Environment Agency

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Questionnaire survey on the use of In-vitro bioaccessibility in human health risk assessment

Science Report: SC040060/SR1

SCHO0906BLLW-E-P

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Our work includes tackling flooding and pollution incidents, reducing industry's impacts on the environment, cleaning up rivers, coastal waters and contaminated land, and improving wildlife habitats.

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Author(s):
Bob Barnes, Albania Grosso, Sohel Saikat, David Westwood

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Research Contractor:
Entec UK Ltd
Canon Court,
Abbey Lawn, Abbey Foregate
Shrewsbury
SY2 5DE
Tel: 01743 342000

Environment Agency's Project Manager:
Bob Barnes, Olton Court

Collaborators:
All the local authorities that kindly participated in the Survey

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Science at the Environment Agency

Science underpins the work of the Environment Agency, by providing an up to date understanding of the world about us, and helping us to develop monitoring tools and techniques to manage our environment as efficiently as possible.

The work of the Science Group is a key ingredient in the partnership between research, policy and operations that enables the Agency to protect and restore our environment.

The Environment Agency's Science Group focuses on five main areas of activity:

- **Setting the agenda**: To identify the strategic science needs of the Agency to inform its advisory and regulatory roles.
- **Sponsoring science**: To fund people and projects in response to the needs identified by the agenda setting.
- **Managing science**: To ensure that each project we fund is fit for purpose and that it is executed according to international scientific standards.
- **Carrying out science**: To undertake the research itself, by those best placed to do it - either by in-house Agency scientists, or by contracting it out to universities, research institutes or consultancies.
- **Providing advice**: To ensure that the knowledge, tools and techniques generated by the science programme are taken up by relevant decision-makers, policy makers and operational staff.

Steve Killeen **Head of Science**

Executive Summary

This report details the results of a questionnaire survey undertaken by the Environment Agency on local authority officers in England and Wales. The survey was designed to obtain information on bioaccessibility testing of metals in soils, specifically:

- The perceived extent and types of metal soil contamination.
- The uptake of bioaccessibility tests in England and Wales.
- The local authorities views on the acceptability of data from bioaccessibility tests in human health risk assessments.

The Environment Agency received responses from approximately a quarter of the authorities and the survey revealed a number of important findings.

- Ninety per cent of participants reported having sites with high levels of heavy metals in their areas.
- The overwhelming majority of participants indicated arsenic as the main metal contaminant of concern, followed by lead, nickel and cadmium.
- The source of this metal contamination was attributed equally to natural background sources and anthropogenic activities.
- Of the participants in this survey, half of them had received bioaccessibility data and/or estimates as part of their regulatory duties with respect to land contamination. All the participants that had received such data had received it for arsenic, while around a quarter of participants had received bioaccessibility data for lead and nickel.
- Of those that had received bioaccessibility data, 85.7 per cent had at some time accepted it when provided as part of risk assessments. Arsenic was the main contaminant for which participants accepted bioaccessibility data.
- Those rejecting bioaccessibility data did so either on the basis of a lack of centralised guidance on its use or due to poor use of the data within the risk assessments.
- Most participants had only occasionally received measurements or estimates of oral bioaccessibility in the past two years, but about half reported that the use of bioaccessibility testing was increasing.

The results have been used to inform the Science Group's programme on bioaccessibility testing.

Contents

Glossary and Acronyms

Anthropogenic	Caused by or relating to human activity
BGS	British Geological Survey
Bioaccessibility	Fraction of the contaminant that is released into solution from the soil during digestion
Bioavailability	Fraction of the dose of the contaminant that is absorbed by the body
CI	Confidence Interval
CLEA	Contaminated Land Exposure Assessment
CLR	Contaminated Land Report – a series of reports published originally by the Department of the Environment and latterly by Defra and the Environment Agency on the management of land contamination
Defra	Department for Environment, Food and Rural Affairs
FSA	Food Standards Agency
GLM	Generalised Linear Modelling
GIS	Geographical Information System
HCV	Health Criteria Value – a summary term for toxicology-based criteria representing a level of intake that pose a minimal risk to human health
HPA	Health Protection Agency
ICRCL	Interdepartmental Committee on the Redevelopment of Contaminated Land – it published soil standards that have since been withdrawn and superseded by the SGVs
ID	Index Dose
In vitro	'In Glass' – in this context an artificial, non-animal bioaccessibility model/extraction and analytical procedure
In vivo	'In Living' – in this context a live animal bioavailability test
MCerts	Environment Agency's Measurement Certification Scheme
ODPM	Office of the Deputy Prime Minister
PBET	Physiologically Based Extraction Test – an in-vitro bioaccessibility test

SGVs	Soil Guideline Values
SNIFFER	Scottish and Northern Irish Forum For Environmental Research
Special Site	A Contaminated Land site defined under Part IIa of the Environmental Protection Act 1990 that is regulated by the Environment Agency
TDI	Tolerable Daily Intake – the amount of a contaminant that can be ingested into the human body below which there is little or no risk of harm to human health

1 Introduction

The Environment Agency acts as an advisor to central Government on many environmental issues, including the assessment of risks to health from land contamination. As part of this role, the Environment Agency, in conjunction with the Department for Environment, Food and Rural Affairs (Defra), has published documents that provide guidance on conducting risk assessments for land contamination (Defra and the Environment Agency 2002a, b and c). These documents include details on generic assessment criteria (also known as Soil Guideline Values (SGV)), which are based on generic assumptions made about soil types, soil pH, contaminant level and exposure scenario (Defra and the Environment Agency 2002d). An SGV is derived by comparing predicted human exposure to a contaminant with a Health Criteria Value (HCV), which denotes the exposure below which there is thought to be little or minimal risk to human health. The oral HCV for a contaminant can be derived from experiments using a number of media (such as food and water), but it is unusual for HCVs to be derived on the basis of soil exposure.

Soils are, by nature, heterogeneous in their geo-physical and chemical properties, and this is likely to affect the level of human exposure to contaminants and their mobility within the human body. This variation in soil properties, combined with the different media used in the derivation of the HCVs, mean that mechanisms of contaminant uptake that have not been considered in producing an SGV may be important at some sites. This could result in risks to health at such sites being over- or underestimated. The current debate in Europe and North America is centred around the application of bioavailability or, more commonly, bioaccessibility testing as a potential tool to refine the risk assessment of land contamination on a site-specific basis (Environment Agency 2005 a,b, US EPA 2005).

The Environment Agency and the British Geological Survey (BGS) have collaborated on two research projects on bioaccessibility in the UK (Environment Agency and BGS 2002 a,b). The first project reviewed and summarised currently available *in vitro* tests for evaluating the oral bioaccessibility of selected metals and metalloids (such as arsenic, lead, cadmium, and copper) in contaminated soils. The project report included a brief outline of the methodologies used and a critical commentary on their robustness and validity for measuring bioaccessibility (Environment Agency and British Geological Survey 2002a).

The second project concentrated on the measurement of arsenic oral bioaccessibility in UK soils using one of the *in vitro* tests reviewed in the first project. The test was used on soils from three sites in the UK known to have elevated levels of arsenic. The results of the bioaccessibility tests from the soils tested varied by 0.5–45 per cent depending on the soil tested. Given all the uncertainties identified by the study, the researchers recommended that further research needed to be carried out to ensure that *in vitro* test data relates to human bioavailability for a wider range of soil types and arsenic concentrations (Environment Agency and British Geological Survey 2002b).

In February 2005, the Environment Agency published a science update on the use of bioaccessibility testing in risk assessments of land contamination (Environment Agency 2005a). The report concluded that, on the basis of the information currently available, the Environment Agency could not recommend the use of bioaccessibility testing at that time. It also stated that should practitioners make use of the techniques and submit them to

the Environment Agency for review, the data should be treated with caution and supported by a significant body of evidence. This should indicate that the methods are scientifically robust, suitable for the site and the contaminants concerned, and that the uncertainties inherent in the methods are understood and have been taken into account.

