

Métodos simplificados en el proceso de autorización de sustancias químicas según el reglamento REACH

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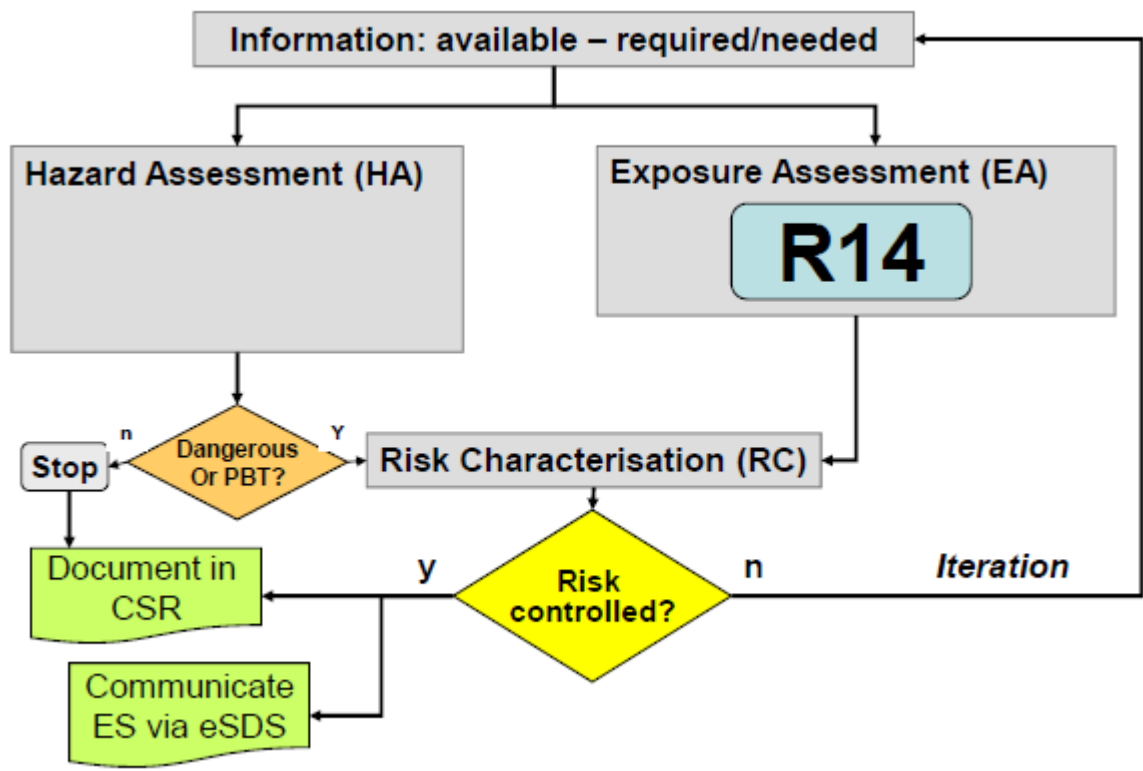
Instituto Nacional de Seguridad e Higiene en el Trabajo.
Centro Nacional de Medios de Protección. Sevilla

Documento de orientación sobre los requisitos de información y sobre la valoración de la seguridad química



**Guidance on
information requirements and
chemical safety assessment**
**Chapter R.14: Occupational exposure
estimation**

VALORACIÓN DE LA SEGURIDAD QUÍMICA (CSA)



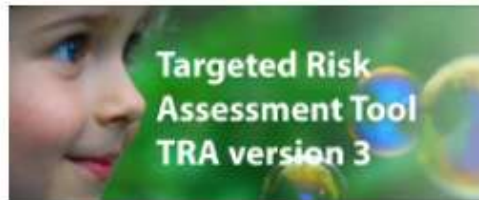
ESTIMACIÓN DE LA EXPOSICIÓN LABORAL (ECHA)

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¿MEDIR O CALCULAR?

