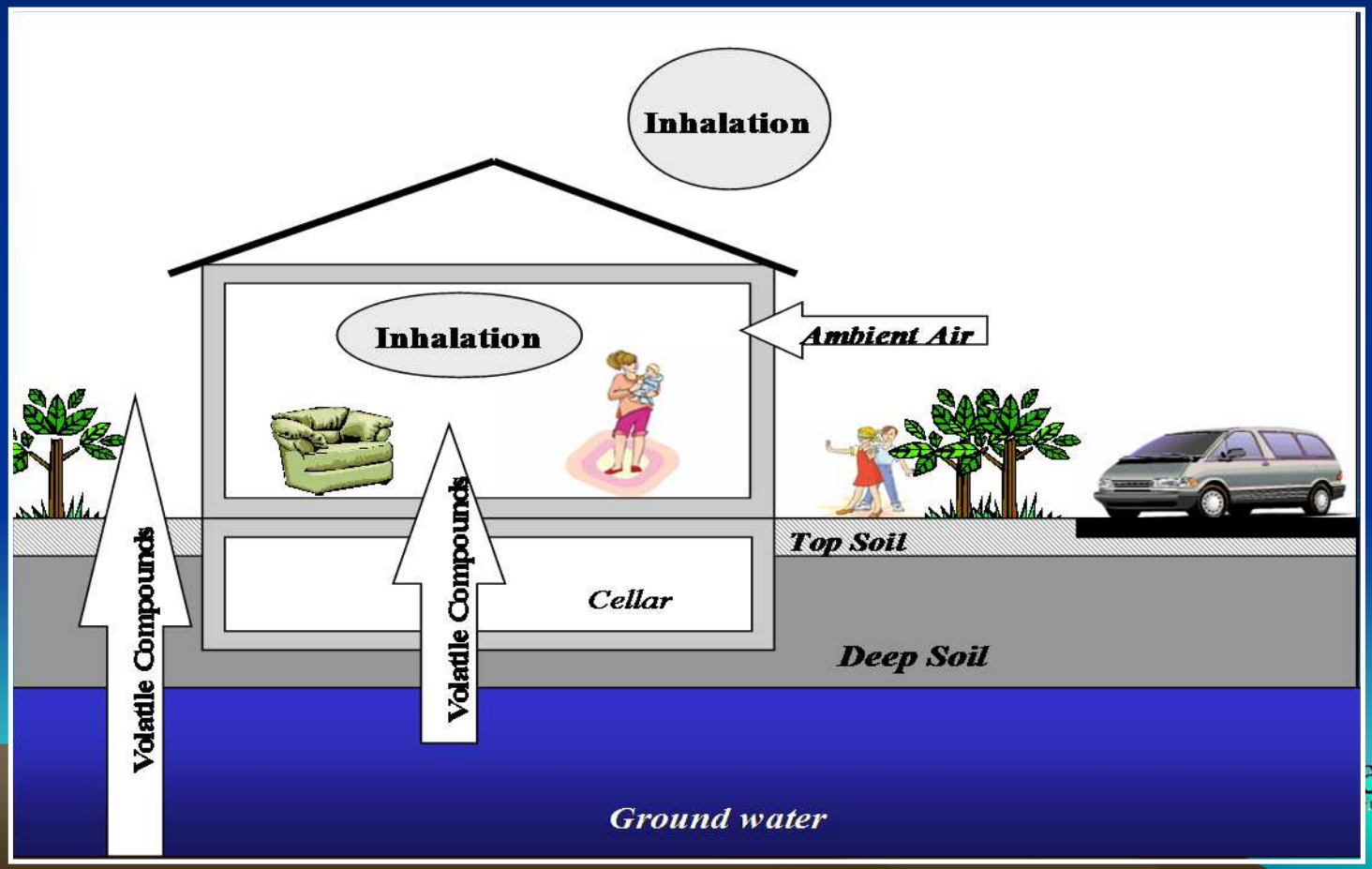
MOA - HRA: Health Risk Assessment Methodology

