DEVELOPMENT, VALIDATION AND APPLICATION OF A HARMONISED BARGE BIOACESSIBILITY METHOD

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INTRODUCTION

The Bioaccessibility Research Group of Europe is a European network bringing together international institutes to study human bioaccessibility of priority contaminants in soils such as arsenic (As), lead (Pb) and cadmium (Cd) via the gastrointestinal (GI) tract. A primary objective is to provide robust and defensible bioaccessibility data that can be used in human health risk assessments and policy making. The correct estimation of bioaccessibility has the potential to make a significant impact on current risk assessment practices. To this end BARGE has been involved in comparing and evaluating physico-chemical processes within the many models that have been developed to measure bioaccessibility and contaminant exposure (Wragg et al., 2011). Because variable results from method comparison studies (Oomen et al., 2002) have hindered the adoption of bioaccessibility methods by some in the regulatory community, BARGE initiated the development of a harmonised in vitro bioaccessibility test: the Unified BARGE Method (UBM).

METHODS

The chosen method was based on a previously published method developed by researchers at the Dutch Institute of Public Health, the RIVM (Oomen et al., 2002). This physiologically-based method had gained a degree of regulatory acceptance in both the Netherlands and Denmark, and was considered more likely to be adopted by testing laboratories. The RIVM method was optimised to provide conservative and robust estimates, and to be applicable to various soils of different parent geologies.

Inter-laboratory trial of the UBM

An International inter-laboratory trial was set-up to determine the repeatability and reproducibility of results within and between testing laboratories (Wragg et al., 2011). The target within and between laboratory reproducibility and repeatability criteria were set at 10% and 20% RSD respectively. Seven laboratories participated, extracting 34 contaminated samples (soils, mine wastes and slag materials). One central laboratory handled all sample transit, analysis, data analysis and data reporting for the trial.

In-vivo validation of the UBM

In parallel to the inter-laboratory trial, INERIS and the University of Nancy undertook the validation of the UBM for As, Cd and Pb using a juvenile swine model. The in vivo end points were liver, bone, kidney and urine and in total 15 soils were tested.

RESULTS AND DISCUSSION

Inter-laboratory trial

The trial showed it was difficult to meet the between laboratory repeatability criteria (20% RSD), which was thought to be a result of minor differences in laboratory techniques despite a standardised method being supplied to all participants. The UBM met the stated benchmark criteria for in vivo validation (a vivo/vitro linear relationship, a very strong correlation coefficient ($r > 0.8$ or $r2 > 0.6$) and a slope > 0.8 and < 1.2) for both the GI phases

for As and the stomach phase for Cd. For the 'stomach & intestine' phase Cd and Pb r and r2 values of 0.51 – 0.76 were returned with slopes of 0.44 – 0.57.

In-vivo validation of the UBM

Caboche (2009) showed that correlation between the relative bioavailability and bioaccessibility of As, Pb and Cd was highly significant, both for the gastric and the gastro-intestinal phases ($p<0.01$). r^2 values of >0.97 and >0.89 were obtained for vivo/vitro correlations for As in urine and Cd/Pb in the kidney respectively. The slopes of the regressions were all > 0.9 and <1.1 and the intercepts were not significantly different from 0. Example in vivo/in vitro correlation plots plots for Pb are shown in Figure 1.

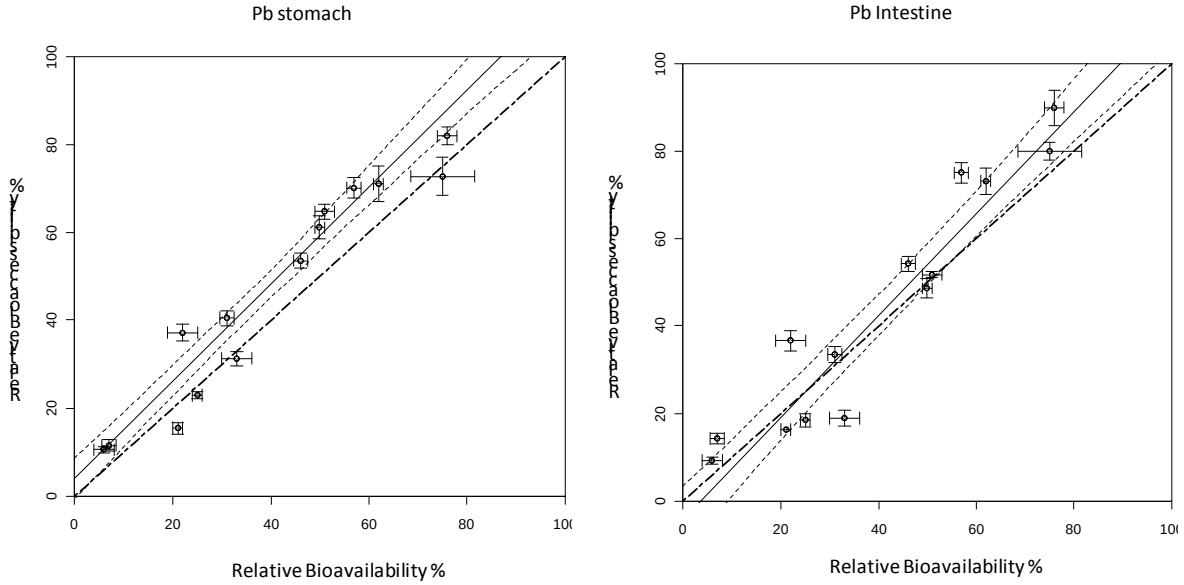

Fig. 1 in vivo/in vitro correlation plots for Pb in the stomach and intestine compartments (dot dash is the line of equivalence, solid is the median regression line and dotted lines are the 95% confidence limits

CONCLUSIONS

A significant amount of work has been carried out by BARGE in order to optimise one method and produce a robust, validated in vitro model for use in human health risk assessment. To date, the in vivo validation has showed that setting of the 'stomach' pH to 1.2±.05 rather than 1.2-1.4, as used in the inter-laboratory trial, may reduce the between laboratory variability to <20% RSD. A follow up trial with a refined laboratory procedure is planned. The UBM is now being used routinely in Europe on a variety of applications to aid in the assessment human health risk from contaminated soils.

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