Alta	Mediciones (CEN, etc.)	Suficiente para decidir
Media	Similar escenario / Medicion	Cercanos al DNEL
Media- Baja	Modelos	Suficiente si margen amplio
Baja	Medición inapropiada Modelo no aplicable	Insuficiente para decidir

- ◀ Ongoing Task Forces
- ◀ Workshops
- ◀ Symposia and other meetings
- ◀ Contributing to international initiatives
- ◀ Science Awards
- ▶ **Targeted Risk Assessment (TRA) History**



E-team project
ECETOC TRA 2,3
Stoffenmanager
RISKOFLERM
MEASE
EMKG-Expo-Tool

Invitation to join a stakeholder group with an interest in worker exposure assessment models under REACH

Introduction

The ECETOC Targeted Risk Assessment (TRA) tool was launched in 2004. The TRA consists of 3 separate models for estimating exposures to workers, consumers

TRA version 3 downloads

Download
Consumer Tool



Consumer Tool user ma

Download
Integrated Tool



Integrated Tool user ma

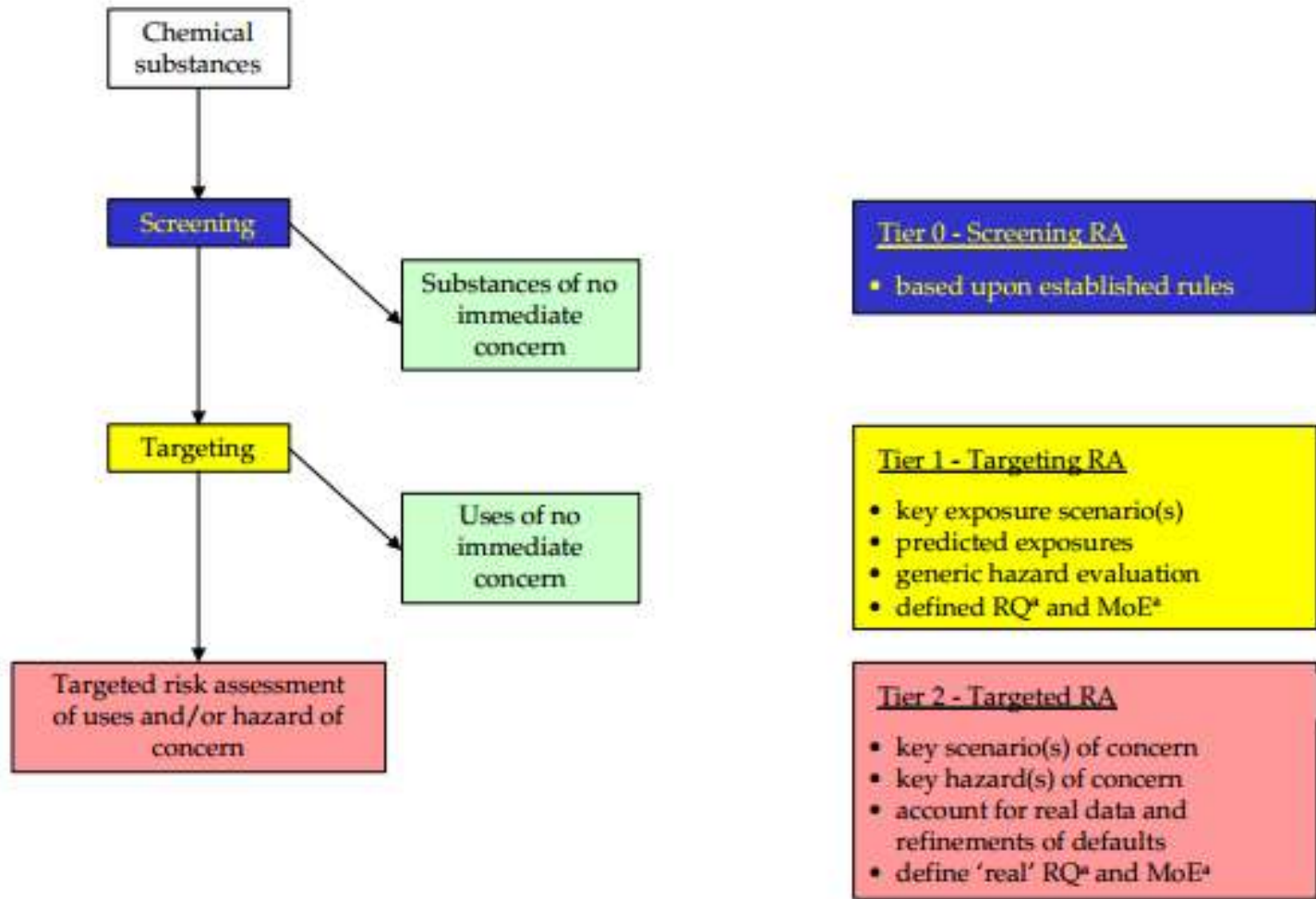
Fortalezas

- Estructura clara
- Información sobre el proceso (process categories (PROCs)) basado en otros apartados de la guía ECHA y usados en la aplicación CHESAR
- Incluye vía inhalatoria y dérmica
- La duración de la actividad/proceso/operación se tiene en cuenta
- Datos basados en el modelo EASE y en información experta de las partes interesadas
- La eficacia de la ventilación localizada tiene en cuenta el tipo de proceso y el uso (profesional o industrial)
- También tiene en cuenta la proporción de la sustancia en el preparado para el cálculo de la exposición inhalatoria
- La reducción de la exposición inhalatoria por el uso de RPE se tiene en cuenta
- Los resultados pueden ser guardados
- Se pueden calcular múltiples situaciones simultáneamente

Limitaciones

- No siempre es fácil distinguir entre uso profesional e industrial
- La cantidad de producto usada no tiene influencia
- Limitadas posibilidades de elección en condiciones operacionales (Ocs) y medidas de gestión del riesgo (RMM; e.g. no es posible distinguir entre un proceso automatizado y uno manual
- No tiene en cuenta la proporción de la sustancia en el preparado para el cálculo de la exposición dérmica, ni está considerada para sólidos
- No incluye EPI para reducir la exposición dérmica
