



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

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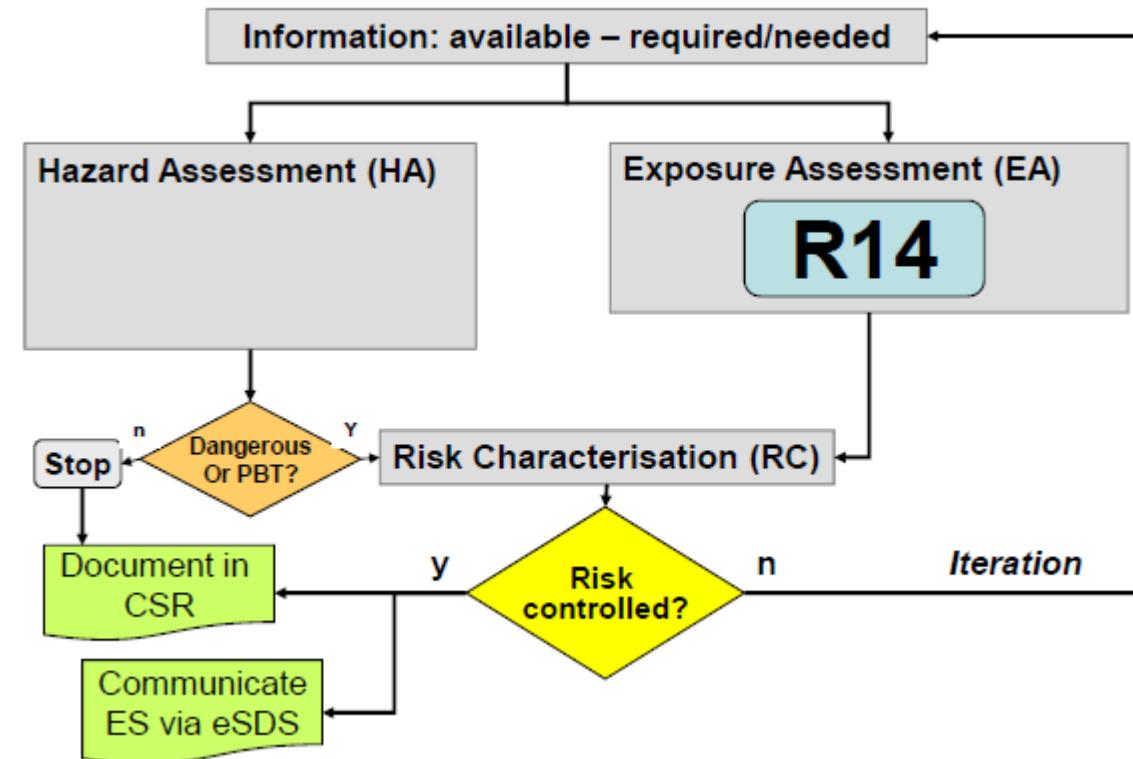


# Documento de orientación sobre los requisitos de información y sobre la valoración de la seguridad química



**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



EUROPEAN CENTRE FOR ECOTOXICOLOGY AND TOXICOLOGY OF CHEMICALS

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↳ Workshops

↳ Symposia and other meetings

↳ Contributing to international initiatives

↳ Science Awards

↳ **Targeted Risk Assessment (TRA) History**



**E-team project**  
ECETOC TRA 2,3  
Stoffenmanager  
RISKOFRERM  
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 manual

Download  
Integrated Tool

Integrated Tool user manual



## Fortalezas

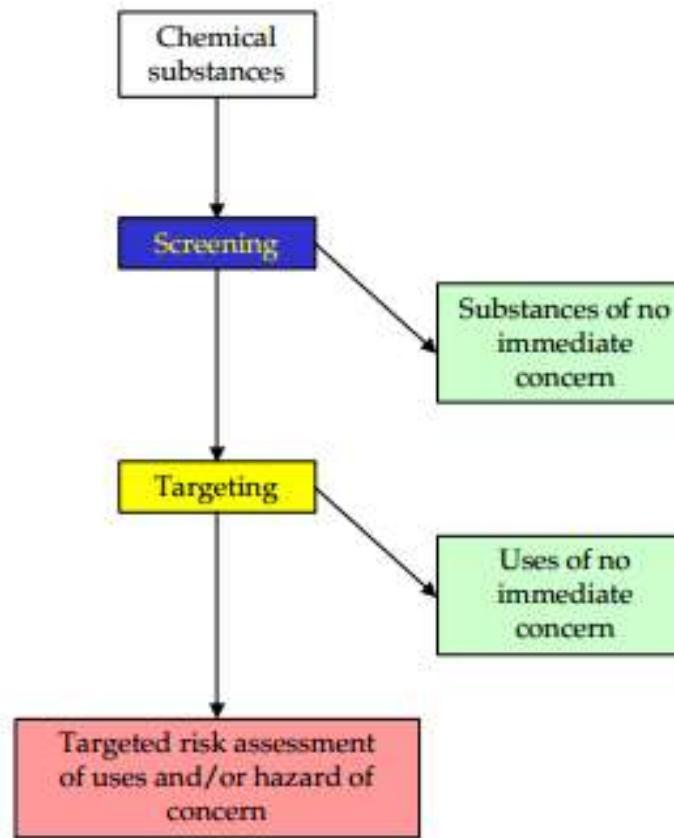
- Estructura clara
- Información sobre el proceso (process categories (PROCs) ) basado en otros apartados de la guía ECHA y usados en la aplicación CHESAR
- Incluye vía inhalatoria y dérmica
- La duración de la actividad/proceso/operación se tiene en cuenta
- Datos basados en el modelo EASE y en información 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 facil 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, comparandolo con el modelo RISKOFDERM.

