COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

The Development of New Screening Levels for Contaminants in Soil

Introduction

1. The Committee's view is sought on a revised toxicological framework to aid the development of new screening levels for contaminated land risk assessment, following revisions to the relevant Statutory Guidance in 2012.

Background

2. The regulatory regime for historical contaminated land in England and Wales primarily comprises "Part 2A" of the 1990 Environmental Protection Act (EPA), which works in conjunction with planning policy under the National Planning Policy Framework (NPPF), the latter being the responsibility of the Department for Communities and Local Government (DCLG). One of the requirements in the NPPF is that, as a minimum, land after remediation should not be capable of being determined as contaminated land under Part 2A. The majority (estimated at 90%) of contaminated sites in England and Wales are remediated under planning and thus, the Part 2A legislation is held in reserve for where there is no prospect of a market solution.

3. The Department for the Environment, Food and Rural Affairs (Defra) in England and the Welsh Government in Wales have responsibility for the Part 2A legislation. In April 2012, the Secretary of State for Defra and Welsh Ministers issued revised Statutory Guidance (see Annex A) for England and Wales respectively that was designed to provide clarity to the contaminated land sector (and Local Authorities in particular) on how the Part 2A legislation was intended to be interpreted and implemented.

Revised Statutory Guidance

4. The Part 2A legislation takes a risk-based approach to defining contaminated land. The Guidance states that regulatory decisions should be based on what is reasonably likely, not what is hypothetically possible and also requires there to be a positive legal test for determining land as contaminated (the starting point is that land is not contaminated land unless there is a reason to consider otherwise). Under Part 2A, for a relevant risk to exist, there needs to be one or more contaminant-pathway-receptor linkages

by which a relevant receptor (e.g. a person) might be exposed to and affected by the contaminants in question.

5. The level of risk raised by land contamination depends on more than simply the amount of contaminants in the soil. For example, it also depends on what form the contaminants take, in which layer they are in the soil (i.e. top few cm or deeper), adsorption to soil and hence bio accessibility and bioavailability, the efficiency of the pathway by which receptors may be exposed, the sensitivity of receptors, the likely degree and duration of exposure and the dose-response relationship. Under the legislation, for cases of risks to human health, land should only be classified as contaminated in the legal sense if significant harm is occurring, or there is a Significant Possibility Of Significant Harm (SPOSH) being caused. A summary of the types of health effects that are, or may be considered to be, significant harm to human health, as specified in the new Statutory Guidance, is provided in Table 1 below.

Table 1 Part 2A Statutory Guidance Definition of Harm to Human Health

	Part 2A Environmental Protection Act 1990 New Statutory Guidance 2012
Always considered as significant harm	Death
	Life threatening diseases (cancers)
	Serious injury caused by the chemical or biochemical properties of the substance, such as injury resulting from explosive or asphyxiating properties of gases.
	Birth defects
	Impairment of reproductive functions
	Other diseases likely to have serious impacts on health
May or may not constitute significant harm	Physical injury
	Gastrointestinal disturbances
	Respiratory tract effects
	Cardiovascular effects
	Central nervous system effects
	Skin ailments
	Effects on organs such as kidney or liver
	Wide range of other health impacts

6. The revised Statutory Guidance introduced a new four-Category approach to identifying whether land should be designated as contaminated in the legal sense for cases of a Significant Possibility Of Significant Harm to human health. Under this system Categories 1 & 2 include land that should be determined as contaminated under Part 2A and Categories 3 & 4 include land that should not be determined as contaminated under Part 2A. Category 4 therefore includes land of lowest concern, whilst Category 3 would include sites that regulators conclude should not be designated as contaminated under Part 2A following a detailed quantitative risk assessment. These categories are illustrated by the diagram in Figure 1 below (as shown in the Impact Assessment that accompanied the Statutory Guidance when it was submitted for approval – see Annex B).

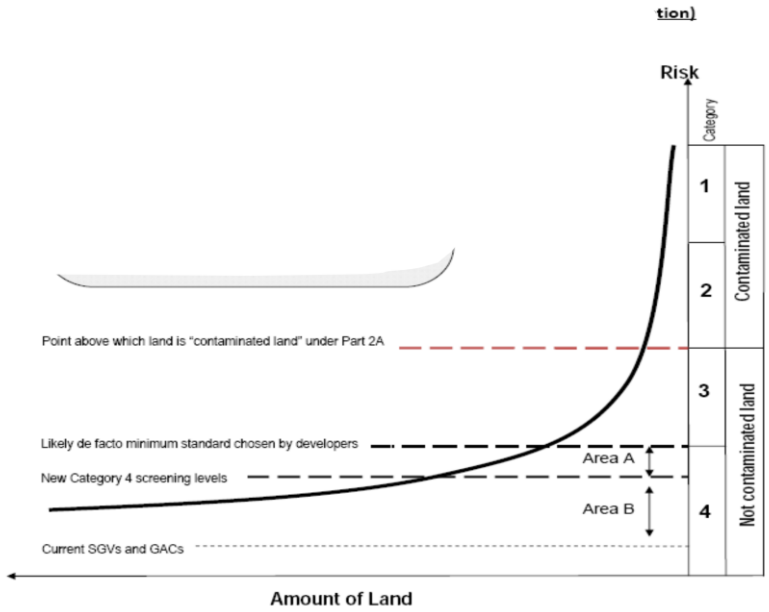

Figure 1: The new four-category system (not scaled)

7. With reference to Figure 1, the curved line and axes illustrate the spectrum of risk presented by land contamination. The idea is to show that a very large amount of land is low risk, and only a small amount of land would pose sufficient risk to be considered as contaminated in the legal sense i.e. pose a Significant Possibility Of Significant Harm (SPOSH). The axes and lines in the diagrams are not to scale, and they have been compressed for the purposes of illustration (in reality for most cases the risks in Category 1 land would probably be orders of magnitude above Category 4 risks, and vastly more land would be in Category 4 compared to the other Categories).

8. The revised Statutory Guidance describes Categories 4 & 3 as shown in the following extracts:

Category 4:

The local authority should not assume that land poses a significant possibility of significant harm if it considers that there is no risk or that the level of risk posed is low. For the purposes of this Guidance, such land is referred to as a "Category 4: Human Health" case. The local authority should consider that the following types of land should be placed into Category 4: Human Health:

(a) Land where no relevant contaminant linkage has been established.

(b) Land where there are only normal levels of contaminants in soil, as explained in Section 3 of this Guidance.

(c) Land that has been excluded from the need for further inspection and assessment because contaminant levels do not exceed relevant generic assessment criteria in accordance with Section 3 of this Guidance, or relevant technical tools or advice that may be developed in accordance with paragraph 3.30 of this Guidance.

(d) Land where estimated levels of exposure to contaminants in soil are likely to form only a small proportion of what a receptor might be exposed to anyway

through other sources of environmental exposure (e.g. in relation to average estimated national levels of exposure to substances commonly found in the environment, to which receptors are likely to be exposed in the normal course of their lives).

The local authority may consider that land other than the types described in paragraph 4.21 should be placed into Category 4: Human Health if following a detailed quantitative risk assessment it is satisfied that the level of risk posed is sufficiently low.

Categories 2 and 3:

(a) Category 2: Human Health. Land should be placed into Category 2 if the authority concludes, on the basis that there is a strong case for considering that the risks from the land are of sufficient concern that the land poses a significant possibility of significant harm, with all that this might involve and having regard to Section 1. Category 2 may include land where there is little or no direct evidence that similar land, situations or levels of exposure have caused harm before, but nonetheless the authority considers on the basis of the available evidence, including expert opinion, that there is a strong case for taking action under Part 2A on a precautionary basis.

(b) Category 3: Human Health. Land should be placed into Category 3 if the authority concludes that the strong case described in 4.25(a) does not exist, and therefore the legal test for significant possibility of significant harm is not met. Category 3 may include land where the risks are not low, but nonetheless the authority considers that regulatory intervention under Part 2A is not warranted. This recognises that placing land in Category 3 would not stop others, such as the owner or occupier of the land, from taking action to reduce risks outside of the Part 2A regime if they choose. The authority should consider making available the results of its inspection and risk assessment to the owners/occupiers of Category 3 land.