- El tipo de EPIR no está especificado para la reducción de la exposición dada
- La exposición dérmica con extracción localizada está infraestimada, comparándolo con el modelo RISKOFDERM.

ECETOC TRA. ESQUEMA



ECETOC TRA. ESQUEMA. TIER 0

DATOS

- El principal uso;
- propiedades físico-químicas;
- presión de vapor(o pulverulencia, para sólidos)
- estado físico
- producción anual de la sustancia

ECETOC TRA. ESQUEMA. TIER 0

Vapour pressure (hPa)	Dustiness	Availability banding
<5	Not dusty	Minimal
5-10	Slightly dusty	Low
10 - 100	Dusty	Medium
>100	Very/extremely dusty	High

Table 2: Exposure potential for minimal band availability substances

Main category of use (TGD)	Annual tonnage					
	1-10	10-100	100-1,000	1,000-10k	10k-100k	>100k
Intermediate used on site (non-isolated and isolated)						
Isolated intermediate used/stored off site		Minimal				
Included into or onto a matrix						
Non-dispersive use - professional				Low		
Wide dispersive use						

Table 3: Exposure potential for low band availability substances

Main category of use (TGD)	Annual tonnage					
	1-10	10-100	100-1,000	1,000-10k	10k-100k	>100k
Intermediate used on site (non-isolated and isolated)						
Isolated intermediate used/stored off site		Minimal				
Included into or onto a matrix						
Non-dispersive use - professional					Low	
Wide dispersive use						Medium

Table 4: Exposure potential for medium band availability substances

Main category of use (TGD)	Annual tonnage					
	1-10	10-100	100-1,000	1,000-10k	10k-100k	>100k
Intermediate used on site (non-isolated and isolated)	Minimal					
Isolated intermediate used/stored off site						
Included into or onto a matrix			Low			
Non-dispersive use - professional						
Wide dispersive use						Medium

Table 5: Exposure potential for high band availability substances

Main category of use (TGD)	Annual tonnage					
	1-10	10-100	100-1,000	1,000-10k	10k-100k	>100k
Intermediate used on site (non-isolated and isolated)	Minimal					
Isolated intermediate used/stored off site						
Included into or onto a matrix			Low			
Non-dispersive use - professional					Medium	
Wide dispersive use	Low		Medium			High