Although the projects and reports detailed above identified all the uncertainties associated with bioaccessibility testing, it was brought to the Environment Agency's attention that these tests were being used in the UK (Environment Agency 2005b). The precise extent to which bioaccessibility tests were being used was not altogether clear and it was therefore deemed necessary to determine whether these tests were being used routinely and what methods were being employed by the contract laboratories conducting the tests.

The following two projects were initiated to answer these questions.

- A questionnaire survey – to determine the extent of use of bioaccessibility tests in the UK and the reasons for using them.
- An inter-laboratory comparative study – to determine the tests/methods provided by the contract laboratories and the intra- and inter-variability of the test results.

The purpose of the questionnaire was to illicit information on:

- the use of bioaccessibility tests in England and Wales;
- and local authorities' experiences and views on the acceptability of the results of such tests in the risk management of land contamination.

The results of the questionnaire form part of the Environment Agency's science programme to inform any potential future policy in this area. This report presents information on the approach adopted for conducting the survey, together with its findings.

2 Approach

The lead regulators for land contamination are the local authorities, under both the planning system (ODPM 2004) and the Contaminated Land Regulations (DETR 2000, WAG 2001). Under these regimes, the issues of assessing and mitigating risks and harm to human health fall to local authorities, except were land is designated as a 'special site'. In this case, the Environment Agency assumes the role of lead regulator. Given this situation, a decision was taken to send the questionnaire to local authority contaminated land officers (or their equivalent), since these officers were most likely to have experience in reviewing and assessing the results of bioaccessibility tests. In addition, the Environment Agency's area contaminated land officers were also contacted to determine if they had any experience of using bioaccessibility tests.

There are 353 district and unitary local authorities in England and 22 unitary authorities in Wales. Initially, it was intended only to target those local authorities within areas thought to have naturally-occurring elevated levels of arsenic (169 authorities). However, anecdotal information indicated that bioaccessibility tests were being carried out for contaminants other than arsenic. Therefore, it was decided that all 375 districts and unitary local authorities in England and Wales would be contacted.

One of the assumptions of the survey was that arsenic is the predominant contaminant for which bioaccessibility tests are used to assess human health risks in England and Wales. The second assumption was that the response rate to the questionnaire would be greater for areas of England and Wales with elevated levels of arsenic contamination. The questionnaire was therefore designed, in part, to test these assumptions.

Given the large number of authorities that needed to be contacted, the questionnaire was sent to local authority officers in England and Wales who deal with land contamination issues via e-mail. E-mail addresses were obtained from central Government. Unfortunately, given the number of local authorities in England and changes to personnel and IT systems, that information was not completely up-to-date. Environment Agency area officers were requested to inform local authority officers within their areas of the project and questionnaire, in order to help increase the survey coverage.

In March 2005, the questionnaire (see Appendix A) was e-mailed to 375 contaminated land officers at local authorities in England and Wales. Recipients of the questionnaire were invited to respond either by email, fax, or post, in order to make submitting a response as easy as possible and thereby maximise the number of responses.

The questionnaire consisted of thirteen multiple-choice questions. Each question had a minimum of four possible choices and additional space for comment after each question. The fourteenth and final question allowed respondents to make comments on any issue associated with bioaccessibility testing.

Questions 1–3 were designed to determine:

- whether there were high concentrations of metals in the area;
- what metals were perceived to be elevated;
- and whether the source was natural or anthropogenic.

Questions 4–11 were designed to determine:

- if regulatory decisions had been made in the local area on the basis of potential human health risks from land contamination;
- what contaminants were identified as the risk drivers;

- whether bioaccessibility test results were used in the assessment of risks;
- and how the use of the results from bioaccessibility tests were justified.

The basis for questions 12 and 13 was to determine whether there is a perceived increase in the use of bioaccessibility tests and, if so, for what contaminants. The final question was meant to capture anything that the local authorities wanted to report with regard to bioaccessibility testing.

Participants were requested to indicate all appropriate choices that were applicable to their own particular circumstances for each of the questions. Therefore the number of replies to be collected could be greater than the total number of responses and the sum of percentage replies could exceed 100 per cent.

Once the completed questionnaires were received, they were transferred to a spreadsheet. This was set up to evaluate the rate of response to the questionnaire on the basis of the Environment Agency's eight regions and 26 areas. The responses were checked for consistency and clarity. If an inconsistency was identified then the relevant local authority was contacted to clarify the issues. This was done using phone interviews, and the results incorporated into the spreadsheet containing all the responses. In a few instances it was not possible to contact a local authority officer to seek clarification of their answers and resolve inconsistencies. These instances are detailed within the relevant parts of Section 3 below.

The spreadsheet information was subsequently used to calculate information on the response rate for the survey and for analysing each question on the basis of the responses.

3 Results

Of the 375 district and unitary local authorities in England and Wales, 298 were successfully contacted. Responses were received from 99 authorities, representing 33.2 per cent of those contacted and 26.4 per cent of all local authorities. Of the local authorities that responded, only one reported that they had difficulty in putting information into the electronic draft and returned the questionnaire partially completed.

Environment Agency staff indicated that they had not received bioaccessibility test data in the course of their work and they therefore had no influence on the survey. The Environment Agency would only have a role in the assessment of health risks from land contamination where it was the regulator of a special site.

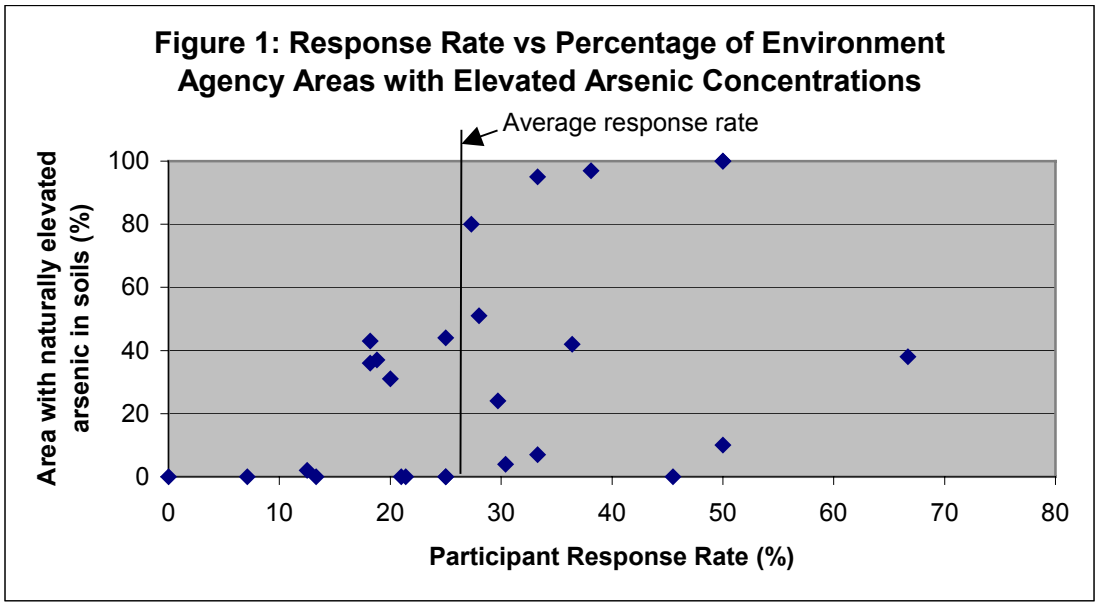
The analysis of responses for each question is presented separately in the following sections. Participants were requested to indicate all appropriate answers for each question that were applicable to their authority. Basically, participants were encouraged to tick as many answers as applicable to each question. Hence the number of replies often exceeded the total number of participants that answered the question. Where percentage values are presented, these values represent the fraction (as a percentage) of the replies received relative to the total number of participants. This explains why the sum of percentage replies often exceeds 100 per cent. The number of responses is given directly below each question. Table B.2 provides details of the number of multiple answers to each question.

