



Chartered
Institute of
Environmental
Health

Professional Practice Note :

The determination of contaminated land: deciding what is an “unacceptable intake”

1 Introduction

Background

1.1 This Professional Practice Note provides interim guidance on the determination of land under Part 2A of the Environmental Protection Act 1990¹ as “contaminated land” due to unacceptable risks to human health. It is intended for use by local authority officers responsible for contaminated land matters

1.2 Specifically, it addresses the decision on whether an intake of, or other direct contact with, chemicals or other substances (but not radioactive materials) in, on or under the land represents an “unacceptable intake”. If there is a reasonable assumption that such an intake etc. might occur, the conditions for the existence of “*significant harm...or...the possibility of such harm*”² – the statutory test for determination – are met.

1.3 In September 2005, the Department for Environment, Food and Rural Affairs (Defra) issued a Contaminated Land Advice Note³ (CLAN 2/05) which identified some of the issues relating to the use of Soil Guideline Values (SGVs) in determining whether in a given case there exists a significant possibility of significant harm and, in particular, the implications of basing those values on Health Criteria Values (HCVs).

1.4 CLAN 2/05 advises local authorities to “*make a firm and deliberate judgement about whether the estimated contaminant intake ... would represent an unacceptable intake or direct bodily contact.....*”.

¹ Part 2A provides the mechanism for the identification and remediation of land “where contamination is causing unacceptable risks to human health or the wider environment, assessed in relation to the current use and circumstances of the land” - paragraph 25, DETR 2/2000

² Note that land may also be determined as contaminated land because of other unacceptable risks, such as risks from explosion or risks to property, protected ecosystems and to water bodies such as rivers and groundwater though these risks are not dealt with in this Note

³ “Soil Guideline Values and the Determination of Land as Contaminated Land under Part 2A” (Defra, Sept 2005)

1.5 Defra is still considering⁴ what further policy advice and guidance it should provide on the question of unacceptable intakes and what implications that would have for the future development of SGVs and their use in simplifying the risk assessment underpinning the determination of land as contaminated land. The Department is nonetheless committed to providing central guidance when these issues have been resolved⁵.

1.6 In the meantime, bearing in mind the uncertainties, the CIEH suggests that the only direct use for SGVs is to indicate where land does *not* present a significant possibility of significant harm; while it is not clear what the full consequences may be otherwise⁶, authorities may wish to assure themselves, in relation to decisions involving the use of SGVs already made, that they can show that they were made in accordance with the statutory guidance and were, in all the circumstances, reasonable⁷.

Objectives

1.7 In that light, the aim of this Note is to outline what options are currently available to local authorities in making the decisions required as part of the determination process. It has three specific objectives:

- to help local authorities identify, interpret and use both current and future technical and policy guidance, whether from Defra or elsewhere, appropriately within the framework of Part IIA;
- by so doing, to assist local authority officers to progress their work in this area, and
- to prompt feedback and discussion on some of the issues determinations raise so as to assist Defra in formulating solutions to the practical problems currently faced by local authorities.

1.8 This Note is not intended unnecessarily to duplicate any work by Defra or others nor, especially, to replace or override the statutory guidance or to diminish the need for local authorities to carry out their own technical assessments and make their own decisions on individual sites on which they should take appropriate advice if required.

Comments

1.9 Comments on this Note are invited by e-mail to h.price@cieh.org or through the risk assessment forum on the CIEH's contaminated land website⁸

⁴ See CLAN 4/06 "Defra update on SGVs" (Defra, April 2006)

⁵ See CLAN 3/06 "Soil Guideline Value Taskforce" (Defra, April 2006)

⁶ See e.g paragraphs 4.40 *et seq* in "Contaminated land – the new regime" Tromans *at al*, Sweet & Maxwell, 2000

⁷ See paragraphs 3.4 and 3.5 below and paragraph B 49 of Chapter B of Annex 3 of DETR 2/2000

⁸ At <http://www.cieh.org/contaminatedland/>

Acknowledgement

1.10 The CIEH gratefully acknowledges the earlier work of Judith Lowe in the production of this Note, the contents of which, including any errors, are nevertheless the responsibility of the CIEH. It has been extracted from a more comprehensive Note being developed by the CIEH on some wider aspects of determinations, completion of which is linked to current work by Defra, the SGV Taskforce and other organisations in which the CIEH is an active participant.