HRA: Health Risk Assessment: ADI Examples

Substance	Nature du risque	Valeur toxicologique chronique				Espèce	Critère / Facteur de sécurité	Organisme
		Voie d'exposition	Organe(s) cible(s)	Valeur	application d'un FET			
2,3,7,8-TCDD	NC	Ingestion	Systèmes hépatique, neurologique, immunitaire, développement fœtal et thyroïdien	7E-10 mg/kg	-	homme	LOAEL / 30	IRIS 2012
		Inhalation	développement, système immunitaire, cutané, neurologique, hépatique, circulatoire	4E-08 mg/m^3	-	rat	NOAEL / 100	OEHHA 2003
	C	Ingestion	développement, système immunitaire, cutané, neurologique, hépatique, circulatoire	130000 [mg/kg/j]$^{-1}$	-	souris	1	OEHHA 2002
		Inhalation	développement, système immunitaire, cutané, neurologique, hépatique, circulatoire	38000 [mg/m^3]$^{-1}$	-	souris	1	OEHHA 2002
2,4,6-Trichlorophénol	NC		Systèmes cutané, circulatoire, oculaire, hépatique, immunitaire et respiratoire	0,003 mg/kg/j	-	Rat	NOAEL / 100	RIVM 2000
	C	Ingestion		0,011 [mg/kg/j]$^{-1}$	-	Rat	-	IRIS 1994
		Inhalation		0,0031 [mg/m^3]$^{-1}$	-	rat	-	IRIS 1994
2,4-D (acide 2,4-Dichloro-phenoxyacétique)	NC	Ingestion	Systèmes circulatoire, hépatique et rénal	0,01 mg/kg/j	-	rat	NOAEL / 100	IRIS 1988
		Inhalation	-	-	-	-	-	-
2,4,5-Trichlorophenoxy acetic acid	NC	Ingestion	Système rénal et développement fœtal	0,01 mg/kg/j	-	rat	NOAEL / 300	IRIS 1989
		Inhalation	-	-	-	-	-	-

MOA - HRA: Health Risk Assessment Methodology

- **HRA: Health Risk Assessment: Exposure Pathways: Conceptual Scheme**



- **HRA: Health Risk Assessment: Exposure Quantification**

Exposure Quantification: Ingestion of soils, water or food:

$$DED_{ing} = Cm \cdot \frac{Qing}{P} \cdot Fa \cdot \frac{Ex}{Ve} \cdot Fexa \cdot Fexd$$

DEDing = Daily Exposure Dose [mg/kg/d]
Cm = Concentration Pollutants Concentration in the exposure medium : Csoil [mg/kg], Cwater [mg/l], Cfood [mg/kg]
Qi = Ingested Soil quantity and/or food [kg/d] or water [L/d], distinct from the Adults (Qing.A) and the Children (Qing.C)
P(a) = Adult Body Weight [70 kg]
P(e) = Child Body Weight [15 kg]
Fa = Absorption Factor (if failing: 100 % = [1])
Ex = Exposure years in Lifetime (Adult or Child) [y]
Ve = Lifetime: Adult or Child [y]. In case of carcinogenic Pollutants: Ve = Ex [y]
Fexa = Yearly Exposure [d/365 d]
Fexd = Daily Exposure [hrs/24 hrs]

MOA - HRA: Health Risk Assessment Methodology

HRA: Health Risk Assessment Methodology Application

Example: Residential and Recreation site use (Park)

Goal: → Real Estate Revalorization by Remediation

Definition of the exposure pathways

Potential exposure channel	Exposure scenario		Medium considered (HESP® model)
	residential	recreational	
• inhalation of pollutant in gaseous form	YES	YES	(3)
• inhalation of dust on which the pollutant is adsorbed	YES	YES	(1)
• inhalation of contaminated water vapour when taking a shower	YES	NO	(5)
• direct ingestion of soil	YES	YES	(1)
• ingestion of home grown fruits and vegetables	NO	NO	(2)
• ingestion of contaminated water from the supply	YES	NO	(5)
• ingestion of water from a private well	NO	NO	(4)
• absorption of soil and dust through the skin	YES	YES	(1)
• absorption through the skin of pollutant from the contaminated water supply when taking a shower	YES	NO	(5)

(1) : surface layer of the soil corresponding to the horizon (0 - 0.3 m),
(2) : concentration in the soil (0 - 1 m layer) via the air in the soil,
(3) : migration of volatile and semi-volatile pollutants via the air in the soil to the surrounding air,
(4) : well water,

MOA - HRA: Health Risk Assessment Methodology

US- EPA toxic equivalency (TEQ) Factors:

Compound	TEF
Polychlorinated dibenzo-*p*-dioxins (*PCDDs*)	
2,3,7,8-TCDD	1
1,2,3,7,8-PeCDD	1
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.01
OCDD	0.0003
Polychlorinated dibenzofurans (*PCDFs*)	
2,3,7,8-TCDF	0.1
1,2,3,7,8-PeCDF	0.03
2,3,4,7,8-PeCDF	0.3
1,2,3,4,7,8-HxCDF	0.1
1,2,3,6,7,8-HxCDF	0.1
1,2,3,7,8,9-HxCDF	0.1
2,3,4,6,7,8-HxCDF	0.1
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.01
OCDF	0.0003

SCENARIO : Industrial site with Workers on Site (adults only):

Pollutant	Health risk		Pollutant	Health risk	
	Non carcino-genic	Carcinogenic		Non carcino-genic	Carcinogenic
Lead	0.109	-	m,p-xylene	0,167	-
Cadmium	0.00124	0.00081×10^{-5}	o-xylene	0.0422	-
Chrome VI	0	0	Trichloroethylene	**2.5**	-
Chrome III	0.0000227	-	Tetrachloroethylene	0.00624	0.16×10^{-5}
Arsenic	0.0160	0.261×10^{-5}	1,1,1-trichloroethane	0.0713	-
Nickel	0.00109	-	**PCDD/F (total TEQ)**	-	**11×10^{-5}**
Mercury	0.657	-	Naphthalene	**2.62**	-
Zinc	0.000782	-	1,2,3-trimethylbenzene	0.01	-
Selenium	0.000241	-	1,2,3-Trichlorobenzene	0.00175	-
Antimony	0.00270	-	1,3,5-Trichlorobenzene	0.00314	-
Ethyl benzene	0.0000428	-	1,3-Dichlorobenzene	0.0000499	-

tal of carcinogenic risks ICR :	**11.16×10^{-5}**	**Limit value: ICR =10^{-5}**
tal of non carcinogenic risks (*) RI :		**Limit value: RI = 1**
Neurotoxicity: Pb + Hg + tri- & tetrachloro-ethylene + trichloroethane	**3.4(*)**	**Limit value: RI = 1**
Blood toxicity: Pb + As + Zn + Sb	0.129**(*)**	**Limit value: RI = 1**
Liver toxicity: tetrachloroethylene + chloro-benzene + ethylbenzene	0.0625**(*)**	**Limit value: RI = 1**
Fetotoxicity : xylenes	0.209**(*)**	**Limit value: RI = 1**

PCDD/F-Cancer Risk ICR = $11 \cdot 10^{-5}$

Total Cancer Risk ICR = $11 \cdot 10^{-5}$

MOA - HRA: Health Risk Assessment Methodology

HR-Management: Additional Medical Needs:

1. Epidemiological studies, including compilation between Site investigation & Health Risk Assessment Results, Geographical Pathologies and Environmental Chemistry, etc.,
2. Medical Laboratory equipment for sampling PCDD/F-, As-, POP- etc. Analyses in Laboratories in Blood, water, Soil and Food-Stuffs,
3. Medical Laboratory Equipment for Agent-Orange, etc. related Pathology-Diagnostic: Oncology, Neurotoxicity; Hepatotoxicity, Nephrotoxicity, Endocrine disruption, etc.,
4. Bio-Medical-Analysis Equipment (Metabolites, Bio-monitoring Parameters, etc.), X-Ray-Tomography, Magnetic Resonance Nuclear Spin Tomography, Ultrasound-Equipment, Computer- Equipment for interpretation, etc. and trained Staff.
5. Clinical – Therapeutic Equipment (4.2 Million AO-sick People in Viet-Nam ! (Oncology, Neurology, Hepathology, etc.).

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Conclusion 1/2

- **A Site specific HRA:** Health Risk Assessment by consideration of Military Chemistry Pollutants **is possible**
- This can by realized **via the MOA-Methodology: Common Toxic Mode of Action** (if in Minimum the Additivity Approach per Toxicological Target Organ is used for MOA-Groups).
- **This approach was shown** for the Agent Orange & Agent Blue Contaminations by PCDD/F-Dioxins, 2,4-D, 2,4,5-T, Chlorophenols and Arsenic Contaminants **in Vietnam.**

Conclusion 2/2

- Individual Chemical (Regulation) Thresholds or Concentration Limits **can't evaluate** Pollutant Cocktail Risks.
- Exposure Models and Models for Pollutant Transfer Simulation should **not be used as Black Box !**

ZEN ?

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