A summary breakdown of responses, including the confidence interval for each response, is presented in Appendix B. These confidence intervals should be taken into account when analysing the results of this questionnaire. Ninety percent confidence limits for proportional response data were calculated using the binomial distribution. These confidence limits were then modified with a finite population technique, as 26.4 per cent of the total number of local authorities responded to the questionnaire survey. These confidence limits for the responses are shown in Table B.1 and as error bars on Figure 3.

Table 1 illustrates the questionnaire response rates grouped into the Environment Agency's eight regions and 26 areas. The fifth column of Table 1 – headed 'Percentage of Area > SGV' – indicates the approximate percentage area within the Environment Agency's regions and areas that may potentially exceed the arsenic SGV for the residential with plant uptake land use scenario as stipulated in CLR10 and SGV1 (Defra and Environment Agency 2002c,d). The numbers are derived from estimates by the BGS of the proportion of the areas and regions that potentially have naturally-occurring elevated levels of arsenic in soils. The data from BGS was constructed on the basis of geostatistics and assumptions.

The response rates ranged from 21.8 per cent to 40.9 per cent for the eight regions, and 0 per cent to 66.7 per cent for the 26 areas. One of the assumptions of the survey was that the expected response rate would correlate with areas of England and Wales that have the potential for naturally-occurring elevated arsenic levels. That is authorities within these areas would be more likely to respond to the questionnaire than those outside.

Figure 1 below shows the response rate of participants within the 26 Environment Agency areas plotted against the percentage of the area assumed to have naturally-occurring elevated arsenic levels in soils.



It would be incorrect to analyse this data using linear regression and to calculate a R^2 value, as the requirements of linear regression are not met by the data. In particular, the requirement for independent random scatter around the line and normally distributed errors. A better way to deal with proportions data is by using Generalised Linear Modelling (GLM). Using this model, the assessor can specify that the 'Y' variable is a binomial response (r responses out of n attempts), rather than assume a conventional continuous variable as required in linear regression (100*r/n). Following a GLM analysis, it was shown that the t value is 2.42, which is statistically significant, single-sided, at $P<0.02$. The single-sided stance is appropriate and justified, as the direction of the association of the data has been stated in advance of the assessment. That is: the greater the percentage area of a participant's authority that is covered by naturally-occurring elevated arsenic levels, the more likely the participant was to reply to the questionnaire.

To summarise, the data in Table 1 and Figure 1 allows us to say with 98 per cent confidence that response rates tended to be higher in areas with elevated arsenic levels. This means that there is likely to be an upward bias in the survey's results for each question.

It is therefore only truly statistically appropriate to view the following results as representing the percentage of those who responded, rather than for England and Wales as a whole.

Table 1 contains the data organised in terms of the Environment Agency's regions and areas. For columns 2 and 3, rows that are not highlighted (the areas) add up to the values presented in the row highlighted above them (the regions). Those highlighted values add up to the value presented in the bottom 'Totals' row.

The values presented in columns 4 and 5 do not continue this relationship. The values in column 5 have been calculated using a GIS (Graphical Information System), on the basis of individual footprints for both areas and regions separately.

Table 1 Response rate of questionnaire survey

Environment Agency Region and Areas	Number of Authorities	Number of Responses	Response Rate (Percentage)	Percentage of Area > SGV
Anglian Region	52	14	26.9	49
Central Area	12	3	25	44
Eastern Area	19	4	21	0
Northern Area	21	7	38.1	97
Midlands Region	64	14	21.9	23
Lower Severn Area	11	2	18.2	36
Lower Trent Area	25	7	28	51
Upper Severn Area	12	3	25	0
Upper Trent Area	16	2	12.5	2
Northeast Region	42	12	26.2	35
Dales Area	15	5	33.3	7
Northumbria Area	16	4	18.8	37
Ridings Area	11	3	27.3	80
North West Region	43	10	23.3	47
Central Area	14	1	7.1	0
Northern Area	6	2	33.3	95
Southern Area	23	7	30.4	4
Southern Region	37	11	29.7	0
Hampshire & Isle of Wight Area	11	5	45.5	0
Sussex Area	12	3	25	0
Kent Area	14	3	21.4	0
Southwest Region	37	12	32.4	61
Cornwall Area	6	3	50	100
Devon Area	10	5	50	100
North Wessex Area	11	4	36.4	42
South Wessex Area	10	0	0	0
Thames Region	78	17	21.8	26
North East Area	37	11	29.7	24
South East Area	30	4	13.3	0
West Area	11	2	18.2	43
Environment Agency Wales	22	9	40.9	27
Northern Area	6	4	66.7	38
South East Area	10	2	20	31
South West Area	6	3	50	10
Totals	**375**	**99**	**26.4[#]**	

[#] This figure is calculated as a percentage of all the English and Welsh local authorities (99/375 x 100) and does not relate to the values above it in the column.

Question 1 - In your area/region, do you have any areas where high concentrations of metals in soils have been identified (i.e. above Soil Guideline Values)?

		Replies ticked	Per cent
a)	Yes – less than 25% of your area	20	20.2
b)	Yes – more than 25% of your area	9	9.1
c)	Yes – more than 50% of your area	1	1
d)	Yes – more than 75% of your area	4	4
e)	Yes – but unsure of area affected	55	55.6
f)	No	5	5.1
g)	Don't know	5	5.1

Total number of responses: 99

For question 1, 90 per cent of those who responded reported having sites with high levels of heavy metal in their areas. Only 5 per cent indicated that such sites had not been identified in their area. The final 5 per cent indicated that they did not know whether contamination existed. Of these, 3 per cent reported that there were grounds for suspecting that elevated levels of arsenic might exist.

Only 34 per cent of participants knew or were prepared to state an estimate of the proportion of their area that might be affected by heavy metal contamination (by ticking a, b, c or d in question 1 above).

Question 2 - If the answer to question 1 is 'yes', please indicate which metals.

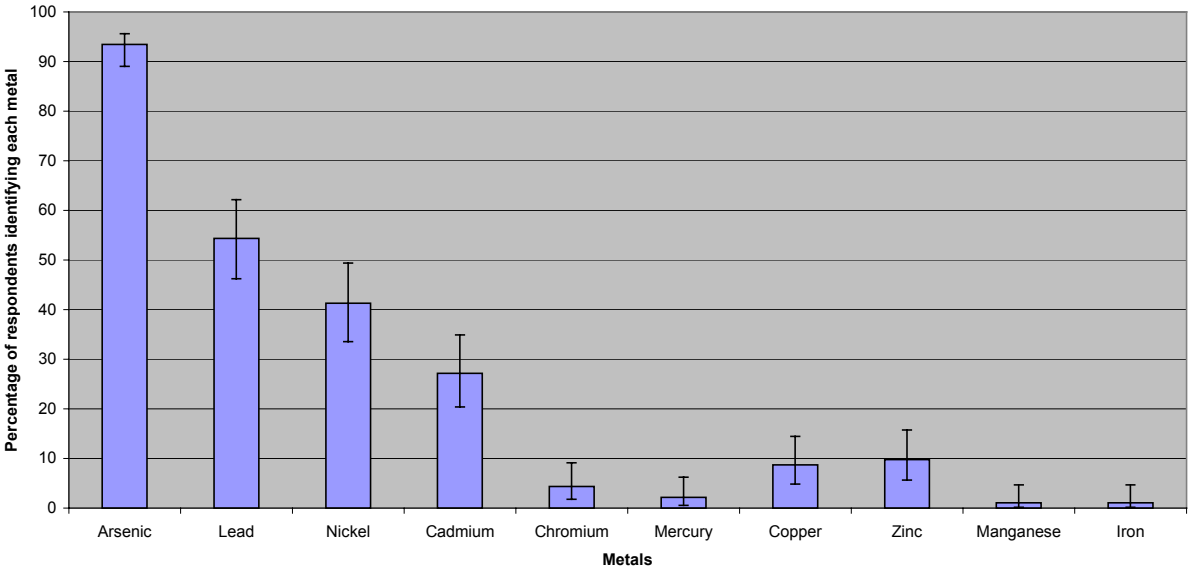
		Replies ticked	Percent
a)	Arsenic	86	96.6
b)	Lead	50	56.2
c)	Nickel	38	42.7
d)	Cadmium	25	28.1
e)	Other, please specify below	11	12.4

Total number of responses: 89

Question 2 was answered by 89 of the 99 participants in the survey.
The overwhelming majority indicated arsenic as a metal of concern followed by lead, nickel and cadmium.