2 Context

The evaluation of pollutant linkages

2.1 If a pollutant linkage has been identified as part of a local authority's detailed inspection of a site, it will need to decide whether the linkage is a "significant pollutant linkage". Only if a significant pollutant linkage has been identified might the land be determined as contaminated land.

2.2 This consideration of individual pollutant linkages, or of combinations of pollutant linkages, is the evaluation stage of risk assessment⁹.

2.3 A local authority must evaluate pollutant linkages in accordance with the statutory guidance¹⁰ given in Chapter A of DETR 2/2000. As with its ultimate decision that the land in question "*appears [to it] to be [contaminated] land*"¹¹, its conclusion will be based on "*the balance of probabilities*"¹².

2.4 In respect of risks to people arising from the intake of, or other direct bodily contact with, a contaminant, the statutory guidance sets specific evaluation criteria for any individual pollutant linkage or combination of linkages¹³. These are the conditions for "significant possibility of significant harm"¹⁴ set out in Table B of Chapter A.

2.5 They reflect two elements of probability within the overall risk¹⁵:

- the probability of the exposure – the likelihood that the receptor "*might take in*" or "*might otherwise be exposed*" to a contaminant; and
- the probability of the adverse consequences in Table A occurring as a result of that exposure, i.e. the degree to which adverse effects could result from the amount of "*intake or direct bodily contact*".

The question of unacceptable intake

2.6 A pollutant linkage thereby becomes a significant pollutant linkage when the amount of intake or other contact that might arise from it "*would represent an unacceptable intake or other direct bodily contact*" for that receptor.

⁹ See "Guidelines for Environmental Risk Assessment and Management" (DETR, EA, IEH, 2000) and Chapter 2 of CLR 11 (EA, 2004)

¹⁰ See s78A(5) EPA 1990

¹¹ See s78A(2) EPA 1990

¹² The normal standard of proof in this type of regulatory regime; see paragraph B 44 (b) of Chapter B of Annex 3 of DETR 2/2000

¹³ See paragraph B 41 of Chapter B of Annex 3 of DETR 2/2000

¹⁴ Abbreviated as "SPOSH" by some practitioners

¹⁵ See paragraph A 27 of Chapter A of Annex 3 of DETR 2/2000

2.7 What intake from (or contact with) a pollutant amounts to an *unacceptable* intake or other bodily contact is a matter for the authority to decide in each situation but it must base its decision on relevant information on the toxicological properties of the pollutant¹⁶ and take account of other factors set out in Table B. The rest of this Note seeks to help with that decision.

¹⁶ See first entry of Table B and paragraph A 31 of Chapter A of Annex 3 of DETR 2/2000

3 How to decide when an intake is unacceptable

3.1 This section looks at the way in which a local authority may decide whether or not an intake is unacceptable. The following section, section 4, goes on to take a look at the policy options then available to local authorities can be put into practice.

Decisions for the authority

3.2 Faced with a particular pollutant linkage, local authorities must decide:

- what is the overall approach of the authority to deciding what degree of risk is unacceptable? Does that fit the requirements of Part 2A?
- what unacceptable intake or direct bodily contact from the pollutant in the pollutant linkage will be used in its evaluation? Specifically:
 - has this been assessed on the basis of “relevant information”?; and
 - how has it taken into account the total intake, the contribution from soil and the duration of exposure? and
- how has the amount that might be taken in by a person (or to which they might otherwise be exposed) been estimated?

The following paragraphs should help.

General considerations

3.3 The statutory guidance under Part 2A emphasises the need for a local authority’s decision on what is unacceptable to be based on “*relevant information on the toxicological properties of the contaminants*”. The term “unacceptable” is not defined in the legislation – this is where an authority must exercise its judgement.