In making its decision on whether land falls into Category 2 or Category 3, the local authority should first consider its assessment of the possibility of significant harm to human health, including the estimated likelihood of such harm, the estimated impact if it did occur, the timescale over which it might occur, and the levels of certainty attached to these estimates.

Screening values

9. It is common practice in contaminated land risk assessment to use "generic assessment criteria" (GACs) as screening tools in generic quantitative human health risk assessment to help assessors decide when land can be definitively excluded from the need for further inspection and assessment, or when further work may be warranted. Most of the widely used GACs relating to human health risk assessment represent cautious estimates of levels of contaminants in soil at which there is considered to be no risk to human health or, at most, a minimal risk to health. Soil Guideline Values (SGVs) (GACs derived by the Environment Agency), as well as other GACs derived by various consultancies and sector groups, have been developed using the Environment Agency's Contaminated Land Exposure Assessment (CLEA) methodology (Environment Agency Science Report, SR3). This CLEA methodology combines toxicological evaluations with generic human exposure modelling of defined land-use scenarios (e.g. residential, commercial use etc) to derive the GAC.

10. The revised Statutory Guidance in April 2012 made clear that new technical tools may be developed and used to help regulators and others apply and conform to the Guidance. For example, the development of new generic screening levels to help assessors decide when land might be assumed to be in Category 4 (so-called "Category 4 Screening Levels (C4SLs)")(Figure 1). The Impact Assessment that was submitted as part of the approval process for the revised Statutory Guidance suggested that the Guidance could bring about a situation where the current SGVs and GACs could be replaced with more pragmatic (but still strongly precautionary) Category 4 Screening Levels, which would provide a *higher* simple test for deciding that land is suitable for its current or intended use and definitely not contaminated land. Such levels should be higher than the existing SGVs or GACs as implied from Figure 1 in the Impact Assessment and would allow low-risk sites to be dismissed from further consideration more quickly and easily and resources to be better targeted at higher-risk sites. The Category 4 Screening Levels will not describe the exact Category 3/4 border because they are generic values, due to the generic exposure model criteria used in the CLEA methodology, and would therefore still be conservative in nature.

Category 4 Screening Level project

11. In July 2012, Defra commissioned a research project to develop a methodology by which these new Category 4 Screening Levels could be developed and to test the methodology by generating Category 4 Screening Levels for six contaminants (lead, chromium VI, arsenic, benzene, cadmium and benzo[a]pyrene). The research project is due to be completed in June 2013. The project comprises three work packages: (i) development of the methodology, (ii) testing of the methodology by generating Category 4 Screening Levels for two of the six contaminants (cadmium and benzo[a]pyrene) (allowing revisions to be made to the methodology) and finally, (iii) the generation of Category 4 Screening Levels for the remaining four substances.

12. The research contract was awarded to a consortium led by Contaminated Land: Applications in Real Environments (CL:AIRE) and is being overseen by a Steering Group comprising Defra, the Welsh Government, DCLG, the Environment Agency, Natural Resources Wales, Public Health England (formerly the Health Protection Agency), the Food Standards Agency and the Homes and Communities Agency.

13. The consortium's chosen approach to the development of these Category 4 Screening Levels has been to make changes to the exposure parameters in the CLEA model and to develop a revised framework for the toxicological evaluation of chemical contaminants in soil. The existing CLEA model uses a 'minimal/negligible risk' Health Criteria Value (HCV), derived from the toxicology evaluation for each contaminant, which is a specific term only used in contaminated land risk assessment as defined in the Environment Agency's Science Report SR2 (EA 2009a).

14. In recognition that the Category 4 Screening Levels should be higher than the existing SGVs or GACs, which are based on minimal risk, the revised toxicological framework establishes a new term called a Low Level of Toxicological Concern (LLTC). The rest of this paper describes the proposed toxicological framework, how it has led to the development of the new term, LLTC, and the implications for Category 4 Screening Levels in contaminated land risk assessment.

A Proposed Toxicological Framework for the Derivation of Category 4 Screening Levels

Building upon the Existing Toxicological Framework in EA SR2

15. It is not a new concept to have a toxicological framework specifically for use in contaminated land risk assessment. In 2001, COT reviewed a toxicology approach as published in the Environment Agency CLR9 report (in the form of using a Tolerable Daily Intake (TDI) for thresholded chemicals, or an Index Dose (ID) for non-thresholded chemicals). An ID uses the principles of minimal risk as discussed by the Committee on Carcinogenicity (COC) in 2004. CLR9 was used to publish the first set of SGVs between 2002 and 2005, and following a Government-led review was revised and replaced by SR2 in 2009, which supported the publication of a second set of SGVs in 2009 and 2010. The underlying principles of minimal and tolerable risk remained consistent between the two documents.(Environment Agency Science Report (SR2; EA, 2009a) – see Annex C). The SR2 report was developed in close collaboration between the Environment Agency, the Health Protection Agency and the Food Standards Agency. HCVs are specific for use in contaminated land assessment and have been generated by the Environment Agency for a range of soil contaminants using minimal risk interpretations of the underlying toxicological evaluation.

16. The recommendation by the project consortium is that the existing framework described in the Environment Agency SR2 report is built upon and modified appropriately, incorporating the latest scientific guidance and allowing the most up to date evidence to be used. A new framework for C4SL derivation should use information from a quantitative evaluation of the toxicological dose response (where possible) of all relevant human health hazards together with appropriate exposure scenarios. Scientific evidence should be provided in the most transparent way possible, to inform and enable risk assessors/risk managers to define C4SL in the new four category system. The consortium is required to deliver proposed C4SLs for six contaminants in June 2013.

17. Taking a scientific approach (and building upon SR2 for the toxicological part of the evaluation) the development of C4SLs may in principle be achieved by modifying either the exposure or toxicological parameters or both. The initial work of the consortium (reported in the SP1010 Project Work Package 1 report – see Annex D) suggests that

modifications to the exposure parameters in a generic CLEA model as well as the toxicological evaluation are reasonable to enable the four-category risk continuum to be described more realistically and characterised more fully.

18. The overall approach proposed to derive a C4SL is illustrated in Figure 2. Analogous to the HCV that is needed to underpin the calculation of an SGV, a chosen toxicological intake dose (in mg kg^{-1} bw day^{-1}) is needed to input into the CLEA model to calculate a C4SL. To be distinct from the HCV, a new term – a Low Level of Toxicological Concern (LLTC) – has been proposed to represent such an intake dose for the C4SL derivation. The HCV represents an intake of minimal/negligible concern. Therefore the LLTC should represent an intake of low concern that remains suitably protective of health, and definitely does not approach an intake level that could be defined as a Significant Possibility of Significant Harm (SPOSH).

