

### INTERDEPARTMENTAL GROUP ON HEALTH RISK FROM CHEMICALS

# STEERING COMMITTEE Eleventh Meeting

### **AGREED MINUTES**

Minutes of the 11<sup>th</sup> meeting held on 23<sup>rd</sup> November 2007 at the Food Standards Agency, Aviation House, 125 Kingsway, London, commencing at 11.00am

Present: Dr Diane Benford FSA

Dr Ian Dewhurst PSD
Dr Simon Dyer DH
Dr Steve Fairhurst HSE
Dr Robin Fielder HPA
Ms Alison Gowers EA
Dr David Harper (Chair) DH

Prof Len Levy IEH, Cranfield University

Prof Michael Moore NERC
Dr Vyra Navaratnam Home Office
Mr Henry Stemplewski MHRA

Dr Paul Harrison (Secretariat)

Dr Rebecca Slack (Secretariat)

Ms Elaine Jones (Secretariat)

IEH, Cranfield University

IEH, Cranfield University

IEH, Cranfield University

Apologies: Ms Christine Knox BERR

Ms Laura NottonBBSRCMr Poul PetersenDefraDr Jane StratfordDefraMr Nick TomlinsonFSA

### Action

### 1. Welcome

1.1 The Chair, Dr Harper, welcomed all members to the 11<sup>th</sup> meeting of the IGHRC Steering Committee, including Dr Benford who was deputising for Mr Tomlinson and Dr Navaratnam who was deputising for Mr Buckley.

The Chair introduced himself and welcomed Prof Levy, who succeeded Prof Purchase as Chair of the Executive Committee. The Chair noted the excellent work carried out by Prof Purchase.

The Chair also introduced Dr Harrison and Dr Slack to the IGHRC Secretariat, having recently replaced Prof Levy and Dr Newman respectively on the Secretariat.

#### Action

## 2. <u>Minutes from the Previous Meeting and Matters Arising</u> (IGHRC/SC/min/01/07)

2.1 A few minor amendments to the minutes of the last meeting were requested by Dr Benford, Dr Dewhurst and Prof Moore.

Secretariat to amend draft minutes accordingly

- 2.2 With these amendments agreed, the minutes were accepted to be a true and accurate record of the 10<sup>th</sup> meeting.
- 2.3 All matters arising were covered by the Secretary's Report (Item 3).

### 3. Secretary's Report (IGHRC/SC/01/06)

- 3.1 Dr Slack updated the Steering Committee on the actions from the last Steering Committee meeting in January 2007. Dr Slack noted that several actions were awaiting completion:
- 3.2 Action 4.1: Staff and resourcing for the future work programme remains a concern and will be discussed further in the Executive Committee Chair's presentation.

See 4.5 below

3.3 Action 7: The Steering Committee supported the commissioning of Dr Sue Barlow to carry out a brief evaluation of the Phase 2 work programme.

Secretariat to organise Phase 2 evaluation by Dr Barlow

3.4 There were no questions or comments regarding the Secretary's Report from the Steering Committee members.

# 4. <u>Update from Professor Levy on the activities and work programme</u> of the IGHRC

- 4.1 Prof Levy outlined the final steps required to complete the *Chemical Mixtures A Framework for Assessing Risks* document. Dr Fielder asked whether any comments had been received from the BTS; he was informed by the Secretariat that there were none so far.
- 4.2 Prof Levy stated that the *Exposure Modelling* document would need to be signed off by the Steering Committee but, as it does not provide guidance, it will not need to be submitted for expert committee review. Ms Gowers clarified that the lead for this document was Ms Albania Grosso, although Dr Bridget Butler had recently taken over this role, and Ms Gowers questioned whether the document would have a default value focus. The Secretariat assured Ms Gowers that the focus of the document was not default values but rather the approaches adopted by IGHRC members to exposure modelling.
- 4.3 Two training courses have been run in the interval since the last Steering Committee meeting: *Developing & Explaining Chemical Risk Assessments* and *Chemical Exposure Assessment*. Prof Levy described the very good feedback received from the courses and Dr Fairhurst asked whether it may also be valuable to seek feedback a few months after each course in order to assess whether the course has had any practical impact. Dr Benford supported this proposal as it is consistent with the need for evaluation of personal development under the IiP

Secretariat to investigate format for long-term course feedback, including seeking advice from the Cranfield School of Management, and contact participants from Phase 2 courses.

scheme. Mr Stemplewski emphasised that it is important that the right questions are asked in any feedback form. Dr Slack said the issue of CPD had been discussed at the recent Executive Committee meeting and that the Secretariat will evaluate possible accreditation bodies/schemes.

### **Action**

Secretariat to evaluate CPD schemes.

Prof Levy said that the Secretariat had approached Dr Peter Bennett, as suggested in Action 5.11 of the previous minutes, to lead a session in the *Developing & Explaining Chemical Risk Assessments* course. Dr Bennett's session was very well received by the course participants.

