

Environment Agency withdrawal of 2009 Nickel SGV¹:

"The Environment Agency has withdrawn the Soil Guideline Value (SGV) for nickel and its supporting reports. You may still view them on the Environment Agency national archive site. The reason for this is that the European Food Safety Authority (EFSA) published a report in February 2015 containing new recommendations about nickel. The Environment Agency have no plans to update the documents or produce any new SGV reports."

European Food Safety Authority - February 2015

Since the publication of the LQM/CIEH S4ULs for Nickel (Chapter 9, Nathanail et al., 2015), new expert opinion analysis has been published by the European Food Safety Authority (EFSA, 2015). EFSA's assessment (2015) led them to recommend a Tolerable Daily Intake for chronic oral exposure (TDI_{oral}) of 2.8 µg kg⁻¹ BW day⁻¹ for Nickel². This is based on the reproductive and developmental effects (pre- and perinatal mortality in offspring) in experimental animals (rats). EFSA (2015) used benchmark dose (BMD) modelling of the combined data from two studies (1- and 2-generation studies) to derive a lower 95% confidence limit for a benchmark dose at 10% extra risk (BMDL₁₀) of 0.28mg kg⁻¹ BW day⁻¹ (dose response analysis of incidence of litters with post-implantation loss in rats). A default Uncertainty Factor (UF) of 100 was then applied to account for inter-species differences and human variability to derive the TDI_{oral}.

Following the publication of the new EFSA expert opinion and the consequential decision of the Environment Agency to withdraw the SGV for Nickel as well as supporting documentation (Environment Agency, 2009a, 2009b, 2009c), LQM consider the TDI_{oral} proposed by EFSA (2015) to be a more appropriate Health Criteria Value (HCV) for oral exposure than that used to derive the previously published S4ULs (12 µg kg⁻¹ BW day⁻¹) and so have revised the published S4ULs for Nickel.

Tables 9-2, 9-4 and 9-5 in the S4UL publication (Chapter 9, Nathanail et al., 2015) have been revised to reflect this change in oral HCV. The S4ULs for the Residential with Homegrown Produce, Allotment and Park Public Open Space (POS_{park}) landuses are lower than the previously published values due to the dominance of the oral exposure pathway for these land uses.

Further details of the reason for this revision can be found in FAQ entry number 22 available under the Documents tab at <http://www.lqm.co.uk/publications/s4ul/>.

Table 9-2: Toxicological values for nickel (Revised August 2015)

Threshold effects		Non-threshold effects	Exposure Routes
Oral TDI (µg kg ⁻¹ BW day ⁻¹)	Oral MDI (µg day ⁻¹)	Oral ID (µg kg ⁻¹ BW day ⁻¹)	-
2.8	134	Not applicable	Oral + dermal + inhalation
Inhalation TDI (µg kg ⁻¹ BW day ⁻¹)	Inhalation MDI (µg day ⁻¹)	Inhalation ID (µg kg ⁻¹ BW day ⁻¹)	-
0.006	0.259	Not applicable	Inhalation (local)

Table 9-4: LQM/CIEH S4ULs for Nickel according to land use (Revised August 2015)

Land Use	S4ULs (mg kg ⁻¹ DW) ^{a,b,c}
	Nickel
Residential with homegrown produce	130 ^d
Residential without homegrown produce	180 ^e
Allotment	53 ^d
Commercial	980 ^e
POS _{resi}	230 ^e
POS _{park}	800 ^d

^a Based on a sandy loam soil as defined in SR3 (Environment Agency, 2009d) & 6% soil organic matter (SOM); ^b Figures rounded to two significant figures; ^c In applying the rules for non-soil background to the S4ULs, the background ADE is limited to being no larger than the contribution from the relevant soil ADE; ^d based on comparison of exposure from all pathways with TDI_{oral}; ^e comparison of exposure from inhalation pathways with TDI_{inhal}

¹ <https://www.gov.uk/government/publications/land-contamination-soil-guideline-values-sgvs>, accessed 18/08/15

² The TDI_{oral} recommended by EFSA (2015) does not account for acute toxicity relating to systemic contact dermatitis (SCD) in Ni-sensitive humans. It is estimated that 15% of the population may have allergic contact dermatitis and that some of these may develop SCD. EFSA (2015) derive a lowest BMDL₁₀ of 1.1 µg kg⁻¹ BW for SCD following oral exposure to Ni in human volunteers (highly sensitive group exposed to a form with absorption likely to be higher than via food or soil). Consequently, EFSA (2015) state: "The TDI of 2.8 µg Ni/kg b.w. per day may therefore not be sufficiently protective of individuals sensitized to nickel".