Participants that ticked 'Other, please specify below' in Question 2 identified chromium (4 responses), mercury (2), copper (8), zinc (9), manganese (1) and iron (1) as being elevated within their areas.

Figure 3: Question 2: If the answer to question 1 is "yes", please indicate which metals



Question 3 - What is the source of these metals?

		Reply ticked	Percent
a)	Natural background sources	53	55.8
b)	Historical anthropogenic activities, please describe below	51	53.7
c)	Don't know	17	17.9
d)	Not applicable	4	4.2

Number of responses: 95

Question 3 was answered by 95 of the 99 participants in this survey. Where the sources of contamination were known, natural background and anthropogenic activities were equally attributed as sources (56 per cent and 54 per cent). However, 18 per cent of participants did not know the source of the contamination.

Of the 54 per cent of participants that ticked answer b to question 3 (attributing anthropogenic activities as sources), just under half of them (23) actually described the activities in the comments box. These activities can be categorised as:

- elevated levels associated with **made ground** (7 replies);
- resulting from **metal processing** (5 replies);
- **mining** (7 replies);
- and **various** or **none attributed** industrial processes (15 replies).

Please note that some participants identified more than one anthropogenic activity, as reflected in the numbers in the brackets above.

Question 4 - Have you had to make regulatory decisions regarding the potential risks presented to humans by high metal concentrations in soils?

		Replies ticked	Percent
a)	Yes – as part of the planning process	84	86.6
b)	Yes – as part of the contaminated land regime	36	37.1
c)	Yes – as part of another regulatory process, please specify below	6	6.2
d)	No	4	4.1
e)	Not applicable	0	0

Number of responses: 97

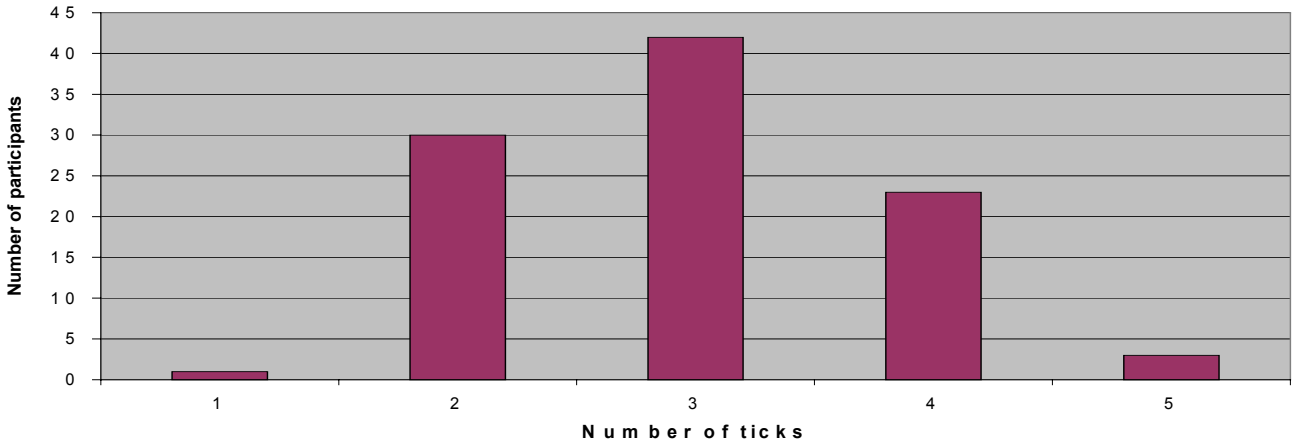
Question 4 was answered by 97 of the 99 participants. The majority of participants (87 per cent) had made regulatory decisions under the planning regime with regard to heavy metals in soils.

A smaller percentage (37 per cent) reported that decisions had been made under the contaminated land regime (Part IIA of the Environmental Protection Act 1990).

This finding is to be expected, as the planning regime is the primary regulatory tool for managing land contamination in the UK. What came as a surprise was the fact that of the 37 per cent (36 participants) that had made decisions under the contaminated land regime, nine reported that they had not made such decisions under the planning regime.

Six per cent of participants stated their authorities had made use of other legislation for making such decisions. Only half of these identified the legislation used: building control regulations (2 replies) and legislation dealing with environmental assessment for the sale of council land (1 reply).

Figure 4: Distribution of Multiple Answers to Question 5



Question 5 - If you have had to make regulatory decisions regarding human health risks associated with high concentrations of metals in soil, how have you made these decisions?

		Replies ticked	Percent
a)	Relied upon Soil Guideline Values published by Defra and the Environment Agency	76	77.6
b)	Relied upon other Generic Assessment Criteria (e.g. ICRCL Threshold trigger concentrations, Dutch target/intervention values, consultant derived screening values, etc.), please specify below	40	40.8
c)	Relied upon Site Specific Assessment Criteria or Site Specific Risk Assessment	69	70.4
d)	Other, please specify below	6	6.1
e)	Not applicable	4	4.1

Number of responses: 98

All bar one of the participants answered question 5.

Of those that answered, 78 per cent had used SGVs to make regulatory decisions, 41 per cent had used other generic assessment criteria and 70 per cent had relied upon site-specific assessment criteria or a site-specific risk assessment.

The breakdown of the number of participants ticking one, two, three, four or all five of the possible answers to question 5 is presented in Figure 4 below.

Of the 6 participants relying on other means of making the decisions, they cited criteria such as:

- relying on consultant's statements on bioaccessibility;
- and research and scrutiny of original published scientific literature and consideration of bioavailability testing and interpretation.

Question 6 - If you have received site specific risk assessments of human health risks associated with high concentrations of metals in soil (i.e. above Soil Guideline Values), i.e. ticked yes to box 5c, have these assessments included measurements or estimates of oral bioaccessibility?

	Replies ticked	Percent
a) Yes – site specific determinations of oral bioaccessibility	47	51.1
b) Yes – estimates of oral bioaccessibility from literature or other sites/locations	13	14.1
c) No	27	29.3
d) Not applicable	15	16.3

Number of responses: 92

Question 6 was answered by 92 of the 99 participants. Based upon the answers to question 5, it would be expected that only 69 participants would answer a, b or c to this question, with the remainder either answering d or not answering the question at all. However, in response to this question, 77 participants indicated that they had received site-specific risk assessments.

Of those who relied upon site-specific assessment criteria or site-specific risk assessments to make their regulatory decisions, 47 indicated that bioaccessibility data had been included. Responses also showed that 13 participants had received reports containing bioaccessibility data that were not site-specific but had been obtained from literature or other sites.

The important answers to this question, which are relevant to the issue of bioaccessibility data in human health risk assessment, are the number of participants that ticked a and/or b to question 6.

Whilst the table above shows that 47 participants ticked a and 13 ticked b, it is important to note that nine participants ticked both a and b, whilst four ticked only b and not a.

Of the 99 participants in this survey, 51 of them have received bioaccessibility data and/or estimates as part of their regulatory duties with respect to land contamination. It would be incorrect to state that 60 participants had received such data and/or estimates, because doing so would double count those participants that had received both.