# ECETOC TRA. ESQUEMA



## Tier 0 - Screening RA

- based upon established rules

## Tier 1 - Targeting RA

- key exposure scenario(s)
- predicted exposures
- generic hazard evaluation
- defined RQ<sup>a</sup> and MoE<sup>a</sup>

## Tier 2 - Targeted RA

- key scenario(s) of concern
- key hazard(s) of concern
- account for real data and refinements of defaults
- define 'real' RQ<sup>a</sup> and MoE<sup>a</sup>

# 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 <sup>a</sup>		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 <sup>b</sup>
R46	Toxic	Mutagen Cat.1, 2	High <sup>b</sup>
R60, R61	Toxic	Reproduction Cat.1, 2	High <sup>b</sup>
R26	Very Toxic	Acute toxicity inhalation	High
R27	Very Toxic	Acute toxicity dermal	High
R28	Very Toxic	Acute toxicity oral	High

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

<sup>b</sup>Substances classified R45, R49, R46, R60 or R61 are of very high concern.



# ECETOC TRA. ESQUEMA.

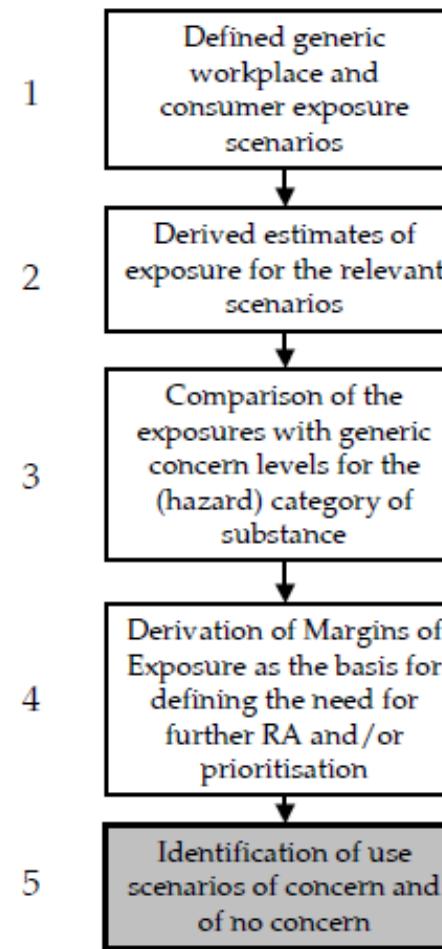
## TIER 0

*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 <sup>2</sup> ) assumed.
Use in a batch process including chemical reactions and/or the formulation by mixing, blending or calendering 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 <sup>2</sup> ) 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 <sup>2</sup> ) 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

Experience gained in  
previous risk  
assessment of Existing  
Chemicals

Major projects  
completed under REACH  
(2010)

HERAG

ART

> MEASE

Dermal Absorption

home

contact

imprint

links

## Industrial Chemicals – REACH | Recent projects and references

MEASE - The Metals' EASE

MEASE - Occupational Exposure Assessment Tool for REACH

Downloads

01 MEASE documentation





# German EMKG-Expo-Tool

## 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)

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)



