



Our ref p&t/HP

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Dear Mr Coleman

## Assessing risks from land contamination – a proportionate approach Soil guideline values: the way forward

I refer to the above Discussion Paper published by the Department in November 2006, the proposals in which certainly represent a comprehensive package covering toxicology, exposure modelling, numerical methods etc.

It must have been difficult to write and many readers reported finding it complicated. Ideally, they would have liked more time to consider it but though those comments probably reflect the nature of the subject matter as much as the paper's style itself, separate annexes, divorcing from the main paper the reasons for taking forward some proposals and for rejecting others were not helpful. On the other hand, the concept of zones was useful and we appreciate nonetheless all the work and consideration put into the current proposals by Defra and its Advisers over the past year in particular. We were glad to have had the opportunity to assist in a small way the process leading up to the paper's publication and look forward to supporting Defra as much as the regulatory community in implementing the various changes proposed. We hope they will restore confidence in the process of determination which is likely to become more important as the supply of more readily-developed sites dries up.

We gave some initial reactions at a Brownfield Briefing conference at the beginning of December. We have had more time to consider the paper since then and have consulted

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widely among local authorities via our Standing Conference on Land Contamination but have found little reason to depart significantly from our early views. The few areas in which we disagree with the Department – on the application of cost-benefit considerations and on guideline values in planning especially – are, however, significant.

### *Background*

The subject matter is complex, both scientifically and in its regulation. Even now, few people have a complete grasp of it and the underlying science is still lacking. We understand why the Department does not want to revisit the legislation, nevertheless the mismatch between the toxicology and the statutory test might have been avoided had the latter taken better account of the former in 1995 and some concerns remain about the responsibility the legislation places on individual authorities. We know it is an underlying aim of the paper to reduce the scope for inconsistency and it is a pity there appear to be legal barriers to going further, nevertheless we think the fundamental approach ie based on addressing unacceptable risks remains sound. It is neither possible nor desirable to try to remove all risks, in particular ubiquitous or minimal risks, to which we might add advertent risks – those which people choose to take upon themselves.

The paper is, of course, fundamentally about future Guideline Values (GVs)(which we distinguish from the current Soil Guideline Values). These are essential stepping stones on the path to determination. If the paper promises a firmer footing for them, we are aware nonetheless of widespread suspicion that they will be generated with an eye to reducing the number of sites determined. While we do have some concerns about some features of the proposals (eg the apparently inconsistent different risk benchmarks for single/multiple non-threshold substances), we do not share that suspicion. Our understanding is that the combination of a reasonable worst case approach to exposure and the precaution still embodied in the derivation of TDIs will continue to provide a significant margin of safety for the great majority of the population. That is reduced only where an unusual exposure is not fully represented. Where thought necessary, however, that can be compensated-for in the course of a site-specific DQRA, maintaining the equity principle described in para 5.32. The Department may nevertheless need to provide some reassurance to the wider regulatory community.

The following detailed comments focus on aspects of the “Emerging conclusions”.

### **Human toxicology and health effects**

This is the most difficult part of the paper to comment on. Many of the responses made to us confess some lack of understanding, not so much of technical matters on which we have trained extensively as on the underlying concepts of the process, but nowhere so much as on the toxicology. Nevertheless, the revelation in Taskforce meetings of the use and scale of “uncertainty factors” has been an eye-opener to the extent of the lack of science here and it is difficult to have confidence in, or to accept, the resulting estimates as authoritative. We understand uncertainty in science and the variation of human reactions to contaminants but the way of dealing with those, whether in line with international practice or not, is simply arbitrary. We would have welcomed greater scrutiny of this area and while in our view there is ultimately no substitute for proper health studies, where such devices are employed, as a minimum, they must be declared.

### *More weight on observations*

If toxicology has been and remains the Achilles heel of the whole regime, it is a small but nonetheless valuable step in the right direction to propose to base TDIs on observed

effects and we agree that greater use should be made of LOAELs. If that is out of step with international practice in health protection, it appears inevitable given the way our statutory test is framed and so be it. We do not agree that an approach based on this is necessarily difficult to present to the public nor that the objection – that some risk may theoretically exist below LOAELs - is stronger than that using NOAELs could result in unnecessary expense and disruption. Bearing in mind nonetheless the uncertainties in deriving TDIs and the consequences of those, where alternative ways of estimating health effects of soil contaminants exist or can be developed, we would support those. That is, at least if they introduced more certainty. We would be surprised however if, as para 1.4 of annex A suggests, this was not possible for substances other than lead and asbestos.