3.4 Such judgements must observe the familiar rules, in particular that they must be made only by those properly authorised to make them; they must be based on relevant considerations and no irrelevant considerations; they must not be fettered by any self-imposed rule or policy; and they must be such as any reasonable authority, directing itself appropriately, might make in all the circumstances¹⁷. Local authorities’ decisions and the reasons for them should be carefully documented¹⁸.

3.5 Local authorities’ discretion in these cases is additionally constrained by the procedural requirements of the statutory guidance which says that the decision whether or not a postulated intake is unacceptable should be based on a number of factors including:

- the nature and degree of harm anticipated;

¹⁷ So-called “*Wednesbury* reasonableness”.

¹⁸ See e.g. paragraph B 52 of Chapter B of Annex 3 of DETR 2/2000

- the susceptibility of the receptors, and
- the timescale within which the harm might occur.¹⁹

It will also need to take account of the nature of the contaminant, i.e. whether it exhibits “threshold” or “non-threshold” effects²⁰.

3.6 While it must still have regard to the circumstances of each situation, an authority may wish to take into account the policy relevant to the introduction of Part 2A. At the time of publication of the statutory guidance this could be summarised as:

- for threshold substances - an intake or exposure above an authoritative estimate of the limit for a Tolerable Daily Intake (TDI)^{21, 22}
- for non-threshold substances - an intake or exposure which represented a level of risk considered unacceptable in other comparable situations, benchmarked as having in general an upper limit of 10^{-4} (i.e. 1 in 10,000) excess lifetime risk of developing cancer from exposure to any one source.^{23 24}

3.7 Before making its final decision, the authority may also wish to reflect that if levels of contaminants indicate determinations only to find that assessment of the seriousness of the risk never justify the likely costs involved, its intervention levels are likely to have been set too low for them to be regarded as “unacceptable”²⁵.

Particular considerations for substances which exhibit threshold effects

3.8 Though CLAN 2/05 reminds authorities that the Tolerable Daily Intake is an estimate of the amount of contaminant that can be ingested daily “*without appreciable health risks*” and CLR9 states that even “*exceeding the TDI...provided that this only occurs on rare occasions... would not create undue concern*”, the latter document nevertheless confirms that “*traditionally,...doses above the TDI are assumed to have some (unknown) probability of causing adverse health effect*”²⁶.

3.9 The implications are that an intake above the TDI over any appreciable period could be detrimental – and thus that the public could expect TDIs to be used by the authorities as a limit on what should be considered acceptable.

¹⁹ See paragraph A 28 of Chapter A of Annex 3 of DETR 2/2000

²⁰ See for example paragraph 2.13 and figure 2.2 of CLR 9.

²¹ Note that “tolerable” refers here to physical toleration, not to acceptability by an individual or society.

²² See draft statutory guidance dated 5 May 1995 presented to Parliament for House of Commons’ Standing Committee’s consideration of the definition of contaminated land (CIEH library)

²³ See draft technical guidance proposed by DETR on establishing toxicological criteria for use in assessing land contamination, circulated to stakeholders for comment during the formal consultation on the statutory guidance (CIEH library)

²⁴ Corresponding to an annual excess cancer risk of about 10^{-6} (one in a million) per year

²⁵ See Part V of Chapter C of DETR 2/2000

²⁶ See paragraph A 5 of CLR 9

3.9 Alternative approaches are nonetheless possible. For example, it could be argued that determination should be triggered at the precise limit of intake at which adverse effects would start to occur, rather than at a more precautionary level. Data of this certainty would, however, be virtually impossible to obtain.

3.10 More detailed scrutiny of studies which indicate the levels at which adverse effects are actually observed to occur in particular circumstances are also relevant: in effect – in interpreting toxicological studies - a NOAEL²⁷ would represent a lower bound and a LOAEL²⁸ could be used to define an upper bound. Using upper bounds to define intervention levels, however, would leave a “grey zone” in which adverse effects from contaminants *could* occur and which at least the people exposed to them might think an unacceptable risk.