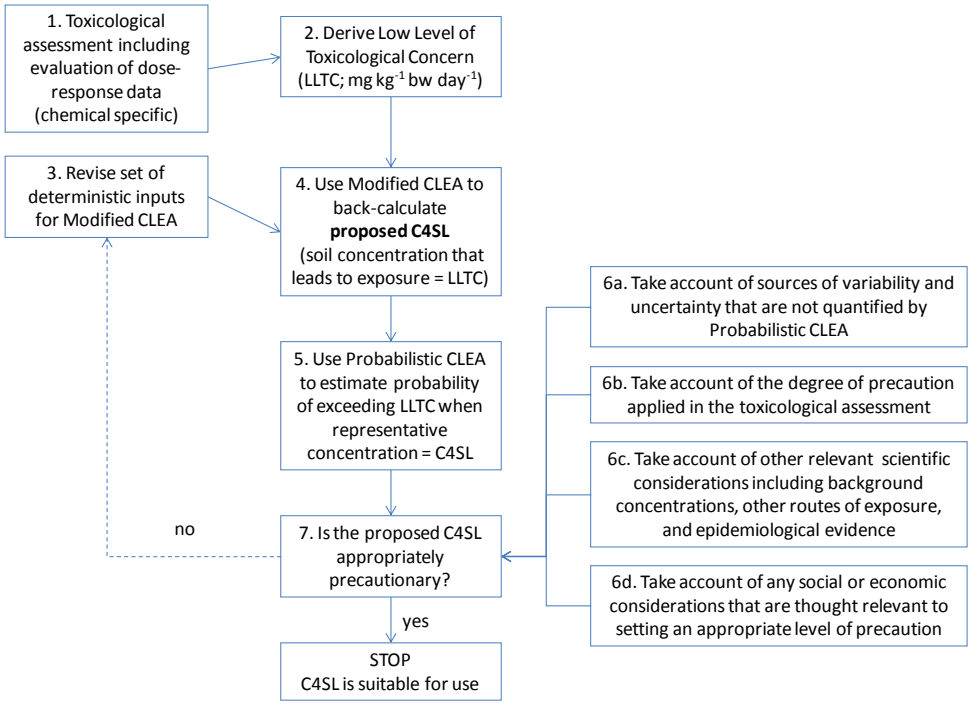

Figure 2 Overall approach to developing Category 4 Screening Levels

19. The first step of the overall approach is to evaluate the available toxicological data for a contaminant. As part of the output from Defra's research project SP1010, a revised toxicological framework (Figure 3) has been developed specifically to deliver an LLTC into the overall approach shown in Figure 2. The toxicological framework is designed to be worked through by a person suitably qualified in interpreting the toxicology data for a contaminant, i.e. a person who understands the nature of the toxicology data.

20. Typically, the contaminants for which C4SL are to be derived are data-rich chemicals with extensive and sometimes complex toxicology data packages. The key difference between the proposed toxicological framework

and that published within the Environment Agency SR2 report (EA, 2009a), is that more information relating to the quantitative dose-response can be used to inform the risk assessment, rather than only delivering and communicating the lowest minimal risk data point derived from the data. In providing minimal risk values alone, the risk assessor working on a potentially contaminated land site has little authoritative quantitative guidance from a toxicological perspective to help ascertain whether or not a site with a soil contaminant level just above an SGV would still present only a low level of concern.

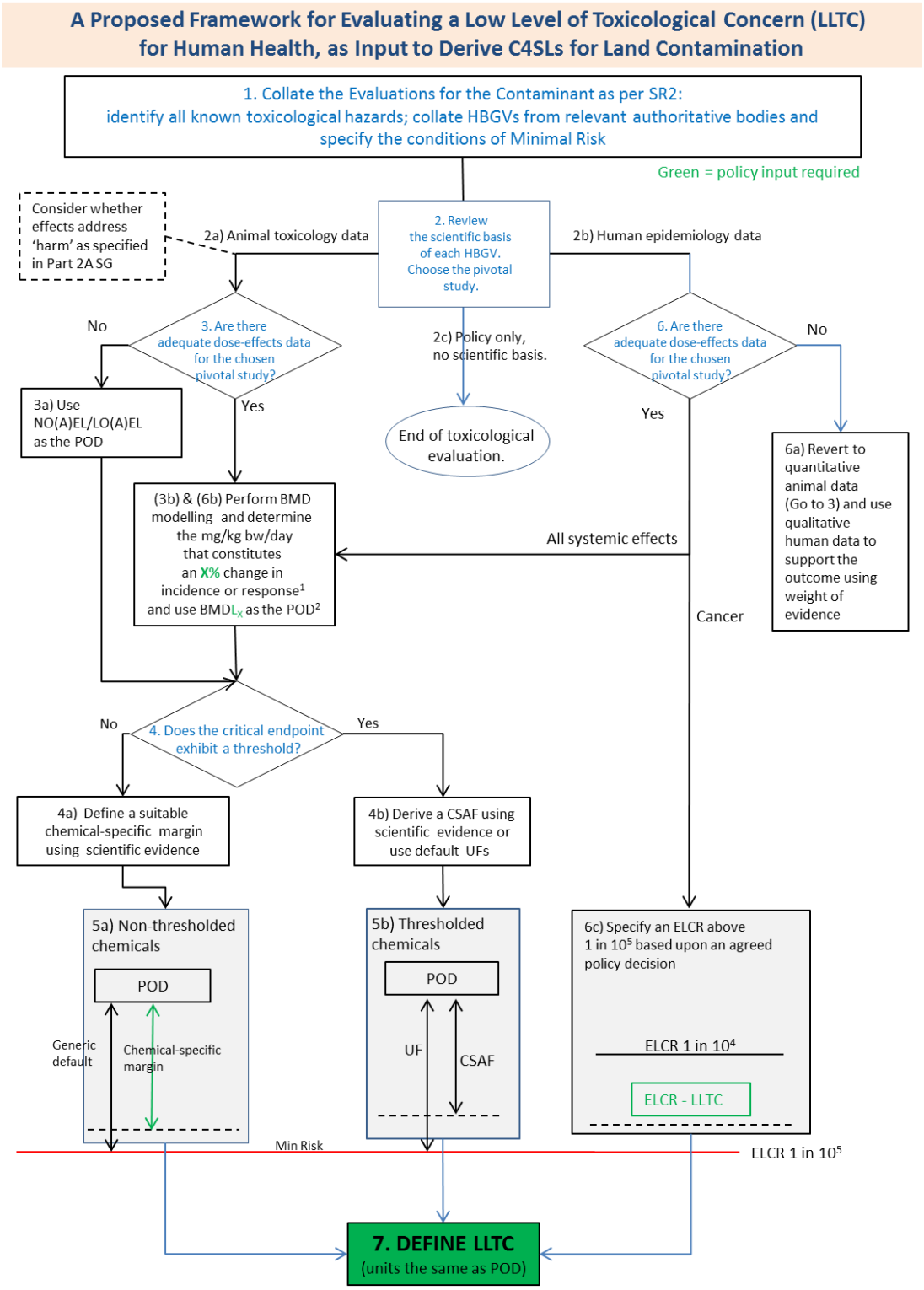

Figure 3 Toxicological Framework for Defining an LLTC for C4SL derivation

Brief Description of the Key Steps of the New Toxicological Framework

21. ***Flowchart Element 1***: **Collate the Evaluations for the Contaminant as per SR2: identify all known toxicological hazards; collate health based guidance value (HBGVs) from relevant authoritative bodies and specify the conditions of minimal risk**. The toxicological framework is the foundation of the hazard characterisation and should be completed by a qualified person who understands the nature of the toxicology data. The first task is to collate existing HBGV evaluations for each route of exposure separately (oral, inhalation or dermal). A checklist of information from authoritative bodies (e.g. World Health Organisation (WHO), US Environmental protection Agency (US EPA), Agency for Toxic Substances and Disease Registry (ATSDR), European Food Safety Authority (EFSA) etc.) should be collated, as per the process in SR2.

22. In some cases, new toxicology studies may be available (e.g. via the National Toxicology Program (NTP)) but the studies should have been reviewed by authoritative bodies before being used to develop an LLTC. Pertinent primary literature from peer review journals may also be included, if relevant, to provide supporting detail or raw data. However, reviews by authoritative international and national bodies are preferred over the open scientific literature for the purpose of guideline derivation.

23. It is important at this stage of the evaluation to identify all the possible toxicological hazards and identify the most sensitive endpoint and whether there may be overlapping dose responses. Previously, in defining minimal risk and a HCV, one only needs to identify and quantify the most sensitive of all effects, and choose the best quality study to evaluate the effect. By default a HCV is protective of all potential hazards. We are now advocating that the contaminated land risk assessor is provided with more information on the toxicological dose-response curve where possible. If a point of departure (POD) is chosen on the dose-response curve for the most sensitive effect and it is higher than that for minimal risk, it is important to consider the possibility that it could overlap with the dose-response curve of the next most sensitive effect. Therefore, in setting an LLTC, ALL overlapping sensitive endpoint evaluations must be borne in mind. This is an important principle in choosing a value higher than minimal risk and is an important departure from the principles of how SR2 and minimal risk evaluations are implemented.