It is concerning to note that a small percentage of participants are receiving bioaccessibility data that is not site-specific.

Question 7 - If you have received measurements or estimates of the oral bioaccessibility of metals, for which metals have you received this information?

		Replies ticked	Percent
a)	Arsenic	49	100
b)	Lead	12	24.5
c)	Nickel	13	26.5
d)	Cadmium	6	12.2
e)	Other, please specify below	2	4.1

Number of responses: 49

Question 7 was answered by 49 participants. This question invites those who answered either a and/or b to question 6 to identify those metals for which they had received such data. As such, one would have expected 51 participants to have answered this question. Unfortunately, two participants that had answered either a or b to question 6 did not answer question 7 and were unavailable to clarify their original answer.

All participants that answered question 7 indicated that they had received oral bioaccessibility data for arsenic. Bioaccessibility data for lead had been received by about a quarter of respondents (24.5 per cent), with a similar percentage receiving bioaccessibility data for nickel (26.5 per cent).

Data on cadmium bioaccessibility were received by 12 per cent of participants. One participant had received bioaccessibility data for chromium and one had received data for mercury.

Question 8 - In making your regulatory decisions regarding human health risks associated with high concentrations of metals in soil, have you accepted oral bioaccessibility measurements if they have been undertaken?

		Replies ticked	Percent
a)	Yes – whenever provided	20	22.2
b)	Yes – sometimes when provided	22	24.4
c)	No	6	6.7
d)	Not applicable	42	46.6

Number of responses: 90

Question 8 was answered by 90 of the 99 participants. Based upon the answers to question 7, we would have expected 49 to answer a, b or c for question 8.

Of the 49 participants that had received bioaccessibility data (as indicated in question 7), 20 replied that they always accepted the results of oral bioaccessibility measurements in their regulatory decisions, if the measurements have been taken. Twenty-two answered that they sometimes accepted them, whilst six answered that they never accepted them.

Forty-two participants stated that the question was not applicable and we assume this means that they had not received bioaccessibility data. However, one of those participants indicated that they had received bioaccessibility data in answer to question 7, but went on to state that this question was 'not applicable'. In the comments, the participant added that:

> '*I have seen bioaccessibility data for arsenic for two sites. At both of these sites remediation was still necessary due to the presence of other metal and benzo(a)pyrene. No bioaccessibility testing was carried out for these substances. If it were the case that a site was affected by high levels of metals and a decision was made not to remediate solely on the basis of bioaccessibility testing then I would need to give the assessment more consideration and possibly seek outside advice.'*

Forty-nine participants had received bioaccessibility data as part of their duties relating to the management of land contamination. Of these, 85.7 per cent had at some time accepted oral bioaccessibility data when provided as part of assessments (answered a or b in question 8), and only 12.2 per cent of participants had rejected it (answered c). One participant did not need to take the bioaccessibility data into account as other contaminants drove the need to remediate the sites.

Fifty-five per cent of participants that always accept bioaccessibility data (answered a to question 8) and 64 per cent of those that sometimes accept bioaccessibility data (answered b to question 8) are based within areas of naturally-occurring elevated arsenic levels. Of the participants that have not accepted bioaccessibility data (answered c to question 8), only 33 per cent are based within areas of naturally-occurring elevated arsenic levels. This was estimated with reference to the areas indicated in Table 1.

From these figures and the breakdown in Table 2, it seems that the existence of naturally-occurring elevated levels of arsenic is a driver for participants to accept bioaccessibility testing.

Table 2 Collated responses to Question 8

Environment Agency Region / Area	Number of Responses	Percentage of Area > SGV	Always Accept Results	Sometimes Accept Results	Have Not Accepted Results	Not Applicable / did not answer Qu 8
Anglian Region	14	49	1	6	0	7
Central Area	3	44	0	3	0	0
Eastern Area	4	0	0	0	0	4
Northern Area	7	97	1	3	0	3
Midlands Region	14	23	2	1	0	11
Lower Severn Area	2	36	1	0	0	1
Lower Trent Area	7	51	1	0	0	6
Upper Severn Area	3	0	0	0	0	3
Upper Trent Area	2	2	0	1	0	1
Northeast Region	12	35	2	3	1	6
Dales Area	5	7	1	1	0	3
Northumbria Area	4	37	1	1	0	2
Ridings Area	3	80	0	1	1	1
North West Region	10	47	2	3	1	4
Central Area	1	0	0	0	0	1
Northern Area	2	95	0	0	0	2
Southern Area	7	4	2	3	1	1
Southern Region	11	0	1	0	0	10
Hampshire & Isle of Wight Area	5	0	0	0	0	5
Sussex Area	3	0	1	0	0	2
Kent Area	3	0	0	0	0	3
Southwest Region	12	61	4	5	0	3
Cornwall Area	3	100	2	1	0	0
Devon Area	5	100	1	1	0	3
North Wessex Area	4	42	1	3	0	0
South Wessex Area	0	0	0	0	0	0
Thames Region	17	26	7	3	3	4
North East Area	11	24	3	3	3	2
South East Area	4	0	2	0	0	2
West Area	2	43	2	0	0	0
Environment Agency Wales	9	27	1	1	1	6
Northern Area	4	38	0	0	1	3
South East Area	2	31	1	0	0	1
South West Area	3	10	0	1	0	2
Totals[#]	**99**	**36**	**20**	**22**	**6**	**51**

[#] These totals are calculated by summing the 'region' rows highlighted in grey; the 'area' rows provide a further breakdown of the data in the region rows above them.

Question 9 - If the answer to question 8 is 'yes' (ticked boxes 8(a) or 8(b)), for which metals have you accepted oral bioaccessibility measurements to support your regulatory decisions?

		Replies Ticked	Percent
a)	Arsenic	42	95.5
b)	Lead	8	18.2
c)	Nickel	6	13.6
d)	Cadmium	1	2.3
e)	Other, please specify below	1	2.3
f)	Not applicable	31	

Number of responses (not including 'Not applicable'): 44

Two participants that answered no to question 8 nevertheless answered question 9 stating arsenic. Again, as with question 8, this inconsistency could not be resolved.

Of the participants that have accepted bioaccessibility data, all bar two had accepted arsenic data. In a few cases, lead or nickel bioaccessibility assessments had also been accepted (19 per cent and 14 per cent respectively). Although cadmium bioaccessibility data had been submitted to six participants (see Question 7), it had only been accepted by one of them.

Question 10 - If the answer to question 8 is 'yes' (ticked boxes 8(a) or 8(b)), what justification have you been provided with to support the use of these measurements or estimates?

		Replies Ticked	Percent
a)	Literature values provided only	3	7.0
b)	Laboratory measurements provided only	27	62.8
c)	Literature measurements supported by laboratory values provided	14	32.6
d)	Additional justification provided, please specify below	6	14.0
e)	Not applicable	30	

Number of responses (not including 'Not applicable'): 43

Seventy-three participants answered question 10, but 30 of these stated that the question was not applicable. The percentages shown in the table above and text below have been calculated on the basis of the 43 participants who ticked a, b, c and/or d.

Only three participants (7 per cent) indicated that risk assessments had been accepted without measurements from the site concerned.

Some of the additional justifications given (ticked d to question 10) are detailed below.

- ‘In respect of an allotments site we were looking at we also looked at crop samples which adjusted the arsenic value due to the concentration factor.’
- ‘Site history, geology, mineral species etc.’
- ‘We have used bioaccessibility alongside vegetable uptakes and TDI [Tolerable Daily Intake] calculations. We have also consulted with the HPA [Health Protection Agency] and FSA [Food Standards Agency].’
- ‘Laboratory measurements provided and the results incorporated into site-specific assessment criteria derived using the SNIFFER [Scottish and Northern Irish Forum for Environmental Research] risk assessment model.’

Question 11 - If the answer to question 8 is 'no' (ticked box 8(c)), on what grounds did you decide the bioaccessibility measurements or estimates were not acceptable?

