

INTERSOL - Paris – 24 mars 2015

PNEC, DNEL:

What about chemicals legislation in the management of contaminated sites ?

Laurent GRINFOGEL

Avocat au Barreau de Paris

Certificat de spécialité en droit de l'environnement

1.- INTRODUCTION

In its chemicals legislation, the European Union has introduced toxicological and ecotoxicological threshold concentrations of substances below which no adverse effects are expected to occur for human beings and for the environment. These concentrations are known as Predicted No-Effect Concentrations (PNECs), Derived No-Effect Levels (DNELs) and Derived Minimal Effect Levels (DMELs).

Reach Annex 1, art. 1.0.1. and 3.0.1 :

“The objectives of the human health hazard assessment shall be [.....] to derive levels of exposure to the substance above which humans should not be exposed. This level of exposure is known as the Derived No-Effect Level (DNEL)”.

« The objective of the environmental hazard assessment shall be [....] to identify the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur. This concentration is known as the Predicted No-Effect Concentration (PNEC)”.

1.- INTRODUCTION

Key point : Guidance of ECHA: *“R.8: Characterisation of dose [concentration]-response for human health”, “R.10: Characterisation of dose [concentration]-response for environment”*

Extensive, built up on OECD, WHO and other health agencies' guidance.

Precise rules of extrapolation and uncertainty factors

1.- INTRODUCTION

If a substance is registered with an annual production > 10 tons/year :

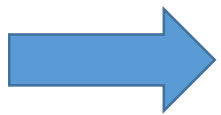
- DNEL to be established for each route of exposure (inhalation, dermal, ingestion) and for exposed populations.

- PNEC to be established for each environmental compartment (surface water, sediment, soil, STEP, secondary poisoning - freshwater/marine)

2.- A RELUCTANT ACKNOWLEDGEMENT BY FRENCH DOCTRINE OF DNELs/PNECs TO EVALUATE THE RISKS OF CONTAMINATED SITES

According to an Information Note of the French health and environment ministries from 30 Oct. 2014, DNELs/DMELs should not be used to evaluate health risks in the management of contaminated sites, but these values *“may be one element to consider, just like tentative EPA or OEHHA values”*.

Why ? : the methods to derive DNELs/DMELs are not published and few DNELs/DMELs are validated by ECHA



Then all non harmonized classifications and labellings of chemicals, all safety data sheets are doubtfull and should not be used !

2.- A RELUCTANT ACKNOWLEDGEMENT BY FRENCH DOCTRINE OF DNELs/PNECs TO EVALUATE THE RISKS OF CONTAMINATED SITES

- The guidance on toxicity reference values from French health agencies (Afsset/ANSES) makes no reference to ReaCh guidance and is mostly aligned of the methodology of the US-EPA.
- However, in its report from 31 Oct. 2008 *“De la méthodologie VTR à l'établissement des DNEL : Comparaison méthodologique et études de cas »*, INERIS's conclusions were strongly in favor of an harmonization of toxicity reference values with ReaCh guidance :

« Whereas the methodologies are close and that DNELs will potentially rely on more comprehensive toxicological profiles, it therefore seems justified and appropriate to recommend the establishment and use of DNELs”

“The methodology for establishing DNEL is more accurate [than a “VTR”] and enables a consideration of all the information available for obtaining a more refined DNEL, that may be less conservative to health”.

2.- A RELUCTANT ACKNOWLEDGEMENT BY FRENCH DOCTRINE OF DNELs/PNECs TO EVALUATE THE RISKS OF CONTAMINATED SITES

French vs. German authorities :

Umweltbundesamt, *“Bestimmung von stoffbezogenen Umweltqualitätskriterien”*, Aug. 2011, in collaboration with the Fraunhofer Institut :

- Water quality standards of EU water legislation could be harmonized with PNECs
- Contaminated soils : differences between threshold values of German soil protection law and PNECs are due to different regulatory perspectives : German soil threshold values take into account 3 different types of soil and more weight of evidence by expert than ReaCh.

Technical Working Group of German Länder (LAWA 2004) and the federal draft ordinance for the use of recycled granulates and other soil materials provides for the use of PNECs when there is no german legal environmental quality standard, because *“they are derived from the latest state of knowledge, according to strict and harmonized standards (so called Technical Guidance Documents) ...”*.

3.- WHAT ABOUT PNECs and DNELs IN THE MANAGEMENT OF CONTAMINATED SITES ?

Is it possible to go beyond French doctrine “PNECs/DNELs as one element to consider in the absence of a published toxicity/ecotoxicity reference value” ?

3.- WHAT ABOUT PNECs and DNELs IN THE MANAGEMENT OF CONTAMINATED SITES ?

If both PNECs/EQS respectively DNELs/toxicity reference values are available, check how far these values stand apart from one another, and try explain the difference if this may have an impact on site remediation.

Check test data used for the derivation of PNECs/DNELs/reference values

Check assessment factors of EQS/DNEL(s) - how conservative are they ?



Expertise in toxicology/ecotoxicology

3.- WHAT ABOUT PNECs and DNELs IN THE MANAGEMENT OF CONTAMINATED SITES ?

EQS is an overall threshold that protects all receptors and routes, whereas the exposure routes (“schéma conceptuel”) may be more specific depending for instance on the future use of the contaminated site and identified water use.



Advantage of PNEC is that it is refined for each environmental compartment

3.- WHAT ABOUT PNECs and DNELs IN THE MANAGEMENT OF CONTAMINATED SITES ?

3rd case : substances put on the market in small quantities (drugs

Check whether PNECs are made available - for instance : GlaxoSmithKline publishes the PNEC of its drugs and its material safety data sheets.

4th case : substance is no longer on the market, metabololite



Thank you for your attention !

lgr@grinfogel-avocats.com

www.grinfogel-avocats.com

30, place de la Nation 75012 PARIS

Tél: 01 49 28 56 30