24. ***Flowchart Element 2***: **Review the scientific basis of each HBGV? Choose the pivotal study.** Different authoritative bodies worldwide make different decisions about how a risk assessment should be conducted, although principles are beginning to be harmonised. UK authoritative sources have developed generic guiding principles on chemical risk assessment, e.g. those recently published by the COC in October 2012 for risk assessing carcinogens (COC, 2012) or Environment Agency SR2 (EA, 2009a). In general, good quality human data when available are preferred over animal data.

25. This second task of the toxicological framework is for a qualified person(s) to review the key toxicological data and choose the pivotal study from all the evaluations, taking into account the most recent guidance and opinions from UK authoritative sources. The chosen study should underpin the derivation of the LLTC. This will often be the same dataset as that chosen for the existing HCV derivation, unless new data have been published. However, as noted (in paragraph 24 above), it may also be necessary to evaluate more than one effect, when there are overlapping dose-response curves.

26. ***Flowchart Elements 3 and 6*: Are there adequate dose-effects data for the chosen pivotal study?** Irrespective of whether the pivotal data are derived from an animal or human study, if the answer to this question is 'yes', and there are good quantitative dose-response data then the user is advised to either use the benchmark dose (BMD) modelling data performed by an authoritative body or, if not available and if the data allow, perform bespoke BMD modelling using the latest version of the publically available US EPA BMD modelling software. The BMD modelling should be transparent and performed according to the accompanying guidance from the US EPA. A BMD approach is preferred over the use of a NOAEL or LOAEL to derive a POD. If the answer to the question is 'no - there is not adequate dose-effect data' it may not be possible to calculate a BMD – hence the option to use a NOAEL or LOAEL still exists in the framework. Note: a POD based on a T25 value is now not included in this framework, which is consistent with advice from COC (2012).

27. The UK COC has recently advised using the BMD approach for the interpretation of carcinogenicity data (COC, 2012), and other worldwide authorities are preferentially using BMD approaches for chemical risk assessment (e.g. US EPA, US ATSDR, EFSA, WHO etc.). For carcinogenicity, a benchmark response of 10% tumour incidence, with a lower 95% confidence limit ($BMD(L)_{10}$) is commonly used largely due to the 10% response being at or near the limit of sensitivity in most cancer bioassays (Benford *et al*., 2010). Non-carcinogenicity endpoints (e.g. chronic kidney effects seen with cadmium; neuro-behavioural effects from lead) can also be modelled using BMD approaches. Some datasets can allow for BMDs to be derived corresponding to lower benchmark response levels (e.g. 1 or 5% response). Therefore, in the framework, the BMD(L)s for a range of benchmark response levels that are appropriate to describe the nature of the pivotal data, and information on the steepness of the dose-response curve can be provided to the risk assessor.

28. ***Flowchart Element 4:* Does the critical endpoint exhibit a threshold?** The handling of uncertainty in the derivation of an LLTC is different depending upon whether the endpoint effect exhibits a threshold or not. This is consistent with the approaches described in EA SR2. This proposed framework incorporates the guidance for carcinogens from COC (2012).

29. ***Flowchart Element 4a)*** If the answer is 'no', the effect is non-thresholded. Some chemicals exhibit an effect that does not have an observable threshold in experimental studies (i.e. there is no dose under which no effects occur). This is often a cancer-related effect although neurobehavioural toxicity for lead also shows no threshold in human epidemiological studies. Specifically, genotoxic carcinogens that damage DNA in genotoxicity assays, are considered to have no threshold dose. For these substances, all doses, however small are assumed to carry a risk of an effect, even at the level of minimal risk described in SR2. Minimal risk therefore does not equal zero risk.

30. SR2 is based on guidance from the COC in 2004. This has been superseded as of October 2012, as the COC published a new guidance document (G06) for the risk assessment of chemical carcinogens (COC, 2012). However, the basic principles for defining minimal risk as described in SR2 remain consistent with this new advice.

31. For circumstances where exposure to non-thresholded chemicals is unavoidable, COC (2012) states:
'For carcinogens which do not show a threshold for effect, exposure should be as low as reasonably practicable (ALARP). In addition, the Committee recommends that the Margin of Exposure (MOE) approach be adopted as a tool *to indicate the level of concern* in situations where exposure is unavoidable. When it is necessary to set a standard or guideline value for a genotoxic contaminant, identification of a minimal risk level may be appropriate.'
Later it continues: 'The derivation of a minimal risk level for a genotoxic and carcinogenic contaminant or impurity involves assessment of all available dose-response data for carcinogenicity to determine an appropriate point of departure and *use of expert judgement to identify a suitable margin between this point of departure and a level of exposure which would result in a minimal risk*. One proposal is that a suitable margin might be 10,000 (Gaylor, 1994; Gold *et al*, 2003), which parallels the margin of exposure approach, where an MOE of 10,000 is considered to be *unlikely to be of concern* when based on a BMDL10 from an animal study. For a genotoxic and carcinogenic contaminant or impurity, a comparison of the minimal risk level with estimated exposure can be informative to risk managers.'

32. The classical way of implementing a margin of exposure (MOE) approach is to divide the POD by an exposure intake value estimated using a model of the exposure scenario (e.g. the Local Authorities (or their consultants) would need to use the CLEA model to derive an average daily exposure (ADE) for each site assessed and compare this value with the POD to calculate a MOE. The Local Authority would then need to decide in the context of risk management as to what level of concern the MOE represented. They may also have to decide if the principle of ALARP should be applied.

33. The UK COC (2007) presented MOE bandings for genotoxic carcinogens when based on a $BMDL_{10}$ from an animal study, for use in risk management and communication, as follows:

Table 2. MOE bands (as agreed by COC, 2007) for use with a $BMDL_{10}$ from an animal study

MOE band	Interpretation
< 10,000	May be a concern
10,000 – 1,000,000	Unlikely to be a concern
>1,000,000	Highly unlikely to be a concern

EFSA (2005) considered that when using a $BMDL_{10}$ from an animal study, an MOE of 10,000 represents a default 100-fold difference between the POD and human exposures to allow for general species differences and for human variability. An additional 100-fold difference is considered appropriate to allow for any additional uncertainties (such as human variability in cell cycle control and DNA repair, or using a POD that is not equivalent to a NOAEL). If BMD(L)s for benchmark responses lower than 10% are used or if human data are used, then this could warrant use of a different (lower) margin.

34. It should be noted for the purposes of deriving C4SL here, that whilst MOE is a useful approach to risk characterisation, the MOE approach *per se* does not lead to a HBGV, which is a necessary input parameter for the CLEA model used to derive a C4SL. The conceptual difference between the use of guideline values versus MOE approaches in risk characterisation, means that for the purpose here of deriving an LLTC, a margin has to be decided upon either for each specific contaminant or generically for all genotoxic carcinogens.

35. When deriving guideline values for non-thresholded carcinogens, there is support by COC (2012) for adopting an approach that parallels the MOE approach. In the framework in Figure 3, the chemical-specific margin (CSM) applied to the POD is a nominal value derived to represent a specified level of uncertainty for each specific contaminant. It is derived by reviewing the toxicological evidence, reviewing the uncertainties in the data, using expert judgment (the basis for which should be well documented) and also with good knowledge of the exposure model context and uncertainties within the exposure parameters.

36. The default margin of 10,000 between human exposure and a $BMDL_{10}$ from an animal study is considered to be 'unlikely to be a concern' (COC, 2007 & 2012). This echoes the way of defining minimal risk as per SR2 (EA, 2009b), DEFRA (2008) and COC (2004), where using a $BMDL_{10}$ for non-threshold carcinogenic effects divided by a default margin of 10,000 achieves the minimal risk level of 1 in 100,000 (EA, 2009). There is no UK guidance at present as to what margin, in relation to a POD, would constitute low concern. This remains a matter of judgement with appropriate advice.

37. For other non-cancer non-thresholded effects, there is also currently no UK guidance for margins that should be applied to PODs to yield a level of low concern. Therefore, a judgment would need to be made in conjunction with Defra and the relevant government agencies as to what an appropriate margin would be.