Particular considerations for substances which exhibit non-threshold effects

3.11 Whereas Table 2.2 of CLR 9 states that “*exceedance of the index dose, even in the short term, indicates an increase in the risk to health and is not acceptable*”, CLAN 2/05 points out that the “index dose” – allocated to substances for which a threshold of adverse effects cannot be presumed – is the level at which the risk is nevertheless considered minimal.

Risks from soil in particular

3.12 The assessment of unacceptable intake must also relate specifically to the intake from the pollutant in the pollutant linkage and must take into account²⁹:

- *“the likely total intake of, or exposure to, the substance or substances which form the pollutant from all sources including the pollutant linkage;*
- *the relative contribution of the pollutant linkage in question to the likely combined intake of, or exposure to, the relevant substances; and*
- *the duration of intake or exposure resulting from the pollutant linkage in question.”*

3.13 The first of these factors allows local authorities to consider whether the contribution from soil over and above the background intake would be unacceptable, whilst the second factor allows the local authority to consider at the same time whether intervention to deal with the risks posed from soil is proportionate to the risks from that substance arising elsewhere.

3.14 The requirements for the assessment of unacceptability also prompt specific consideration in relation to the duration of exposure – for example, the risk may be

²⁷ “No observed adverse effect level”

²⁸ “Lowest observed adverse effect level”

²⁹ See first entry of Table B of Chapter A of Annex 3 of DETR 2/2000

cumulative over time and a risk may not reach unacceptable levels if the pollutant linkage could exist only for a limited period.

3.15 Current technical guidance sets out the basis for deriving Tolerable Daily Soil Intakes (TDSIs), described as “*the proportion of the TDI that can be identified as an exposure that can be tolerated from contaminants in soil*”³⁰. This takes into account the exposure from dietary and other sources (as Mean Daily Intake (MDI))³¹ and, in general, the intake from soil is assumed to be equal to the difference (i.e. TDI less MDI).

3.16 In some circumstances, however, the MDI is about the same as, or greater than, the TDI and CLR9 proposes for these that 20% of the TDI should be allocated to soil where the MDI > 80% of the TDI. Though this calculation takes into account both background intake and presents a figure for the relative proportions of intakes, the contribution of substances in soil, however, represents an increment which is likely to be undetectable in the background variation in actual intakes. Particularly in the light of CLAN 2/05, local authorities will now need to consider whether this is a sufficient basis for deciding that the intake from soil is “unacceptable”.

3.17 Care must also be taken to note some substances for which a different approach is more appropriate, e.g. that developed for lead. For others, particularly for non-threshold contaminants, CLR 9 explains that it is not appropriate to subtract the risks from other sources as the level of risk is already set solely in relation to the exposure from soil.

Other considerations

3.18 There are other policy choices regarding the way in which toxicological data is obtained and evaluated and the degrees of precaution and protection which are considered appropriate. In general, policy in these areas is set by the Department of Health (DoH) and/or the Health Protection Agency (HPA), but in some cases will also reflect Defra’s views on environmental protection as a whole.

3.19 Currently set parameters include, for example:

- specific consideration of intake or exposure to substances in soil by children;
- the treatment of variations of exposure such that 95% of the population would be protected from unacceptable effects of living on land affected by contamination (rather than, say, only 50%).

3.20 The statutory guidance also requires local authorities to consider:

- additive or synergistic effects between potential pollutants³²; and

³⁰ See paragraph 2.28 and 3.22 to 3.27 of CLR 9

³¹ See paragraphs 2.26 and 2.27 and 3.16 to 3.20 of CLR9

³² See paragraph B 41(a) of Chapter B of Annex 3 of DETR 2/2000

- the effects of combinations of several different potential pathways linking one or more potential pollutants to a particular receptor³³
at least where these are known and adequately documented.