In the approach to identifying a benchmark for the intake from soil of threshold chemicals, we do not believe it makes sense to ignore “known” intakes of contaminants from sources other than soil. Some allowance needs to be made, otherwise, as the annex explains under 3(a), any non-soil intake results immediately in an exceedance of TDI and is inequitable to those living on more contaminated sites. If the 20% assumption is wrong, we would be content to see it reduced. We would, however, prefer to see that done on a contaminant-specific basis rather than by an arbitrary change to 50% though we would be prepared to accept that as a pragmatic compromise.

To the extent it is suggested that cost-benefit considerations should figure in benchmarks for soil intake, we disagree; we think it is important for public confidence that benchmarks of unacceptable risk should be established transparently and as a matter of health policy. Where the practicability and societal impacts of managing the risks posed by different substances vary, that should be considered subsequently, openly, and in particular in a way that can be separately identified, as part of the basket of practical considerations.

### **Exposure pathways**

We approve of the aim to refine the CLEA model better to represent real life. Assessors nevertheless need to be in no doubt about what parameters the model is based on in order to make site-specific adjustments where needed. The model needs, hence, to be as transparent as possible.

#### *More realism*

As with the toxicology, we would prefer that exposure pathways were developed on the basis of observation rather than assumptions which we and others have perceived as exaggerating exposures. As a case in point, our members working on allotment sites report the presence of children at a much lower level than has been assumed and we approve of the proposal to review the worst case assumption here. On the same basis, we also approve of the proposal to reduce the assumed soil ingestion rate which we are told better reflects the long-term reality, though the lower rate still might not reflect an unacceptable intake in the case of substances (such as BaP) which adhere to soil.

Some review still appears needed elsewhere, however; assuming a 43-year exposure in the case of workplaces looks excessive when the best the survey data apparently reveals is that 24 percent of workers in the cohort had worked for the same employer for just 30 years. It is difficult, moreover, to accept that the quality of any linkage would remain constant over such a period. We are also not convinced by the repetition that various small changes to exposure frequencies and durations, though that would bring more realism, would have a negligible effect when the aggregate effect of that seems not to have been considered.

### *Default pathways*

Likewise, while opinions vary, we think there is still room for debate whether the default pathways should continue to include plant uptake (which in any event does not consider fruit, only selected vegetables), the risks from which are wholly advertent and might be amenable to some extent to “flanking controls”. Notwithstanding, if that pathway does remain we note that the consumption range assumed in CLEA is still higher than that used in other countries. The application of the reasonable worst case, based on the small self-sufficient minority, has been different too and the proposal to exclude them, putting the emphasis less on “worst” and more on “reasonable”, would be justified. Better reflecting international practice too, it would seem to leave few people at significantly greater risk. In similar vein, we would welcome improved guidance on a tiered approach to estimating vapour intrusion into buildings.

### *Making CLEA deterministic*

The biggest change proposed in this zone, however, is to make CLEA fully deterministic. Such models already exist of course, eg SNIFFER, and while deterministic models are inherently less able to reflect variabilities, there are concerns that this will be less protective in the absence of more site-specific data. We nevertheless support this for all the reasons set out in annex B but in particular because, in line with some other proposals, and as para 76 says, it would remove some of the more extreme exposure estimates from the calculation of Guideline Values. Though that might suggest a reduction in protection for people at the extremes of the population, that is in part a matter for choice of the average values chosen which should be appropriate (and indeed could be more appropriate than the current distributions if better data is available). It should also increase understanding of how the model works and allow easier manipulation of it (since the probabilistic parameters are not amenable to adjustment). For transparency though, the output ought to indicate clearly where default parameters have been altered.

To maximise accessibility, we recommend that the revised model be web-based and that there should be maintained on-line a database of physico-chemical properties of contaminants and authoritative tox data, presented in a form intelligible to non-toxicologists, to allow findings of new studies to be taken account of as quickly as possible. The ability in the future to take account of the degradation of volatile contaminants will bring further realism.

We would also encourage the development of Guideline Values for scenarios not covered so far, in particular schools and public open spaces including parks and playing fields. CLEA UK should in addition incorporate a pathway for exposure via groundwater.

### **Practical and Policy considerations**

The proposal not to remove naturally occurring substances and ubiquitous anthropogenic contaminants from the regime is supported though we are not convinced that to exclude the former would necessarily require new legislation; notwithstanding that Part 2A refers to “any natural...substance” it is a matter of construction whether such substances in their natural geological state are encompassed by the term “contamination”. Though there may be no practical way to deal with these ultimately, their inclusion is a matter of health protection however, moreover in some cases there is no way to distinguish between naturally-occurring and anthropogenic substances.