38. ***Flowchart Element 4b)*** If the answer is 'yes', the effect is thresholded. For a thresholded effect, a chemical-specific assessment factor (CSAF) may be applied to the POD to account for uncertainties, as discussed in SR2 (EA, 2009). For all thresholded chemicals, an uncertainty factor (UF) approach was previously recommended by COT (2007). For thresholded carcinogens, the COC (2012) guidance also advocates the use of an UF approach. This has not changed from the COC guidance of 2004 on which SR2 is based. Therefore, the new framework remains consistent with UK guidance.

39. The choice of UFs used for non-genotoxic carcinogens depends on the quality of the data and the uncertainties in the evaluation of the toxicological data (COT, 2007; COC, 2012). Moreover, for non-genotoxic carcinogens, the COC also advocates that default factors could be replaced in part or in full by CSAFs if the available data provide adequate information on interspecies or human variability (COC, 2012; Meek *et al.*, 2002).

40. When basing a HBGV on a NOAEL from a chronic animal study, a default UF of 100 is typically used, consisting of a factor of 10 for interspecies variability (4 for toxicokinetics and 2.5 for toxicodynamics) and 10 to account for intraspecies differences (3.2 for toxicokinetics and 3.2 for toxicodynamics) (COT, 2007; EFSA, 2012a). In many cases, the use of default UFs that are not chemical- or species-specific will result in conservative HBGVs, as the underlying data supporting them are generic and show wide variability. Therefore, using CSAF based on robust scientific evidence for particular chemicals (if available) is recommended in the derivation of the LLTC.

41. ***Flowchart Element 6c: Human cancer data evaluation***. In quantitative dose-response modelling, approaches are used to derive a numerical estimate of a dose that corresponds to an excess lifetime cancer risk (ELCR) (EA, 2009; DEFRA, 2008). Some authoritative bodies (e.g. US EPA and WHO) have calculated such ELCR from animal data. However, COC (2012) have reiterated the limitations of extrapolating high dose animal data to low dose human exposures. Defra has considered that an ELCR of 1 in 100,000 based on suitable human cancer data is appropriate to represent "minimal risk" (DEFRA, 2008). Given that C4SLs are designed to represent "low risk", consideration could be given to proposing an ELCR that represents such a low risk in the derivation of an LLTC.

42. ***Flowchart Element 5a:*** The LLTC calculation is performed for non-threshold effects by dividing POD/CSM or generic default margin = LLTC

43. ***Flowchart Element 5b:*** The LLTC calculation is performed for threshold effects by dividing POD/CSAF or generic UF = LLTC

44. ***Flowchart Element 6c:*** The LLTC calculation is performed using human cancer data - Dose = ELCR of 1 in X (where X is between 10,000 and 100,000) = LLTC

45. ***Flowchart Element 7:*** **Define LLTC** (for C4SL derivation). The project to date is exploring a range of possible LLTCs for six contaminants that could be recommended following different choices made in a toxicological evaluation, as representing levels that could represent low concern. For example:

- If a BMDL is chosen as the POD for a minimal risk HCV calculation, then a BMD could be chosen as the POD for the LLTC derivation.

- If a default margin of 10,000 is appropriate for the minimal risk HCV, a lower chemical-specific margin (e.g. 5000) could be regarded as appropriate for the LLTC.

- If an ELCR of 1 in 100,000 is appropriate for the minimal risk HCV, a higher ELCR (e.g. 1 in 10,000, 50,000, 75,000 etc) could be appropriate for the LLTC.

- If a 95th percentile value (e.g. a lower 95th percentile confidence limit or lower 95th percentile of population data) is chosen for a minimal risk HCV, a 90th percentile value could be chosen for the LLTC.

The places where a choice has to be made for deriving an LLTC in the Toxicological Framework are shown in green in Figure 3.

46. Annex E illustrates how the framework has been put into practice for the first two contaminants, cadmium and benzo[a]pyrene, being assessed in the Defra-funded Category 4 Screening Level Project.
47.

<u>Questions on which the views of the Committee are sought</u>

48. In the context of contaminated land, the Committee is asked the following questions:

i). Does the Committee have any comments regarding the use of a new term LLTC (Low Level of Toxicological Concern) that suitably reflects “low” concern in the context of deriving Category 4 Screening Levels for contaminants in contaminated land risk assessment?

ii). Does the Committee support the general approach taken in this research project and is the proposed methodology for developing LLTCs scientifically valid and robust given the role of LLTCs in assessing risk of exposure to contaminants in soil?

iii). Does the Committee think that the use of a chemical-specific margin (CSM), which parallels the MOE approach, is appropriate to derive a LLTC for non-thresholded chemicals? This could be either based on scientific uncertainties or be a policy chosen margin.

iv). Does the Committee think that, in the context of cancer, the use of an Excess Lifetime Cancer Risk (ELCR) higher than 1 in 100,000 is appropriate

when defining a LLTC using quantitative dose-response modelling (based on human data)?

v). Does the Committee have any comments that it would like the project consortium to take into account in finalising this research project?

Secretariat
May 2013

References

BENFORD D, BOLGER PM, CARTHEW P, COULET M, DINOVI M, LEBLANC JC, RENWICK AG, SETZER W, SCHLATTER J, SMITH B, SLOB W, WILLIAMS G, WILDEMANN T (2010). Application of the Margin of Exposure (MOE) approach to substances in food that are genotoxic and carcinogenic. Food and Chemical Toxicology, 48 Suppl 1, S2-24.

COC, 2004. Guidance on a strategy for the risk assessment of chemical carcinogens. Accessed online at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4091207.pdf

COC, 2007. COC Annual report. Accessed online at http://cot.food.gov.uk/pdfs/cocsection07.pdf

COC, 2012. Risk Characterisation Methods. COC/G06. October 2012.

COT, 2007. COT report on variability and uncertainty in toxicology (2007). Accessed online at http://cot.food.gov.uk/cotreports/cotwgreports/cotwgvut

DEFRA, 2008. Guidance on the legal definition of contaminated land. Defra, London. Accessed online at http://archive.defra.gov.uk/environment/quality/land/contaminated/documents/legal-definition.pdf

EA, 2009a. Human health toxicological assessment of contaminants in soil. Science Report Final SC050021/SR2. Environment Agency, Bristol, UK. Accessed online at http://www.environment-agency.gov.uk/static/documents/Research/TOX_guidance_report_-_final.pdf

EA, 2009b. Updated technical background to the CLEA model. Science Report – SC050021/SR3. ISBN: 978-1-84432-856-7. Environment Agency.

EA/DEFRA, 2002. Contaminants in Soils: Collation of toxicological data and intake values for humans. No longer accessible on the Environment Agency website.

EFSA, 2005. Opinion of the Scientific Committee on a request from EFSA related to a harmonised approach for risk assessment of substances which are both genotoxic and carcinogenic. EFSA Journal, 282, 1-31.

EFSA, 2012a. Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data. *The EFSA Journal*, 10 (3), 2579

MEEK, M.E. RENWICK, A., OHANIAN, E., DOURSON, M., LAKE, B., NAUMANN, BD., VU, V. 2002. Guidelines for application of chemical-specific adjustment factors in dose/concentration-response assessment. Toxicology, 181-182, 115-120.

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

The Development of New Screening Levels for Contaminants in Soil

Annex A – Relevant extracts from the revised Part 2A Statutory Guidance (published April 2012).

Full text is available at:

http://www.defra.gov.uk/publications/files/pb13735cont-land-guidance.pdf

Use of generic assessment criteria and other technical tools

3.27 It is common practice in contaminated land risk assessment to use "generic assessment criteria" (GACs) as screening tools in generic quantitative human health risk assessment to help assessors decide when land can be excluded from the need for further inspection and assessment, or when further work may be warranted.

3.28 Local authorities may use GACs and other technical tools to inform certain decisions under the Part 2A regime, provided: (i) they understand how they were derived and how they can be used appropriately; (ii) they have been produced in an objective, scientifically robust and expert manner by reputable organisations; and (iii) they are only used in a manner that is in accordance with Part 2A and this Guidance.