³³ See paragraph B 41(b) of Chapter B of Annex 3 of DETR 2/2000

4 Practical guidance

4.1 The technical approach to identifying an unacceptable intake has to observe the conditions in Table B of the statutory guidance but, subject to that, also reflect the particular policy choices of the local authority, taking into account the discussion above. The following section briefly illustrates some possible approaches for local authorities.

Setting the overall approach of the local authority

Officers should establish the policy of their local authority on how they should assess what is an unacceptable intake based on toxicological information. This must meet the conditions in Table B of the statutory guidance but, within that, can, for example, include some or all of:

- use of Government guidance where this provides a clear benchmark for unacceptable intakes;
- independent consideration of toxicological information;
- consideration of advice from consultants who are competent in the evaluation of toxicological data, and
- consideration of site specific advice from other bodies, e.g. HPA, PCT, having verifiable relevant expertise.

4.2 The interpretation of toxicological information to quantify the particular intake of a pollutant which meets any given criteria for an unacceptable intake must be based on toxicological evidence of the effects of the substance. This is a complex task, requiring specialist knowledge and expertise. Guidance on the general approach is provided in CLR 9 and information on particular pollutants has been published in daughter “tox” reports³⁴.

4.3 For Part 2A, it can be considered as consisting, essentially, of two steps.

Unacceptable intake – first step

4.4 The first step is for the authority to assess the relevant toxicological information to establish benchmark unacceptable intakes for substances. The boxes below illustrate options for different policies for threshold and non-threshold substances and the corresponding technical approaches.

³⁴ Available via: <http://www.environment-agency.gov.uk/subjects/landquality/>

For threshold substances

Option 1: *The authority considers that a value representing the greatest concentration or amount of a substance, found in experiment or observation, which causes no observable adverse effects (the “NOAEL”) - i.e. the basis of a TDI as defined by the World Health Organisation - provides an appropriate level of certainty and precaution to use as a level above which any intake is unacceptable.*

- *It therefore uses the TDIs presented in CLR daughter tox reports where these are published*
- *It obtains information on TDIs for substances not yet covered by published CLRs, either by:*
 - *Exchanging authoritative information with - for example - other local authorities or by*
 - *Commissioning its own research by suitable experts*

Option 2: *A local authority has decided to base its decision on unacceptable intake on an intake which represents a reasonably precautionary estimate of the level above which adverse effects could occur.*

- *The authority sets a level of 10% above the TDI as the maximum conservative limit on the margin above a TDI before which intake is regarded as unacceptable.*
- *The authority determines a level between NOAEL and LOAEL which corresponds more closely to the specific level at which effects could occur, either by*
 - *establishing a collaborative research study or by*
 - *independently commissioning expert toxicologists.*

Option 3: *A local authority has decided to base its decision on unacceptable risk on an intake which has been observed to cause adverse effects and which can be extrapolated to humans.*

- *The authority determines a LOAEL which corresponds to this either by:*
 - *exchanging authoritative information with - for example - other local authorities or by*
 - *independently commissioning expert toxicologists.*

Option 4: *A local authority has decided that any decision on unacceptable intake should be based on advice from the Health Protection Agency.*

- *It presents its estimation of the amount that might be taken in on a particular site to the HPA and asks its advice on whether or not this intake might be unacceptable. The authority then considers this advice and its underlying reasons when making its judgement.*

For non-threshold substances

Option 1: *An authority decides that it will consider any intake above the index dose as unacceptable, relying on the statement in CLR 9 that exceedance of this is not acceptable, and that even below this level, intakes should be reduced to as low as is reasonably practicable (ALARP).*

- *The authority uses index doses already published, and*
- *for chemicals without a published index dose, the authority either*
 - *exchanges authoritative information with - for example - other local authorities or*
 - *appoints expert toxicologists to review the toxicological information based on the approach presented in CLR 9 to establish an index dose..*

Option 2: *An authority decides that it will only consider risks above 10^{-4} additional lifetime risk to be unacceptable, providing the substances are not expected to have a synergistic effect with other substances present.*

- *It establishes a dose corresponding to this level of risk either by:*
 - *exchanging authoritative information with - for example - other local authorities or*
 - *commissioning expert toxicologists to review toxicological information such as that presented in CLR 9 and the daughter tox reports.*
- *It also considers a different benchmark for the amount of intake where there may be additive or synergistic effects.*

4.5 The cost and the relative scarcity of sufficiently expert toxicological advice is nonetheless recognised.

Unacceptable intake – second step

4.6 The second step is for the authority to establish specifically what intake from substances in soil in the pollutant linkage it would consider unacceptable.