That dealt with, we find it difficult to understand why (*vide* para 5.35) it should be more difficult to express a level of unacceptable risk for contaminated land than elsewhere. There may, of course, be technical challenges in identifying when such a threshold is breached but setting it is Government's job and, in principle, it appears straightforward yet the paper reveals some anomalies in the approach.

#### *Cost considerations should be separate*

As some of our comments above hopefully show, we expect the process of risk assessment to be scientifically justified and like the Department, we could not, for example, support simply multiplying SGVs by a "fudge factor". Nor, however, could we agree that costs and practicalities should determine values intended, broadly, to equate to "SPOSH". We cannot understand why they should be allowed to influence the choice of unacceptable intakes either. These should surely be a function of the toxicology alone. If costs and/or practical considerations render a Guideline Value unachievable, there is a strong feeling that condoning higher contaminant concentrations, perhaps with appropriate flanking controls, is then a matter for policy but should be transparent. We should add, though, that we are wary about flanking controls which might be appropriate in some circumstances, eg where an exceedance is marginal, but may not be reliable in all.

#### *Some anomalies*

In the case of non-threshold substances, while we do not disagree with the benchmark suggested for single substances in the context of Part 2A assessments, we cannot understand why a ten-fold increase – or in fact any increase - in excess lifetime cancer risk should be acceptable where there are multiple contaminants. Appearing similarly anomalous is the proposal for the unacceptable level of risk from Arsenic to remain based on the drinking water standard which is out-of-step with the approach to other substances also found in drinking water and we find it difficult to support substance-specific adjustments to risk benchmarks in the case of ubiquitous contaminants in general; as para 1.23 of annex A says, that would jeopardise the achievement of consistent levels of health protection and we see a possible way forward here through bioaccessibility testing.

### **Site-specific decisions**

#### *Bioaccessibility/availability*

The problems of ubiquity and of natural substances whose background levels can be considerable require special consideration. But in the case in point of Arsenic at least, we believe that the scientific basis for a measure of the fraction which is bioaccessible has now been sufficiently established through *in vitro* tests to allow its application to the risk assessment process. We do understand the Environment Agency's caution and do not underestimate the scientific difficulties here eg that uptake to foodcrops can depend, for example, on cultivation methods and even on the individual cultivar, nevertheless we have been frustrated by the slow speed of progress in this area. Not least when such data is increasingly being presented to regulators in developers' reports, this needs to be given a higher priority. In view of the very large area of land in England affected by this problem, we suggest that a preliminary guidance note on the underlying scientific principles along with a code of practice for bioaccessibility sampling, testing and interpretation should be developed with some urgency.

#### *The quality of guidance*

We agree that Guideline Values cannot be produced for all contaminants and generic assumptions may not apply to all sites thus, though the new Guideline Values are intended

to be presumptive of "SPOSH", the days of DQRA are not, as some consultants fear, over (and, indeed, that is a reason why new Guideline Values should not be dubbed "SPOSH Values"). If this means that despite the current amount of guidance, there is room for more (and we have plans for more of our own) the emphasis should be on clarity and user-friendliness (and perhaps some consolidation) rather than volume. That will be challenging. We nevertheless welcome proposals for signposting guidance and more on the incidence of asbestos species in soil, associated risk assessment procedures, "guideline values", and potential remediation techniques which may be appropriate. The nature of this hazard and its risks are entirely different to those of any other contaminant of course, and this requires a unique approach. Asbestos was identified by the SGV Taskforce as a "contaminant of concern", implying some priority, and the publication of guidance which we understand to be in development needs to be brought forward to mitigate the over-reaction of local communities to its presence and avoid excessive remediation.

### *Numbers*

Along with that, we agree there is a need to improve the use of numerical methods in site investigation, including in determining appropriate sampling strategies and interpreting the results of those, and we know this work is already underway. We look forward to the revised CLR7 and we have already identified this topic as a priority for training. The adequacy of sampling and the subsequent interpretation of the results can be a cause of dispute between developers and regulators; if refreshed guidance implies more sampling, the potential for disputes will remain even if their focus is changed, heightened by the likelihood that fewer sites will require remediation. We hope new guidance will address this explicitly. Guidance on the sampling of imported fill should be incorporated. Other suggestions we have received include guidance on the modelling and assessment of vapour intrusion and on the assessment of risks to controlled waters and ecological receptors.