3.29 GACs[1] relating to human health risk assessment represent cautious estimates of levels of contaminants in soil at which there is considered to be no risk to health or, at most, a minimal risk to health. With regard to such GACs:

(a) They may be used to indicate when land is very unlikely to pose a significant possibility of significant harm to human health. This is on the basis that they are designed to estimate levels of contamination at which risks are likely to be negligible or minimal and far from posing a significant possibility of significant harm to human health.

(b) They should not be used as direct indicators of whether a significant possibility of significant harm to human health may exist. Also, the local authority should not view the degree by which GACs are exceeded (in itself) as being particularly relevant to this consideration, given that the degree of risk posed by land would normally depend on many factors other than simply the amount of contaminants in soil.[2]

[1] Paragraph 3.27 refers specifically to the Soil Guideline Values produced by the Environment Agency, and other published GACs produced on similar basis by LQM/Chartered Institute of Environmental Health and the Environmental Industries Commission using the Agency's Contaminated Land Exposure Assessment methodology as existed when this Guidance came into force.

[2] The level of risk raised by land contamination will depend on more than simply the amount of contaminants in the soil. For example, it will also depend on what form the contaminants take, where they are in the soil, the efficiency of

(c) They should not be seen as screening levels which describe the boundary between Categories 3 and 4 in terms of Section 4 (i.e. the two Categories in which land would not be contaminated land on grounds of risks to human health). In the very large majority of cases, these SGVs/GACs describe levels of contamination from which risks should be considered to be comfortably within Category 4.[3]

(d) They should not be viewed as indicators of levels of contamination above which detailed risk assessment would automatically be required under Part 2A.

(e) They should not be used as generic remediation targets under the Part 2A regime. Nor should they be used in this way under the planning system, for example in relation to ensuring that land affected by contamination does not meet the Part 2A definition of contaminated land after it has been developed.

3.30 New technical tools and advice may be developed and used in accordance with paragraph 3.28 above to help regulators and others apply and conform to this Guidance. This may be undertaken by government bodies, regulators or other organisations in the land contamination sector. Tools might be developed to help assessors apply the Category 1-4 approach (as described in Section 4 of this Guidance) in relation to specific substances or situations. For example, this might include the development of generic screening levels to help assessors decide when land might be assumed to be in Category 4; or tools to help describe how estimates of risk and/or bodily uptake of a contaminant might indicate that land should be placed within certain Categories.

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the pathway by which receptors may be exposed, the sensitivity of receptors, the likely degree and duration of exposure, the dose-response relationship, etc. These factors will vary from case to case, sometimes very substantially.

[3] The question of how comfortably land at the SGV/GAC levels would fall into Category 4 depends on the specific GAC in question and the site circumstances, given that different GACs have different levels of precaution built into them and that risks will depend on many factors other than merely the amount of contaminants in soil. In some cases it may be that GAC levels can be exceeded by a substantial degree (sometimes by orders of magnitude) and the land might still fall within Category 4, but in other cases there may be a considerably smaller margin and in some cases it may be that GAC levels are exceeded by only a few times and land would fall outside of Category 4.

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

The Development of New Screening Levels for Contaminants in Soil

Annex B – Relevant extracts from Defra's Impact Assessment that accompanied the revised Statutory Guidance.

Full text is available at:

http://archive.defra.gov.uk/environment/quality/land/contaminated/documents/contaminated-land-ia.pdf

Note: The document above is in the public domain and individuals can obtain it electronically by application to appropriate sources.

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Extracts from Defra's Impact Assessment that accompanied the revised Part 2A Statutory Guidance

What is the problem under consideration? Why is government intervention necessary?

England and Wales have a considerable legacy of land contamination from historical industrial activity. The Government is strongly committed to a precautionary approach to dealing with contaminated land, and current primary legislation remains strong in achieving this aim. However the accompanying Statutory Guidance, which is supposed to explain when land does (and does not) need to be remediated has created significant uncertainties. This has forced developers and other businesses into wastefully expensive remediation, which creates a deadweight burden on the UK economy. It has also led to poor value for taxpayers' money used to fund public sector land remediation projects

What are the policy objectives and the intended effects?

We intend to make the Statutory Guidance more usable for those that deal with land contamination and remediation. In particular, a new four category test is intended to clarify when land does and does not need to be remediated, and how it should be remediated to ensure a high standard without being excessive. By reducing regulatory uncertainty, this policy aims to make the regime target higher risk land more efficiently. It also aims to support the Government's growth agenda by removing excessive cost burdens on the house building sector and house buyers. The changes are also intended to support the development of technical tools by the land contamination sector to increase consistency over time.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

The range of options was limited by the nature of this policy. Two options (do nothing and update the Guidance) were formally consulted on. Within the broad "update the Guidance" option various potential changes, tools and updates were tested and discussed with practitioners, and final changes to the Guidance have been chosen with careful consideration of expert opinion from across the sector.
The preferred option is to update the Guidance and the main changes include:
- a new four category test to help decide when land is and is not contaminated land in the legal sense
- clarification of the status of technical screening levels ("SGVs and GACs") and how to use them
- clarification that "normal" background levels of contamination would not be contaminated land

- clarification of what would constitute a "reasonable" level of remediation.

Problem 1: Uncertainty over when land qualifies as "contaminated land"

12. Since the contaminated land regime came into force there has been substantial uncertainty over how to decide when land is (and is not) "contaminated land", and in particular over how to decide when land meets the legal test of "significant possibility of significant harm to human health". In some cases, it is inherently difficult to decide when land poses a significant risk because there is often substantial scientific and technical uncertainty over precisely what level of risk is posed at any given site[4]. Given the technical uncertainty and the broad spectrum of risk there is a substantial

potential for „regulatory creep", and it is vital that the regulatory regime is clear about what it aims to achieve. It is also very important to be clear about when land lies outside its scope, given the large costs and other impacts associated with remediation.

13. The current Statutory Guidance fails to give an adequate explanation, particularly on the key legal trigger of when land would pose a "significant possibility of significant harm to human health". It merely says that a "significant" risk would exist if human exposure to a contaminant would *represent an unacceptable intake or direct bodily contact, assessed on the basis of relevant information on the toxicological properties of that pollutant*. But it does not explain how to decide what "unacceptable" means. It also inadequately explains how to proceed if toxicological information does not (in itself) point to an obvious answer, as is often the case given scientific and technical uncertainties.

14. The reason why the current Statutory Guidance does not explain how to decide when land is contaminated land is that it was published on the assumption that (non-statutory) "guideline values" would be produced that would describe levels of contamination above which there could be assumed to be a significant risk. However, to date (despite various attempts) it has not been possible to publish satisfactory guideline values. Annex 4 explains this in more detail, but in essence: (a) the risks posed by soil contamination depend on so many site specific factors that it has not been possible to produce workable "one size fits all" guideline values; and (b) the Statutory Guidance gives no advice on what the guideline values should be trying to achieve, and thus there is no legal framework on which to build.

[4] There are many technical reasons for the high levels of uncertainty that often underlie risk assessments. There is often significant scientific uncertainty over possible effects of most substances on human health, particularly at low doses. Furthermore there is often significant uncertainty over how likely it is that people will be exposed to substances, particularly where the effect is likely to be low level exposure over decades. In practice, sometimes the levels of risk are clearly so high or low that regulatory decisions are straightforward. However, in other cases decisions are far less easy to take because there is substantial uncertainty over what the risks might be and estimates of risk may rely heavily on assumptions made in risk modelling rather than on "hard" evidence.

15. The result has been substantial regulatory uncertainty. In effect, it has meant that regulators have been left to make decisions about where to intervene on sliding scales of risk with little or no statutory advice on what they should be seeking to achieve.

16. In 2002, the situation was inadvertently compounded when “soil guideline values” (SGVs) were published for ten contaminants commonly found in soil. Despite their name, the SGVs were not the guideline values foreseen by the Statutory Guidance because they did not seek to describe the legal trigger point above which there would be a “significant” risk to human health. Instead, they were cautious estimates below which, in a reasonable worst case scenario, there would be a very low level of risk, or no risk at all. As such, the SGVs were a technical tool that could be used early in risk assessment to screen out contaminants that were clearly posing a very low risk. However, unfortunately for some years the SGVs were often mistaken as the envisioned guideline values that described the legal trigger point, and as a result some very precautionary decisions were taken.