ECETOC TRA. ESQUEMA. TIER 0

Risk phrase	Classification	Descriptor	Hazard category
	Unclassified ^a		Low
R20	Harmful	Acute toxicity inhalation	Low
R21	Harmful	Acute toxicity dermal	Low
R22	Harmful	Acute toxicity oral	Low
R65	Harmful	Aspiration	Low
R67	Harmful	Drowsiness	Low
R36	Irritant	Irritation eye	Low
R37	Irritant	Irritation respiratory system	Low
R38	Irritant	Irritation skin	Low
R66	Irritant	Irritation skin (repeated)	Low
	Unclassified or classified as acutely harmful or irritant and no information on repeated dose toxicity		Medium
R48	Harmful	Prolonged exposure	Medium
R40	Harmful	Carcinogen Cat.3	Medium
R68	Harmful	Mutagen Cat.3	Medium
R62, R63	Harmful	Reproduction Cat.3	Medium
R23	Toxic	Acute toxicity inhalation	Medium
R24	Toxic	Acute toxicity dermal	Medium
R25	Toxic	Acute toxicity oral	Medium
R39	Toxic	Irreversible effects	Medium
R43	Irritant	Sensitisation: skin	Medium
R41	Irritant	Severe eye irritation	Medium
R34, R35	Corrosive	Corrosion	Medium
R42	Harmful	Sensitisation/inhalation	High
R48	Toxic	Prolonged exposure	High
R45, R49	Toxic	Carcinogen Cat.1, 2	High ^b
R46	Toxic	Mutagen Cat.1, 2	High ^b
R60, R61	Toxic	Reproduction Cat.1, 2	High ^b
R26	Very Toxic	Acute toxicity inhalation	High
R27	Very Toxic	Acute toxicity dermal	High
R28	Very Toxic	Acute toxicity oral	High

^a Based on data (at minimum information requirements as described in [Appendix D](#)) and sufficient information on repeated dose toxicity.

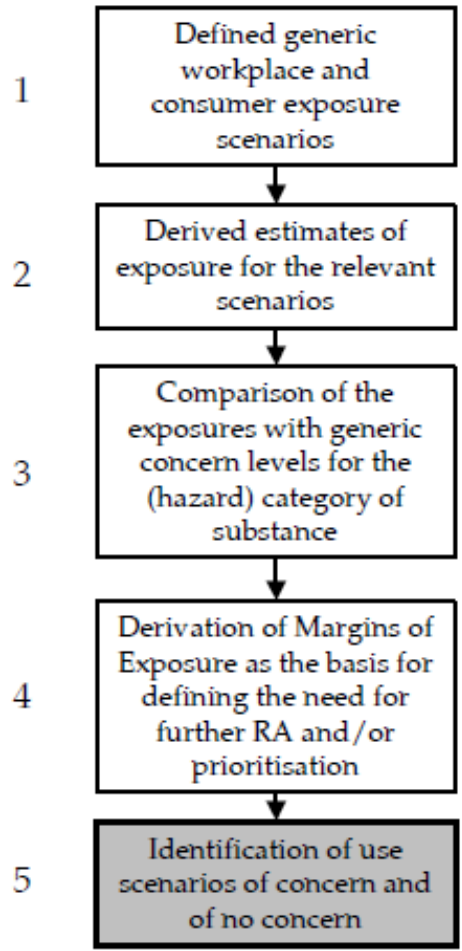
^b Substances classified R45, R49, R46, R60 or R61 are of very high concern.

ECETOC TRA. ESQUEMA. TIER 0

Table 7: Tier 0 risk matrix

Hazard potential	Exposure potential			
	Minimal	Low	Medium	High
Low	No immediate concern	No immediate concern	Higher tier RA	Higher tier RA
Medium	No immediate concern	Higher tier RA	Higher tier RA	Higher tier RA
High	Higher tier RA	Higher tier RA	Higher tier RA	Higher tier RA

ECETOC TRA. ESQUEMA. TIER 1



ECETOC TRA. ESQUEMA.