4.7 To do this it must establish the intake from other sources (the background intake) and consider the two relevant factors in the statutory guidance,³⁵ namely:

- what is the total intake taking into account the background intake? Is the intake from soil unacceptable taking into account the total intake? The simplest

³⁵ See Table B, Chapter A of Annex 3 of DETR 2/2000

circumstances on which to judge the decision are those where for example, the total intake by a child exposed to the contaminant would exceed the unacceptable intake, whilst the total intake of a child living on land with lower concentrations of contaminants would not exceed the unacceptable intake.

- What is the relative contribution of the linkage to the total intake of that substance? Is the intake from soil unacceptable taking account of this relative contribution? Again, the simplest circumstances to make a judgement are those where the intake from soil represents the major contribution to the total intake.

4.8 However, the actual relationship between intake from soil and that from other sources is more complex, and both these factors need to be considered and a balance struck between them. The authority has two clear choices for threshold substances:

- it can decide to use the TDSIs presented in CLR9 and the daughter tox reports on the basis that these are set at precautionary levels, fixing the contribution from soil to that which ensures that a TDI is not exceeded. However, not only does this assume that the TDI is the unacceptable intake, in some cases, the intake from soil would have a substantially lower potential impact than other sources. The authority may therefore risk being challenged to demonstrate that its decision on unacceptable intake has fully taken into account the factors in the statutory guidance.
- Alternatively, it can develop its own basis for making the judgement required for Part 2A. A possible approach is shown in the box below.

Example 1 – threshold substances

The “unacceptable intake” from a substance is X mg/kg body weight per day. Estimated national mean background intake from other sources is Y mg/kg body weight per day.

The authority considers that a reasonable position is that:

- *Where background intake is – or could be over the timeframe of the exposure calculation - between 0 and $0.45X$, the intake from the pollutant linkage should never be $> X - Y$, so that the linkage does not tip the balance of whether an unacceptable intake occurs, up to the point where:*
- *if other sources of intake are – or could be over the lifetime of the exposure calculation – greater than $0.45X$, the intake from the pollutant linkage should be no more than $0.55X$*

This is based on the following considerations:

- *not allowing the pollutant linkage to result in an intake above the unacceptable intake where the background is below $0.45X$ takes into account the total intake*
- *limiting the intake from the pollutant linkage to $0.55X$ takes into account both the*

total intake and the relative contribution of the pollutant linkage because:

- *Although the unacceptable intake is exceeded, once the MDI exceeds 0.55 of this limit, the linkage itself is not the main contributor,*
- *However, although the intake from the pollutant linkage could range from 100% to a much lower percentage of the background intake, it still represents more than half of the unacceptable intake.*

4.9 For non-threshold substances, the authority is more likely to be using a value for unacceptable intake that already corresponds to the overall relative risk from soil.

4.10 This may, however, still need specific consideration where risks from soil are relatively much lower than risks of the same substance from other sources. This is illustrated in the table below.

Example 2 – non-threshold substances

The intake from substance A is Z mg/kg body weight per day which appears to represent a level of additional lifetime risk of cancer of 1 in 10,000. However, typical concentrations of substance A in housing already provide an intake which corresponds to an additional lifetime risk of cancer of 1 in 100.

- *The authority establishes that most other authorities consider this level of risk from soil to be unacceptable and that intervention to reduce the risks is appropriate. However, it first considers ways in which it can assist householders to reduce the level of risk from other sources.*

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