Table 9-5: Contribution to total exposure for the relevant pathways as calculated for Nickel by the CLEA software for the generic land-uses. The lowest of the route specific assessment subcriteria is selected as the S4UL, these values and the associated contributions are shaded grey. (Revised August 2015)

Land Use	Route-specific assessment subcriteria (mg kg ⁻¹ DW)											
	Residential with homegrown produce		Residential without homegrown produce		Allotment		Commercial		POS _{resi}		POS _{park}	
Comparison of exposure from all pathways with oral TDI	126		188		53		3064		374		804	
Comparison of inhalation exposure with inhalation TDI	181		181		3694		983		231		6600	
	Contribution to exposure from soil and background sources (%) ¹											
	All pathways	Inhalation only	All pathways	Inhalation only	All pathways	Inhalation only	All pathways	Inhalation only	All pathways	Inhalation only	All pathways	Inhalation only
Ingestion of soil and indoor dust ²	33.3	NA	49.7	NA	3.8	NA	48.9	NA	49.5	NA	49.7	NA
Consumption of homegrown produce and attached soil	16.5	NA	NA	NA	46.1	NA	NA	NA	NA	NA	NA	NA
Dermal contact (indoor)	<0.1	NA	<0.1	NA	NA	NA	0.2	NA	<0.1	NA	NA	NA
Dermal contact (outdoor)	<0.1	NA	<0.1	NA	<0.1	NA	0.2	NA	<0.1	NA	0.3	NA
Inhalation of dust (indoor)	<0.1	50.0	0.1	50.0	NA	NA	0.3	49.7	0.2	50.0	NA	NA
Inhalation of dust (outdoor)	0.0	<0.1	0.0	<0.1	0.0	50.0	0.0	0.3	0.0	0.2	<0.1	50.0
Inhalation of vapour (indoor)	0.0	0.0	0.0	0.0	NA	NA	0.0	0.0	NA	NA	NA	NA
Inhalation of vapour (outdoor)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Oral background	49.9	NA	49.9	NA	50.0	NA	49.7	NA	49.8	NA	50.0	NA
Inhalation background	<0.1	50.0	0.1	50.0	0.0	50.0	0.3	50.0	0.2	50.0	<0.1	50.0

¹ Rounded to one decimal place; ² Treated as one pathway (Environment Agency, 2009)
ADE = Average Daily Exposure; HCV = Health Criteria Value; NA = Not applicable (This exposure pathway is not included in the generic land use)

References (used in this update)

EFSA. (2015). EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2015. Scientific Opinion on the risks to public health related to the presence of nickel in food and drinking water. *EFSA Journal* 2015, 13(2), 4002, 202. doi:doi:10.2903/j.efsa.2015.4002

Environment Agency. (2009a). *Soil Guideline Values for Nickel in Soil*. Environment Agency (Bristol, UK).

Environment Agency. (2009b). *Supplementary information for the derivation of SGV for nickel*. Environment Agency (Bristol).

Environment Agency. (2009c). *Contaminants in soil: updated collation of toxicological data and intake values for humans: Nickel*. Environment Agency (Bristol).

Environment Agency. (2009d). *Updated Technical Background to the CLEA Model*. Environment Agency: Bristol, UK. Accessed from http://www.environment-agency.gov.uk/static/documents/Research/CLEA_Report_-_final.pdf

Nathanail CP, McCaffrey C, Gillett AG, & Nathanail JF. (2015). The LQM/CIEH S4ULs for Human Health Risk Assessment. ISBN 978-0-9931084-0-2. In *The LQM/CIEH S4ULs for Human Health Risk Assessment*. Land Quality Press: Nottingham. Accessed from <http://www.lqm.co.uk/publications/s4ul/>.