### **One number or two?**

Paragraph 2.7 of the main paper and proposal 20 address what it is convenient to call the "One number or two?" question. It is the other area, the first being at what point cost-benefit considerations should be applied, in which, unfortunately we disagree with the Department. There are several reasons for our view which we know is widely, if not universally, shared.

Our major concern is, of course, that many developers will adopt the new Guideline Values as target values without the will or understanding to adapt them to site-specific circumstances. Concerned with nothing so much as short-term cost, they will press for the lowest standard they can get away with. Whereas by definition the new GV's admit the possibility of some harm resulting, such sites cannot be guaranteed suitable for use and PPS23 seems to acknowledge that where it refers to non-determination "as a minimum". Second, and as that phrase also hints at, while Part 2A is about removing immediate risks from the worst sites, the planning regime is about safeguarding the longer-term future and there is no better or cost-effective opportunity to encourage remediation to a higher standard. Equally, where more risk averse landowners seek a higher standard, to obviate the chance of any future liabilities or perhaps to acknowledge a particular public demand for "safe" land, they want some indication of what that looks like and sets of numbers such as our/LQM's Generic Assessment Criteria fulfil that role. Third and in addition, without similar coarse screening values, many more sites will have to be subject to detailed examination involving unnecessary cost and delay.

For consistency if nothing else, these reasons suggest a need for a second set of numbers, albeit an informal set, rather than a "Guideline Value minus a bit" approach, and the fact is that more than one such set of minimal risk numbers already exist and are in use. We do not understand how Defra and DCLG can continue to ignore that.

## **Outputs and timeframe**

### *An alternative delivery model*

Chapter 6 of the main paper sets out an ambitious programme but though it sets out the "what", it says less about the "how" and we look forward to seeing a detailed timetable and knowing by whom individual items are to be taken forward. Notwithstanding, there is universal incredulity that a new set of Guideline Values can be generated by the end of 2007, matched only by the desire that it should be done. We have said already that to meet that desire, an alternative model is needed, in particular one more cross-sectoral and no longer Agency-led. Practitioners also have concerns about the interim and do not agree that there can yet be "business as usual".

### *Best practice*

Annex B notes suggestions from last March's Workshop that some sort of "determinations database" should be created. We agree and have already discussed this informally with Defra. Changes being considered to the form of "SoCL" reporting could assist. Connected to this, we think there also needs to be a strategy to transfer guidance into Best Practice on the ground, including the funding of best practice projects and the production and reporting of Best Practice case studies under different workstreams eg statistics, sampling, communications etc, possibly supported by the Capital Grants scheme. CL:AIRE already fulfils a similar role for remediation projects and may be willing to accept a wider remit.

### *Communication and training*

Naturally, the Department's conclusions from this discussion need to be communicated to all concerned as soon as possible and we are pleased to have been able to offer it a platform at the next plenary meeting of our Standing Conference in May. In addition, whereas the Department knows we support the development of the SiLC scheme to encourage greater competence among private sector professionals (which implies a training role), provided we retain the necessary freedom to decide our priorities and methods in consultation with our community, we reconfirm our commitment to providing training to local regulators through appropriate vehicles including our "EMAQ+" package. We continue to welcome the participation of Defra in shaping those.

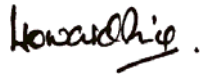
## **Summary**

At its heart, the paper offers the prospect of a new set of Guideline Values for Part 2A which will, as originally intended, support the statutory test regulators have to apply. That will simplify regulatory investigations and help bring greater proportion to the problems of ubiquitous and natural contaminants without, we believe, compromising public protection unacceptably. In addition, the paper promises to fill some information gaps and bring more clarity to future guidance.

Some concerns nevertheless remain for us, among them that cost-benefit considerations should not intrude on the process of risk assessment but, if policy considerations dictate it, they should be considered separately; that the suggested benchmark for multiple non-threshold substances is inconsistent and insufficiently protective; that guidance on bioaccessibility testing is too far away and, not least, that a use for minimal risk numbers

in planning needs to be accepted to prevent developers defaulting to a standard incompatible with longer-term aims. Notwithstanding, the paper does appear to us to result in a better match of science, policy and legislation than currently. We welcome it; overall the implementation of its proposals should go far to removing the current constraints on the application of Part 2A.

Yours sincerely

A handwritten signature in black ink that reads "Howard Price". The signature is written in a cursive style with a prominent underline under the name.

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