# 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

# German EMKG-Expo-Tool

## 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

# German EMKG-Expo-Tool

## 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**



## 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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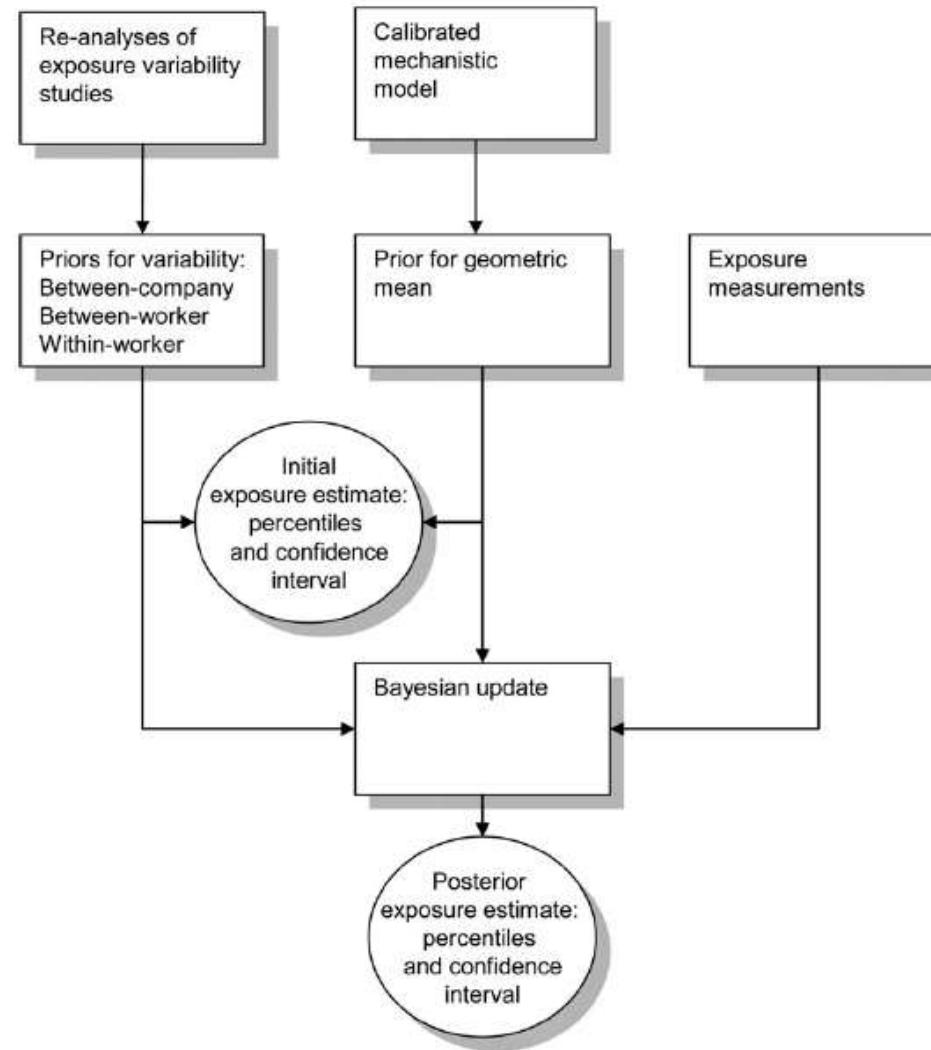
### Latest News

\*\*\*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

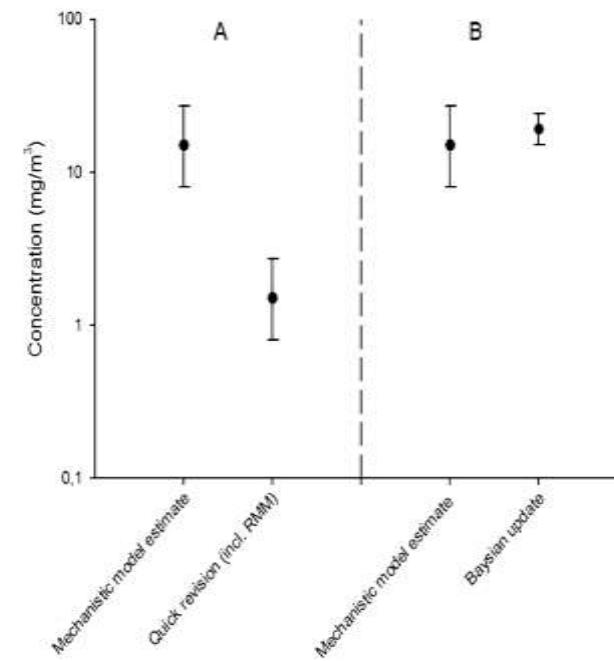
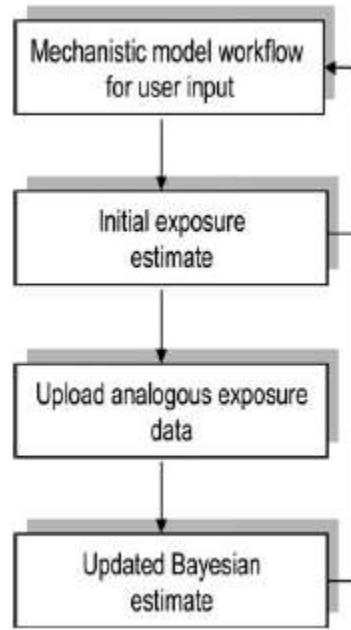
No sirve para estimar la exposición a humos o gases



# ART 1.0

Activity emission potential	Transfer with rate of 1–10 kg min <sup>-1</sup> Routine transfer Drop height >0.5 m
Substance emission potential	Fine dust Dry product 100% active ingredient
Dilution	Indoor in room of 300 m <sup>3</sup> 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  
ATENCION**