		Replies ticked	Percent
a)	Measurements were not site specific	4	23.5
b)	Insufficient number of measurements	4	23.5
c)	Insufficient validation of measurements	4	23.5
d)	Inadequate interpretation of measurements	5	29.4
e)	No guidance from the EA is available to accept bioaccessibility in risk assessments	10	58.8
f)	Other, please specify below	6	35.2
g)	Not applicable	43	

Number of responses (not including 'Not applicable'): 17

Whilst question 11 was designed to elicit responses from those six participants who had ticked answer 8(c), eleven participants who had ticked 8(b) also answered this question. This was because answer 8(b) stated that participants sometimes accepted bioaccessibility data and hence, by implication, sometimes rejected it.

The principal reason cited by 10 participants (61 per cent) for rejecting bioaccessibility assessments was a lack of guidance from the Environment Agency. Four further participants commented (to question 11 or to other questions) that they would not accept bioaccessibility data in future without further guidance. Nine participants (56 per cent) had found assessments at fault and ticked one or more of answers a to d (a lack of site-specific measurements, insufficient number or validation of measurements, or inadequate interpretation).

The other reasons for finding assessments unacceptable included:

- a complete absence of robust statistical treatment of data – 'magic number' approach;
- an over-reliance on professional judgement;
- bioaccessibility analyses were without UKAS (UK Accreditation Service) or MCerts accreditation.

Questions 12 - For sites where metals are contaminants of concern, how frequently have you received measurements or estimates of oral bioaccessibility of metals in the last two years?

		Replies ticked	Percent
a)	Never	34	41.4
b)	Occasionally (<25% of sites assessed)	39	47.5
c)	Regularly (>25% of sites assessed)	6	7.3
d)	Most of the time (>50% of sites assessed)	0	0
e)	Nearly always (>75% of sites assessed)	3	3.7
f)	Not applicable	9	

Number of responses (not including 'Not applicable'): 82

Question 13 - Have you noticed an increase in the application of measurements or estimates of oral bioaccessibility of metals in the last two years?

		Replies Ticked	Percent
a)	No	36	50.7
b)	Yes – a slight increase	18	25.4
c)	Yes – a reasonable increase (e.g. twice as often as two years ago)	11	15.5
d)	Yes – a large increase (e.g. more than twice as often as two years ago)	6	8.5
e)	Not applicable	14	

Number of responses (not including 'Not applicable'): 71

In response to question 12, for sites where metals are contaminants of concern, most participants had only occasionally (<25 per cent) received measurements or estimates of oral bioaccessibility in the past two years. In response to question 13, about half of participants reported that the use of bioaccessibility testing was increasing.

With respect to question 12, only three participants received bioaccessibility data for more than 50 per cent of sites (although all three had actually received bioaccessibility data for more than 75 per cent of sites). In all three cases, this is a recent phenomenon; the participants' responses to question 13 indicated a large increase in the use of bioaccessibility data over the past two years. These participants are based in areas with high proportions of natural levels of arsenic and other heavy metals.

Comments (Question 14)

Question 14 invited comments on the participants' experiences of or opinions on the application of bioaccessibility measurements to land contamination issues; 28 of them provided comments. The answers have been reviewed and grouped into some broad themes.

In the context of the contaminated land regime

The most detailed responses discussed bioaccessibility testing not as a scientific issue, but as a practical and policy element of the contaminated land regime. These participants believe that most of their land area would be judged as contaminated land, if existing SGVs were applied. This indicates some uncertainty over the role of generic assessment criteria in the management of land contamination and, in particular, in the contaminated land regime.

The following extract is an example of a typical response from the participants:

> '*The Borough has an elevated level of naturally occurring arsenic which regularly exceeds the arsenic SGV. In order to allow development, the Council has accepted bioavailability data. This is on the basis that (a) it is impractical to remediate all the affected land in the Borough, (b) the bioavailability tests that have been carried out show that the bioavailable levels are usually below the SGV and (c) this is in line with the risk assessment approach of CLEA [Contaminated Land Exposure Assessment]*.'

Inadequate basis for decision making

As indicated above, many participants commented upon a lack of scientific information or guidance in relation to bioaccessibility of heavy metals and called for a standardised, validated test method. The following description of a validation process from a Borough Council is broadly typical:

> '*Only received once. Accepted results as were based on PBET [Physiologically Based Extraction Test] analysis. Felt that this was the way to go, given: the SNIFFER model provides for a percentage of bioavailability of the contaminant; the fact that CLEA still has not provided a site-specific model; that SGV values are based on 100 per cent bioavailability. I rung up BGS and spoke to the chap who did the PBET tests and asked if the Environment Agency accepted it, he responded that all did except the Yorkshire area. Read up about PBET on the Internet and ultimately came to the conclusion to accept the values on this site*.'

Some participants felt that the problem was inherently intractable, one stated:

> '*Some consultants have proposed using bioaccessibility and I have always refused to accept it. The problem is that you cannot mimic in a test tube what happens in terms of fate in the environment (open system)… Ultimately the question is whether contaminant X at concentration Y is likely to affect receptor Z*.'

Poor use of bioaccessibility in risk assessment and risk management

The participants' comments clearly place an onus on consultants to conduct bioaccessibility assessments at a higher standard of competence than currently seems to

be the case. This is demonstrated by the answers to question 11 above. In one extreme case, a participant stated that:

‘The consultant didn’t even know about the existence of CLEA (Defra and Environment Agency 2002c) or the withdrawal of ICRCL [Interdepartmental Committee on the Redevelopment of Contaminated Land] (Defra 2002)’.

The participants consistently identified several failings in risk management reports that had been submitted to them. It is evident that the bioaccessibility approach, which would otherwise be accepted by many councils, is being rejected because:

- not enough samples are being taken from the site;
- the approach is being applied blindly without an understanding of the science behind it;
- inappropriate literature information is being cited in support;
- and the risk assessments are not being carried out correctly.

One Borough Council stated that ‘magic number’ approaches featuring a ‘complete absence of robust statistical treatment of data’ have been undertaken.

Whilst oral bioaccessibility measurements of heavy metals can only be applied to the soil ingestion pathways of human health risk assessment models, it is clear that consultants have, in some cases, not made this distinction.

‘In the early days it was common for consultants to apply the bioaccessibility factor to all routes of exposure,’ remarked one participant.

4 Discussion

The objectives of the questionnaire survey were to capture the experiences and views of those responsible for regulating land contamination, with particular reference to *in vitro* bioaccessibility testing in risk assessments. Under the existing legislative framework, issues of land contamination fall largely within the remit of local authorities. Therefore local and unitary authorities were contacted as part of this project. Out of 375 potential participants identified, 298 were contacted, of which 99 responded to the questionnaire survey.

In general, the questions elicited a wide range of views and comments from those that participated in the survey. The responses received were useful because they helped to identify the issues that need to be addressed by regulators, industries and research organisations in a future bioaccessibility work programme for England and Wales.

Elevated arsenic levels appear to be a major land contamination issue in large areas of England and Wales, with lead, nickel and cadmium also reported as potential issues. The source of elevated arsenic in soils is perceived by participants of the survey to be either natural (geogenic) or a legacy of historic mining operations.

In vitro bioaccessibility testing is used as part of site-specific risk assessments. The participants had different views regarding bioaccessibility and there appears to be a lack of a consistent approach, policy or stance across England and Wales. A number of local authorities used bioaccessibility data to assist their decision-making processes. Arsenic was the main contaminant assessed using *in vitro* bioaccessibility test methods. However, the survey revealed that these *in vitro* methods are also being used for other contaminants. There were circumstances where bioaccessibility data were either not applicable for or accepted in the decision-making process.