17. In recent years, the status of SGVs has been clarified and the situation has improved to an extent8. In themselves, the SGVs can be useful because they provide a point of reference to help decide when sites are likely to be very low risk. SGVs have also recently been supplemented by other “generic assessment criteria” (GACs) produced by two land contamination sector initiatives for about 120 substances not covered by SGVs. So the sector now has SGVs/GACs for about 130 of the most common contaminants found in soil (although lead and asbestos, two common contaminants, have not been covered by the initiatives).

18. However, the situation is still far from satisfactory because there is nothing in the Statutory Guidance which explains that there is a wide spectrum of risk potentially posed by land contamination, or where regulators should seek to intervene on this spectrum. In this absence of such Guidance, the SGVs/GACs are the only generally available point of reference. This is problematic because the SGVs/GACs describe levels of contamination that are likely to be far into the “clearly not contaminated land in the legal sense” part of the spectrum. In the absence to date of other generally available technical tools to describe other areas of the spectrum of risk, the SGVs/GACs have been given undue prominence, and because they are so cautious they inadvertently have the effect of skewing the whole regime towards being excessively cautious. For example:

- The SGVs/GACs seem to many to offer the only cast-iron guarantee of a point at which land is definitely not contaminated land in the legal sense.
- Often non-experts might get the wrong idea that land which exceeds the SGV/GAC levels is “tainted” even though in many cases land could exceed the levels by several times, and in some cases by tens of times, and still not be problematic.
- The SGVs/GACs are often wrongly used as “one size fits all” remediation targets. This is a problem because they are not intended to

be remedial targets under either Part 2A or the planning system. In practice, deciding whether remediation is needed (and if so to what extent) would normally require the site-by-site judgement of an expert who can take account of the many factors relevant to ensuring that risks are at an acceptable level post-development. In the large majority of cases a standard of remediation considerably less stringent than the SGV/GAC levels would be more than adequate to protect human health and the environment. Therefore, taking a one size fits all approach based on SGVs/GACs is not justifiable because it forces developers and landowners to remediate land to excessively high standards and costs, and can have a range of other negative impacts as discussed in paragraph 6.

19. To illustrate just how precautionary some of the current SGV/GACs are, it is likely that nearly the whole county of Cornwall and large tracts of other parts of England would be above the SGV for arsenic. Also large parts of London and other towns and cities would exceed the (now withdrawn) SGV for lead. If the SGV methodology were to stay as it is, it is likely that any new SGV for lead would be almost ten times lower than the old one, taking it to below the national average level of lead in soil and meaning (among other things) that nearly all urban land in England and Wales would exceed the SGV. This situation cannot be allowed to continue because having such extremely precautionary screening numbers has perverse consequences. It has potential to create serious blight and cost issues that were certainly not the intention of the Act, which was introduced to target high risk sites and to avoid blighting land unnecessarily. It also raises practical problems such as consigning large amounts of low risk soil to landfills, and makes it very difficult to find replacement soil to use on building sites.

20. The lack of clarity given by the current Statutory Guidance has led to various problems for the implementation of the Part 2A regime itself. There have also been various knock-on effects for the construction sector and other businesses and landowners, with construction companies and other businesses reporting that they have been required to remediate land to excessively high standards and incur unnecessary costs. These effects are discussed below (from paragraph 22).

Box 2 – Changes to the Statutory Guidance to address Problem 1 (Uncertainty over when land qualifies as "contaminated land")

New four category test to help decide when land is, and is not contaminated land: The new test will introduce broad categories to describe areas on the broad spectrum of risk encountered by assessors. The new Categories are intended, among other things, to offer a legal framework against which the sector can benchmark technical tools which describe certain categories or indicate the boundaries between categories, with regard to specific substances/situations (see sections on "How would the new Category 1-4 system work?" and "What More Needs to be Done" below).

Category 1 describes land which is clearly problematic for example because similar sites are known to have caused a significant problem in the past.

Categories 2 and 3 cover the less straightforward land where detailed consideration is needed before deciding whether it is contaminated land. The test rests on whether or not the LA believes there is a strong case for regulatory action – and thus whether it should be placed into Category 2 (contaminated land) or Category 3 (not contaminated land). The LA would start by considering health risks alone, and if this leads the LA to consider that land is clearly problematic or non-problematic the decision could be taken at this point. However, if this does not lead to a decision (e.g. because of uncertainty over the risks), the LA would consider wider socio-economic factors (e.g. cost, views of local people, etc) before deciding. If the LA still cannot decide, the default decision is that the positive legal test for contaminated land has not been met and the site should therefore go into Category 3 (not contaminated land).

Category 4 describes land that is clearly not contaminated land. The new Category 4 test is particularly important in terms of reducing uncertainty over when land is clearly not contaminated land in the legal sense. For example, it would clarify that Category 4 land would include land where there are only normal background levels of contamination (unless there is some exceptional reason to consider there may be a problem), and land at SGV/GAC levels is likely to be well into Category 4.

How would the new Category 1-4 system work?