TIER 1

APPENDIX G: DESCRIPTION OF WORKPLACE EXPOSURE SCENARIOS FOR USE AT THE TIER 1 LEVEL

Scenario	Description	Significant dermal exposure?	Assumptions concerning dermal exposures
Use in a closed process with no likelihood of exposure	The use of the substances in a high integrity contained system where little potential exists for exposures, e.g. any sampling is via closed loop systems.	No	None
Use in closed process with occasional controlled exposures, e.g. during sampling	A continuous process but where the design philosophy is not specifically aimed at minimising emissions. It is not high integrity and occasional exposures will arise, e.g. through maintenance, sampling and equipment break-downs.	No	Significant dermal exposure only likely to arise from break-downs and maintenance. Routine elevated exposure expected to be low.
Use in a closed batch process, i.e. where only limited opportunity for breaching arises, e.g. sampling	Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, e.g. through enclosed transfers, but where some opportunity for contact with chemicals occurs, e.g. sampling	No	Sampling unlikely to give rise to significant exposures.
Use in a batch or other process (including related process stages, e.g. filtration, drying) where opportunities for exposure arise, e.g. sampling, discharging or charging of materials	Use in the batch manufacture of a chemical where significant opportunity for exposure arises, e.g. during the charging, sampling or discharge of materials, and when the nature of the design can reasonably be predicted to result in exposures.	Yes	Two hands, face only (480 cm ²) assumed.
Use in a batch process including chemical reactions and/or the formulation by mixing, blending or calendaring of liquid and solid-based products	The manufacture or formulation of chemical products or articles using technologies related to mixing and blending of solid or liquid materials and where the process is in stages or provides the opportunity for significant contact at any stage.	Yes	Two hands, face only (480 cm ²) assumed.
Spraying of the substance or preparations containing the substance in industrial applications, e.g. coatings	Spray applications of a substance or preparations containing it, e.g. paints, adhesives, lacquers. Also includes uses where substantial thermal or kinetic energy is applied to the substance, e.g. welding or grinding.	Yes	Two hands and forearms (1,500 cm ²) assumed.

Extracción localizada + duración

Medidas organizativas + EPI (distinta de guantes o gafas): TIER 2

Incorporación de mediciones reales: TIER 2



Agrochemicals

Biocides

> Industrial Chemicals
– REACH

Services

Background

> Recent projects
and references

Links

Classification and
Labelling

Safety Data Sheets

home

contact

imprint

links

Experience gained in
previous risk
assessment of Existing
Chemicals

Major projects
completed under REACH
(2010)

HERAG

ART

> MEASE

Dermal Absorption

Industrial Chemicals – REACH | Recent projects and references

MEASE - The Metals' EASE

MEASE - Occupational Exposure Assessment Tool for REACH

Downloads

01 - MEASE documentation



/PDF

reach-clp helpdesk

CONTACT
SITEMAP
LEGAL INFORMATION

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search item

START SEARCH
ADVANCED SEARCH

▶ [Homepage](#) ▶ Exposure estimate at the workplace

-A A+ font size

- + REACH-Regulation
- + CLP-Regulation
- + **Exposure estimate at the workplace**
- + Emergency telephone number

Questions to the REACH-CLP Helpdesk?
The service telephone can be contacted from Monday to Friday, from 8 a.m. to 4.30 p.m., on ☎ + 49 231 9071 2971 (BAuA Information Centre)

Exposure estimate at the workplace

EMKG-EXPO-TOOL



The EMKG-EXPO-TOOL is part of the "Easy-to-use workplace control scheme for hazardous substances" (EMKG "Einfaches Maßnahmenkonzept für Gefahrstoffe") of the Federal Institute for Occupational Safety and Health (BAuA). Within the context of REACH the BAuA-Unit 4.1 -Occupational Exposure- offers an IT-tool free of charge for a first exposure estimate at the workplace. This Tier 1 assessment is **only valid for inhalation exposure.**

Download

[EMKG-EXPO-TOOL \(xls, 465 KB\)](#)

German EMKG-Expo-Tool

- Define tres variables que el COSHH no utiliza: Duración de la actividad, cantidad efectiva y duración efectiva del contacto
- Introduce criterios más completos para evaluar las medidas de control que ya han sido implementadas
- Tiene en cuenta la exposición dérmica

Fortalezas

- Clara y sencilla herramienta
- Se tiene en cuenta la cantidad manejada
- Define tres variables que el COSHH no utiliza: Duración de la actividad, cantidad efectiva y duración efectiva del contacto
- Introduce criterios más completos para evaluar las medidas de control que ya han sido implementadas
- Tiene en cuenta la exposición dérmica
- Las fichas de control están disponibles