From the responses to the questionnaire (with only a couple of exceptions), it was not clear whether any rationale was used to evaluate scientifically the bioaccessibility test method or the use of bioaccessibility data in risk assessment. It was also not clear whether scientific evidence has been provided to support the correlation between *in vitro* bioaccessibility data and *in vivo* bioavailability data. There were reports of the extrapolation of data from different locations and from literature values in making site-specific decisions.

In vitro testing is considered to be substance-, form- and soil-specific. However, it also appeared possible that in some instances the same test methods were used regardless of contaminant or soil properties. It was not clear whether the participants recommended a standard protocol for use in sampling, *in vitro* test method application, data reporting and data use as part of the decision-making process. This raises the question of whether users understand the validity, reproducibility and robustness of the *in vitro* bioaccessibility test methods that are currently available in the UK and elsewhere (Environment Agency 2005 a,b).

The survey also indicated that the use of *in vitro* bioaccessibility test methods as part of site-specific risk assessments is increasing.

Some participants indicated that guidance from the Environment Agency would change their position on the acceptability of *in vitro* bioaccessibility testing in site-specific risk assessment. Based on a review of the current science, the Environment Agency's view is

that it cannot recommend the routine use of bioaccessibility testing in risk assessment (Environment Agency 2005a). The view of the Environment Agency is reflected by regulators in North America and Europe, where *in vitro* bioaccessibility test methods have not yet received regulatory acceptance for use in human health risk assessment. *In vitro* bioaccessibility is a useful concept, but in terms of acceptance as a routine tool in risk assessment for most contaminants, including arsenic, it is still an area where further research is needed (Schoof 2004, Environment Agency 2005a,b, USEPA 2005, Saikat 2006).

Nevertheless, this survey demonstrates that bioaccessibility tests have been received by roughly 50 per cent of participants, and that 85.7 per cent of those have accepted them in making regulatory decisions.

There appears to be a need for detailed guidance on all aspects of the use of *in vitro* bioaccessibility approaches for the risk assessment of land contamination. Such guidance should be centred on validated substance-specific *in vitro* test protocols. It should contain information on the applicability of *in vitro* test methods, site characterisation and sampling design. It should clearly state the need to quantify any uncertainty inherent within the protocols, and provide guidance on presenting data and the use of data in the risk assessment process.

5 Summary

The main findings of this survey are detailed below.

- Ninety per cent of participants reported having sites with high levels of heavy metals in their areas.

- The overwhelming majority of participants indicated arsenic as the main metal of concern, followed by lead, nickel and cadmium.

- The source of metal contamination was attributed equally to natural background sources and anthropogenic activities.

- Most of the participants had made regulatory decisions under the planning regime with regard to heavy metals in soils. A smaller percentage (roughly a third) reported that decisions had been made under the contaminated land regime (Part IIA of the Environmental Protection Act 1990).

- Of the 99 participants in this survey, half of them had received bioaccessibility data and/or estimates as part of their regulatory duties with respect to land contamination. All the participants that had received such data had received it for arsenic. In addition, bioaccessibility data for lead and nickel had been received by about a quarter of the participants.

- Of those that had received bioaccessibility data as part of risk assessments, the vast majority had at some time accepted it. Arsenic is the main contaminant for which participants evaluated bioaccessibility data.

- Those rejecting bioaccessibility data did so either on the basis of a lack of centralised guidance on its use or due to poor use of the data within the risk assessments.

- Most participants had only occasionally received measurements or estimates of oral bioaccessibility in the past two years, but about half reported that the use of bioaccessibility testing was increasing.

In parallel to this questionnaire survey, the Environment Agency has been conducting a ring test on current *in vitro* bioaccessibility laboratory methods being used in the UK. This will help our understanding of some of the key uncertainties (such as reproducibility) that are currently not made explicit when using, or reviewing the use of, such data in human health risk assessments. However, the absence of *in vivo* data for the samples used in the ring test study will not allow an assessment to be made of the reliability and robustness of *in vitro* bioaccessibility methods.

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Appendix A

Questionnaire for Local Authority Officers

Name: .....

Position: .....

Organisation: .....

Address: .....

Telephone Number: .....

Facsimile Number: .....

E-mail Address: .....

Please tick as many answers as appropriate:

1) In your area / region, do you have any areas where high concentrations of metals in soils have been identified (i.e. above Soil Guideline Values)?

- ❑ a) Yes – less than 25% of your area
- ❑ b) Yes – more than 25% of your area
- ❑ c) Yes – more than 50% of your area
- ❑ d) Yes – more than 75% of your area
- ❑ e) Yes – but unsure of area affected
- ❑ f) No
- ❑ g) Don't know

Comments: .....

.....

.....

2) If the answer to question 1 is 'yes', please indicate which metals.

- ❑ a) Arsenic
- ❑ b) Lead
- ❑ c) Nickel
- ❑ d) Cadmium
- ❑ e) Other, please specify below

Comments: .....

.....

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3) What is the source of these metals?

- ❑ a) Natural background sources
- ❑ b) Historical anthropogenic activities, please describe below
- ❑ c) Don't know
- ❑ d) Not applicable

Comments :

---

4) Have you had to make regulatory decisions regarding the potential risks presented to humans by high metal concentrations in soils?

- ❑ a) Yes – as part of the planning process
- ❑ b) Yes – as part of the contaminated land regime
- ❑ c) Yes – as part of another regulatory process, please specify below
- ❑ d) No
- ❑ e) Not applicable

Comments :

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5) If you have had to make regulatory decisions regarding human health risks associated with high concentrations of metals in soil, how have you made these decisions?

- ❑ a) Relied upon Soil Guideline Values published by Defra and the Environment Agency
- ❑ b) Relied upon other Generic Assessment Criteria (e.g. ICRCL Threshold trigger concentrations, Dutch target/intervention values, consultant derived screening values, etc.), please specify below
- ❑ c) Relied upon Site Specific Assessment Criteria or Site Specific Risk Assessment
- ❑ d) Other, please specify below
- ❑ e) Not applicable

Comments :

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6) If you have received site specific risk assessments of human health risks associated with high concentrations of metals in soil (i.e. above Soil Guideline Values), **i.e. ticked yes to box 5c**, have these assessments included measurements or estimates of oral bioaccessibility?

- ❑ a) Yes – site specific determinations of oral bioaccessibility
- ❑ b) Yes – estimates of oral bioaccessibility from literature or other sites/locations
- ❑ c) No
- ❑ d) Not applicable

Comments :

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7) If you have received measurements or estimates of the oral bioaccessibility of metals, for which metals have you received this information?

- ❑ a) Arsenic
- ❑ b) Lead
- ❑ c) Nickel
- ❑ d) Cadmium
- ❑ e) Other, please specify below

Comments :

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8) In making your regulatory decisions regarding human health risks associated with high concentrations of metals in soil, have you accepted oral bioaccessibility measurements if they have been undertaken?

- ❑ a) Yes – whenever provided
- ❑ b) Yes – sometimes when provided
- ❑ c) No
- ❑ d) Not applicable

Comments :

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9) If the answer to question 8 is 'yes' **(ticked boxes 8(a) or 8(b))**, for which metals have you accepted oral bioaccessibility measurements to support your regulatory decisions?

- ❑ a) Arsenic
- ❑ b) Lead
- ❑ c) Nickel
- ❑ d) Cadmium
- ❑ e) Other, please specify below
- ❑ f) Not applicable

Comments :

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10) If the answer to question 8 is 'yes' **(ticked boxes 8(a) or 8(b))**, what justification have you been provided with to support the use of these measurements or estimates?

- ❑ a) Literature values provided only
- ❑ b) Laboratory measurements provided only
- ❑ c) Literature measurements supported by laboratory values provided
- ❑ d) Additional justification provided, please specify below
- ❑ e) Not applicable

Comments :

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11) If the answer to question 8 is 'no' **(ticked box 8(c))**, on what grounds did you decide the bioaccessibility measurements or estimates were not acceptable?