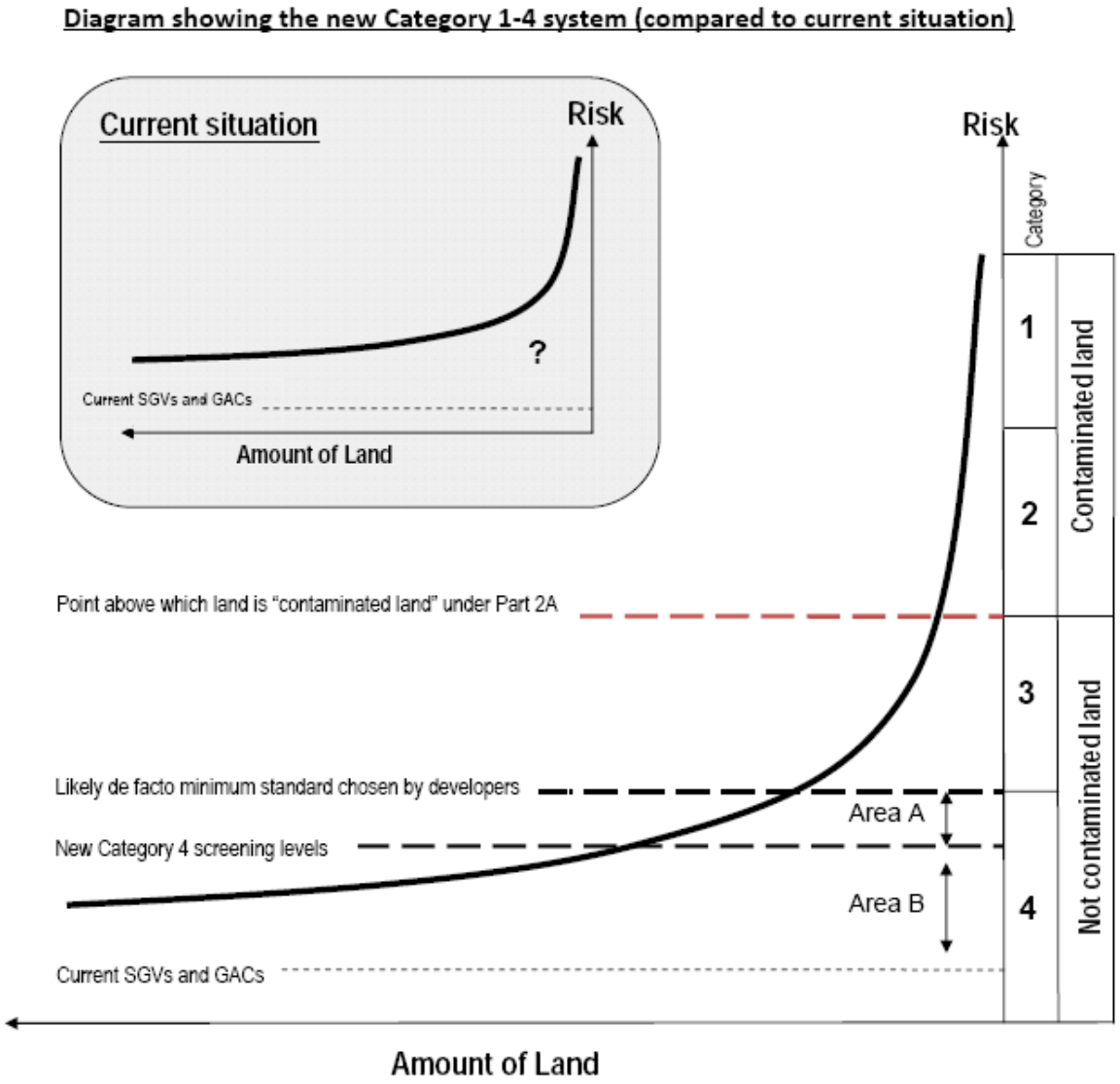

Figure 1: The New Four Category System

47. The diagram above seeks to illustrate, in a simplified manner, broadly what the changes to the statutory guidance on significant possibility of significant harm to human health are intended to achieve. To explain:
(a) The curved line and axes illustrate the spectrum of risk presented by land contamination. The idea is to show that a very large amount of land is low risk, and only a small amount of land would pose sufficient risk to be contaminated land in the legal sense. The axes and lines in the diagrams are not to scale, and they have been compressed for the purposes of illustration (in reality the risks on Category 1 land would probably be orders of magnitude above Category 4 risks, and vastly more land would be in Category 4 compared to the other Categories).

(b) The smaller diagram summarises the current situation. In the area below the SGV/GACs there is near certainty that land is not contaminated land,

however, above the line there is increasing uncertainty. As explained above, currently remediation usually occurs to just below the SGV/GAC level because they are perceived as offering the only cast iron guarantee of when land is definitely not contaminated land. Sometimes consultants are employed to justify remediating to levels above the SGV/GACs, however the further they go away from the SGV/GACs the more legal risk they and their clients are exposed to.

(c) The new statutory guidance will end the current situation, and it would not be legally possible e.g. for individual regulators to ignore the changes being made. For example, as explained above, the new statutory guidance will specifically say: (i) that Part 2A cannot be used to force remediation to below a point where it ceases to be contaminated land in the legal sense (i.e. the Category 2/3 border in terms of the diagram), although responsible parties can choose to go further; (ii) that SGV/GACs cannot be used as one size fits all remediation thresholds under either Part 2A of the planning system; (iii) that “normal” background levels of contamination are not caught by Part 2A; and (iv) that SGV/GACs are well into Category 4, sometimes by only a few times and sometimes by orders of magnitude. These changes and others also provide the legal backing for the development e.g. of Category 4 screening levels, as discussed below.

(d) The new Category 1- 4 system divides the spectrum of risk posed by contaminated land into four different categories, and the statutory guidance will explain how to decide when land falls into each Category. This is more sophisticated than the current statutory guidance, which in effect has only two categories (contaminated land or not) and does not explain how to decide which category land falls into. The new Category 1-4 system reflects what assessors find when they investigate real sites – i.e. some are clearly contaminated land (Category 1); some clearly are not (Category 4); and some are less-straightforward and need some level of detailed assessment before a decision can be taken as to whether or not they are contaminated land (Categories 2 and 3).

(e) In the case of Category 2 and 3 sites, the regulator will have flexibility to take decisions within the parameters set by the new Guidance. There would be less flexibility for Category 2 and 3 sites that clearly pose either a high or low risk. However, the regulator will have considerable flexibility for sites closer to the Category 2/3 border to judge which side of the border a site would fall (e.g. taking account of their understanding of the risks, uncertainties and the interests of the local community). These are often complex decisions which need to be taken case-by-case given the many factors involved.

(f) In the case of Categories 1 and 4 the regulator will have far less flexibility. For example, if a regulator claimed that a site matching the Category 1 description was not contaminated land, or that a site matching the Category 4 description was contaminated land, they would be acting directly against the statutory guidance which the Act requires that they follow, and decisions could be challenged (e.g. in a law court) with a high chance that the challenge would be successful. Among other things, the intention of doing this is to create far more legal certainty around when land is definitely not contaminated land in the legal sense. With the specific wording of the new

statutory guidance, and the supporting tools such as the new Category 4 screening levels, it would be very difficult for a regulator e.g. to threaten landowners with the Part 2A regime, and if they tried to determine land as contaminated land they would be operating in direct opposition to the statutory guidance.

(g) In the many consultation meetings held in developing the Category 1-4 system, all the developers, landowners and consultants we spoke to were strongly of the view that they would want the ensure their land is safely within Category 4 (even though in theory they could remediate to a level within Category 3 and still satisfy Part 2A and planning rules[5]). They would do this for various reasons, including the fact that the flexibility granted to regulators in Categories 2 and 3 means that the further into Category 3 a site gets, the greater the risk that the regulator might decide it is in Category 2. Also they would want to be in Category 4 for reasons of marketability, future proofing etc. So developers and others would have a strong incentive to seek the regulatory certainty of being safely within Category 4. Thus, as far as development taking place under the planning system is concerned, Category 3 would, in effect, normally be a buffer which provides added reassurance that development falling within Category 4 will not be caught by the Part 2A regime.

(h) The new statutory guidance will bring about a situation where the current SGV/GACs are replaced with more pragmatic (but still strongly precautionary) Category 4 screening levels (C4SLs) which will provide a higher simple test for deciding that land is suitable for use and definitely not contaminated land. Above the C4SLs, in Area A on the diagram, there will be much stronger legal backing for experts to use their judgement to make sensible and precautionary decisions on when land should be considered to be towards the top end of Category 4, without fear that land may be caught as contaminated land. This recognises that the generic C4SLs will not be able to describe the Category 3/4 border itself because they are generic and would therefore have to err on the side of caution – whilst a detailed site specific assessment would be able to push further by looking at specific circumstances relating to a specific site.

(i) The very large majority of the monetised benefits of the changes to the regime discussed in this Impact Assessment manifest themselves in Category 4, and in particular in Areas A and B on the diagram. The main effects of moving to the new system would include

- Low risk land falling within Area B (pre-development) on the diagram would no longer have to be remediated because it would fall below the new C4SLs. Similarly land which is in Area A pre-development would no longer need to be remediated if justified by a detailed site-specific

[5] The Department for Communities and Local Government is currently consulting on a proposed new National Planning Policy Framework which would explain that land affected by contamination must be remediated to a standard where it is suitable for use, and as a minimum must not be capable of being determined as contaminated land in the legal sense under the Part 2A regime.

assessment. For these sites the cost of remediation would be removed altogether.

- The cost of remediating land which is initially in Categories 3, 2 or 1 would fall because it would be remediated to the new C4SL levels (or somewhere within Area A if there has been a detailed assessment) rather than the SGV/GAC level. This will have the overall effect of reducing the cost of remediation, with the effect varying according to specific site circumstances, the type of remediation etc.
- Generally the cost of remediation would fall for many affected brownfield land sites. This would have the general effect of making such land more economically viable for development. It would also mean that some land that is not currently economically viable to develop becomes more viable. Among other things this is likely to increase developers‟ options. It may also help reduce pressure to develop greenfield land in some cases.
- The C4SLs will also speed up regulatory decisions on the reuse of brownfield land by providing a simple remediation standard.

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The Development of New Screening Levels for Contaminants in Soil

Annex C – Environment Agency Science Report SR2

Outlines the toxicological evaluation used to derive a Health Criteria Value

(see separate document)

Note: The document above is in the public domain and individuals can obtain it electronically by application to appropriate sources.

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COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

The Development of New Screening Levels for Contaminants in Soil

Annex D - SP1010 Project Work Package 1 report

(see separate document)

Note: The document above is in the public domain and individuals can obtain it electronically by application to appropriate sources.

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The Development of New Screening Levels for Contaminants in Soil

Annex E – Development of LLTCs for Cadmium and Benzo(a)pyrene as in the Work Package 2 reports in the Defra-funded SP1010 research project

(see separate document)

Note: This final annex is not yet in the public domain but will be published by Defra shortly.

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