Limitaciones

- Las partes de evaluación no están visibles para el usuario.
- Las posibilidades de elección son limitadas. Por ejemplo se asume 100 % de la concentración de una sustancia en el producto
- No válido para gases (manejados o producidos) ni para aerosoles generados de composición desconocida
- No válido para CRM

METODOLOGÍAS SUPERIORES

- **Stoffenmanager**
- **RISKOFDERM**
- **ART**

[My Scenarios](#)[Science](#)[Support](#)[Training](#)[Consortium](#)[English](#) | [Deutsche](#) | [Français](#) | [Nederlands](#)

Welcome to the Advanced Reach Tool 1.0

Chemical Safety Assessments can be complex and time consuming. While Tier I models estimating exposure are available, should they be unable to show safe use, then refinement with more data or better assumptions is the only way forward. The Advanced REACH Tool (ART) version 1.0 incorporates a mechanistic model of inhalation exposure and a statistical facility to update the estimates with the user's own data. This combination of model estimates and data produces more refined estimates of exposure and reduced uncertainty.

The ART project has been conducted in close collaboration with a range of stakeholders from industry and member states. The use of ART for workers exposure assessment under REACH is described in ECHA's updated Guidance on [Information Requirements and chemical safety assessment](#).

ART is currently only calibrated to assess exposure to inhalable dust, vapours, and mists. However, for lack of suitable calibration data, ART can not (for the time being) be used for the assessment of fumes, fibres, gases, and dust resulting from emissions during hot metallurgical processes.

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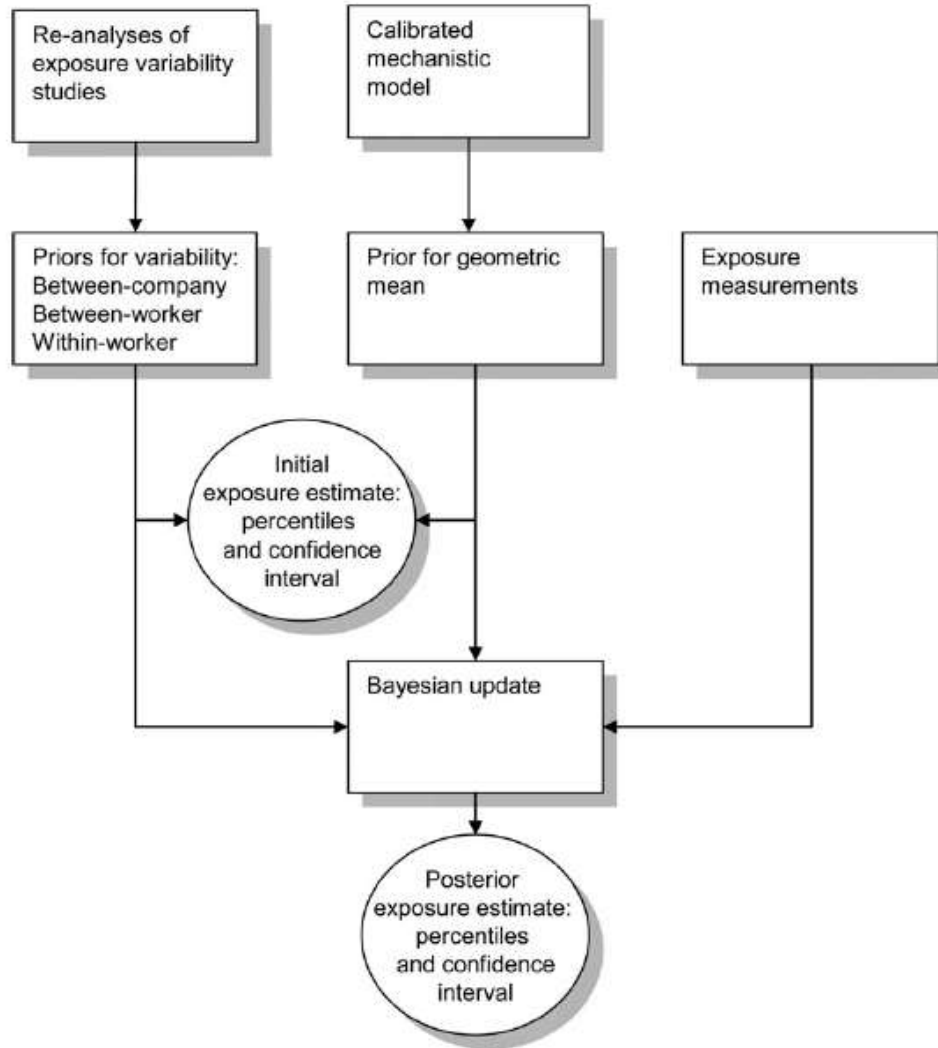
Latest News