- ❑ a) Measurements were not site specific
- ❑ b) Insufficient number of measurements
- ❑ c) Insufficient validation of measurements
- ❑ d) Inadequate interpretation of measurements
- ❑ e) No guidance from the EA is available to accept bioaccessibility in risk assessments
- ❑ f) Other, please specify below
- ❑ g) Not applicable

Comments :

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12) For sites where metals are contaminants of concern, how frequently have you received measurements or estimates of oral bioaccessibility of metals in the last two years?

- ❑ a) Never
- ❑ b) Occasionally (<25% of sites assessed)
- ❑ c) Regularly (>25% of sites assessed)
- ❑ d) Most of the time (>50% of sites assessed)
- ❑ e) Nearly always (>75% of sites assessed)
- ❑ f) Not applicable

Comments :

13) Have you noticed an increase in the application of measurements or estimates of oral bioaccessibility of metals in the last two years?

- ❑ a) No
- ❑ b) Yes – a slight increase
- ❑ c) Yes – a reasonable increase (e.g. twice as often as two years ago)
- ❑ d) Yes – a large increase (e.g. more than twice as often as two years ago)
- ❑ e) Not applicable

Comments :

14) If you have any additional information that you wish to provide on your experiences or opinions of the application of bioaccessibility measurements to land contamination issues please detail below.

15) Would you be happy for us to contact you to discuss your answers further?

- ❑ a) Yes, by telephone
- ❑ b) Yes, by e-mail
- ❑ c) Yes, by post
- ❑ d) No

Comments :

Appendix B

Table B.1 Summary of answers and calculated 90% confidence intervals

Response	No of respondents	Total no of responses	% of respondents	90% conf. interval	
				Lower	Upper
Question 1	99				
Yes < 25%		20	20.2	14.7	26.9
Yes > 25%		9	9.1	5.4	14.4
Yes > 50%		1	1.0	0.2	4.2
Yes >75%		4	4.0	1.8	8.3
Yes Unsure of area affected		55	55.6	48.0	62.9
No		5	5.1	2.4	9.6
Don't know		5	5.1	2.4	9.6
Question 2	89				
Arsenic		86	96.6	92.2	98.8
Lead		50	56.2	48.1	64.0
Nickel		38	42.7	34.9	50.8
Cadmium		25	28.1	21.3	35.8
Chromium		4	4.5	1.9	9.3
Mercury		2	2.2	0.6	6.3
Copper		8	9.0	5.1	14.8
Zinc		9	10.1	6.0	16.1
Manganese		1	1.1	0.2	4.7
Iron		1	1.1	0.2	4.7
Other		11	12.4	7.8	18.7
Question 3	95				

Natural background sources		53	55.8	48.1	63.3
Historical anthropogenic activities		51	53.7	46.0	61.2
Don't know		17	17.9	12.6	24.6
Not applicable		4	4.2	1.8	8.7
Question 4	97				
Yes as part of the planning process		84	86.6	80.5	91.2
Yes as part of the contaminated land regime		36	37.1	30.1	44.7
Yes as part of another regulatory process		6	6.2	3.2	11.1
No		4	4.1	1.8	8.5
Not applicable		0	0.0	0.0	2.6
Question 5	98				
Relied upon Soil Guideline Values published by Defra & the EA		76	77.6	70.6	83.3
Relied upon other Generic Assessment Criteria		40	40.8	33.6	48.4
Relied upon Site Specific Assessment Criteria or Site Specific Risk Assessment.		69	70.4	63.1	76.9
Other		6	6.1	3.2	10.9
Not applicable		4	4.1	1.8	8.4
Question 6	92				
Yes – using site specific determinations of oral bioaccessibility		47	51.1	43.2	58.9
Yes – using determinations of oral bioaccessibility from elsewhere		13	14.1	9.3	20.5
No		27	29.3	22.6	37.0
Not applicable		15	16.3	11.1	23.0

Question 7	49				
Arsenic		49	100.0	94.5	100.0
Lead		12	24.5	15.4	35.8
Nickel		13	26.5	17.1	38.0
Cadmium		6	12.2	5.9	22.0

Other		2	4.1	1.0	11.7
Question 8	90				
Yes – whenever provided		20	22.2	16.1	29.6
Yes – sometimes when provided		22	24.4	18.1	31.9
No		6	6.7	3.4	12.0
Not applicable		42	46.7	38.8	54.7
Question 9	75				
Arsenic		42	56.0	46.9	64.7
Lead		8	10.7	6.0	17.6
Nickel		6	8.0	4.0	14.4
Cadmium		1	1.3	0.2	5.7
Other (not specified)		1	1.3	0.2	5.7
Not applicable		31	41.3	32.7	50.4
Question 10	73				
Literature values provided only		3	4.1	1.4	9.6
Laboratory measurements provided only		27	37.0	28.5	46.2
Literature measurements supported by laboratory values provided		14	19.2	12.7	27.4
Additional justification provided, please specify below		6	8.2	4.1	14.8
Not applicable		30	41.1	32.4	50.3

Question 11	60				
Measurements were not site specific		4	6.7	2.7	13.9
Insufficient number of measurements		4	6.7	2.7	13.9
Insufficient validation of measurements		4	6.7	2.7	13.9
Inadequate interpretation of measurements		5	8.3	3.8	16.0
No guidance from the EA is available to accept bioaccessibility		10	16.7	9.9	25.8
Other		6	10.0	4.9	18.1

Not applicable		43	71.7	61.5	80.3
Question 12	90				
Never		34	37.8	30.3	45.8
Occasionally (<25% of sites assessed)		39	43.3	35.6	51.4
Regularly (>25% of sites assessed)		6	6.7	3.4	12.0
Most of the time (>50% of sites assessed)		0	0.0	0.0	2.9
Nearly always (>75% of sites assessed)		3	3.3	1.2	7.7
Not applicable		9	10.0	5.9	15.9
Question 13	85				
No		36	42.4	34.4	50.7
Yes – a slight increase		18	21.2	15.0	28.7
Yes – a reasonable increase (e.g. twice as often as two yrs ago)		11	12.9	8.1	19.6
Yes – a large increase (e.g. > twice as often as two yrs ago)		6	7.1	3.6	12.7
Not applicable		14	16.5	11.0	23.6

Table B.2 Breakdown of Multiple Reponses to Each Question

No of responses	Q1	Q2	Q3	Q4	Q5	Q6	Q7
0	0	10	4	2	1	7	50
1	99	30	66	67	30	83	29
2	0	21	28	27	42	8	13
3	0	16	1	3	23	1	2
4	0	12	0	0	3	0	4
5	0	2		0	0		1
6	0	3					
7	0	1					
8		4					
9		0					
10		0					
11		0					
Total no of respondents	99	89	95	97	98	92	49
Total no of responses	99	235	125	130	195	102	82
No of multiple responses	0	146	30	33	97	10	33
Responses per respondent	1.00	2.64	1.32	1.34	1.99	1.11	1.67

No of responses	Q8	Q9	Q10	Q11	Q12	Q13
0	9	24	26	39	9	14
1	90	63	66	51	89	85
2	0	11	7	4	1	0
3	0	0	0	3	0	0
4	0	1	0	2	0	0
5		0	0	0	0	0
6		0		0	0	
7				0		
Total no of respondents	90	75	73	60	90	85
Total no of responses	90	89	80	76	91	85
No of multiple responses	0	14	7	16	1	0
Responses per respondent	1.00	1.19	1.10	1.27	1.01	1.00

Note: Each question has a different number of possible answers that participants could have ticked and each question is cut off with regard to the number of responses up to the maximum possible (for example, question 8 has four different possible answers and question 11 has seven).

We are The Environment Agency. It's our job to look after your environment and make it **a better place** – for you, and for future generations.

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Environment Agency
Rio House
Waterside Drive, Aztec West
Almondsbury, Bristol BS32 4UD
Tel: 0870 8506506
Email: enquiries@environment-agency.gov.uk
www.environment-agency.gov.uk