*****ART webinar 25th Nov 2011*****
ReachCentrum and TNO are offering a webinar on ART ... [\[more\]](#)

ART training, May 2011

ReachCentrum and TNO are offering a series

ART 1.0



Fortalezas

Sencilla y bien estructurada herramienta web

Muchos OC y RMM considerados

Efecto de los determinantes basados en datos científicos y opiniones expertas

Modelo calibrado con muchos datos reales

Permite la selección del percentil apropiado

Proporciona una indicación de la incertidumbre asociada a un resultado

Puede realizar estimación global de múltiples tareas consecutivas

Combina las mediciones realizadas con los valores del modelo

Limitaciones

Se necesita una ingente información.

Está dirigida a expertos con elevados conocimientos en toxicología y exposición

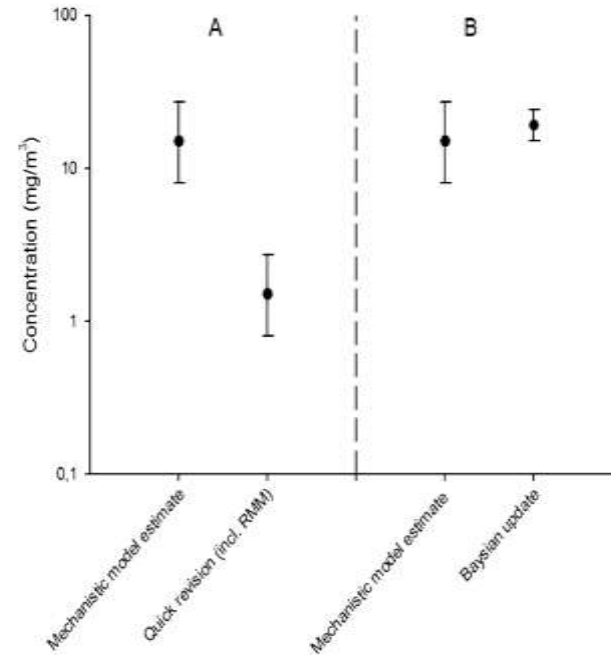
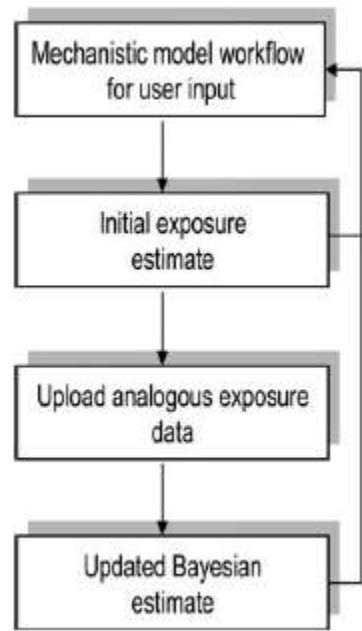
No incluye la vía dérmica

No sirve para estimar la exposición a humos o gases

ART 1.0

Activity emission potential	Transfer with rate of 1–10 kg min ⁻¹ Routine transfer Drop height >0.5 m
Substance emission potential	Fine dust Dry product 100% active ingredient
Dilution	Indoor in room of 300 m ³ Ventilation rate of 30 air changes per hour
Local control	Without any control (Situation 1) and low level of containment which is not air tight (Situation 2)
Segregation	No segregation
Separation	No separation
Surface contamination	Demonstrable and effective housekeeping practice in place
Duration of activity	Full shift (100% of the time)
Near field	Yes
Far field	No

ART 1.0





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**GRACIAS POR SU
ATENCIÓN**