Secretariat to approach speakers for permission to place presentations online.

Prof Levy outlined the possibility of making the course material available on the IGHRC website.

Secretariat to assess the practicality of supporting attendance at externally organised courses.

A training course, *Understanding Epidemiology for Chemical Risk Assessment*, was held in November 2006, coordinated by Dr Lesley Rushton (Imperial College) and the Secretariat. In previous Steering/Executive Committee meetings, it has been suggested that the course should be repeated as an open course run by Imperial College but, as yet, a repeat programme has not taken place. In light of the possibility of IGHRC member departments and agencies sending staff to externally organised courses, Ms Gowers enquired whether IGHRC would pay attendance fees. The Secretariat suggested that this might be problematical.

- 4.4 The guidance document *Route-to-Route Extrapolation of Toxicity Data* has recently been referenced in REACH guidance and will potentially feature in EU work. Prof Levy has sent a number of IGHRC documents to groups within the EU to assist in policy/regulation/research programme development.
- 4.5 Prof Levy highlighted the concerns of the Executive Committee members that departments/agencies might not be able to commit as much human resource to IGHRC activities as they would otherwise like, and raised the question of enlisting additional members onto the Executive Committee. In discussion, it was noted that Executive Committee members were able to enlist assistance for IGHRC work from other personnel in their department/agency.

SC members to make staff /resourcing available to encourage commitment to the current and future IGHRC work programme.

4.6 Steering Committee members discussed *Descriptive vs Quantitative Risk*Assessment in the Future Plan. The main points of this discussion are included in Section 5.4 below.

### 5. The Future of IGHRC and Phase 3 Programme of Work

5.1 Dr Slack introduced this item and drew members' attention to the draft copy of the *Final Report and Forward Plan*, noting that Section 2 of the document comprised the *Final Report* and Section 4 consisted of the *Forward Plan*. Dr Slack requested that the committee comment on the two sections separately.

Secretariat to make corrections required or flagged by SC members.

Ms Gowers said that there were a number of typographical errors and tense changes required for Section 2. No other comments were made.

Several comments were made by Steering Committee members concerning Section 4; these are considered in 5.2 to 5.6 below.

#### Action

5.2 Dr Fielder noted that there is great interest in the benchmark dose (BMD) approach generally and, as such, a course specifically aimed at government departments and agencies would be of considerable benefit and allow confidential discussion between regulators. Dr Fielder recommended that the wording in Section 4.2.1 be changed to reflect the need for an IGHRC organised course using external speakers.

Secretariat to alter Section 4.2.1 to an IGHRC organised BMD course.

Dr Benford asked whether there was scope for the Steering Committee to add further courses and suggested that a REACH-related training course be considered. Dr Fairhurst said that the September 2008 BTS Conference may focus on REACH but, as this is not yet certain, a course/sharing experience session may be useful. Dr Harper suggested the possibility of approaching BTS concerning a joint approach and that a REACH-related course or awareness day should be added to Section 4.2 of the *Forward Plan*.

Secretariat to add REACH course to the Forward Plan.

5.4 Mr Stemplewski asked for further clarification of the Descriptive vs Quantitative Risk Assessment activities (Sections 4.2.2 and 4.3.6 of the Forward Plan). Dr Fairhurst suggested that the topic related to risk assessment of genotoxic carcinogens, particularly the UK approach (descriptive) compared to the international approach (largely quantitative). Prof Levy, however, suggested that the issue of uncertainty and how the two approaches dealt with uncertainty in each step of the risk assessment processes (and the development of acceptable risk levels) should also be considered. Dr Fairhurst warned that a training course was not appropriate as greater debate is needed concerning the merits of each methodology as applied to the regulatory context of carcinogens. Dr Benford was concerned that work in the area of descriptive and quantitative risk assessment of carcinogens should not duplicate that of COC and other expert groups/committees, such as the upcoming EuroTox 2008 satellite meeting on "margin of exposure". It was also noted that EFSA and IPCS have proposed a framework for quantifying uncertainty in exposure assessment but there does not appear to be a framework related to uncertainty in the entire risk assessment. Dr Harrison suggested that the area of work should be de-coupled into two workshops concerning uncertainty and descriptive/quantitative assessment of carcinogens, with a framework determined by the Steering Committee. There was concern that a workshop on uncertainty in risk assessment would be difficult to arrange and maybe not included in the work programme.

Secretariat to divide Sections 4.2.2 and 4.3.6 into two: uncertainty and descriptive vs. quantitative RA. Uncertainty to remain on work programme but to be considered a low priority.

5.5 Dr Fairhurst asked Dr Dewhurst whether the OECD had progressed further in the assessment of *in vitro* data for pesticides (Section 4.3.3). Dr Dewhurst replied that progress has been slow, partly because the remit has been expanded to include biocides and industrial chemicals, and the OECD is using IPCS work in this area to avoid duplication; a draft report is expected in February. Dr Fielder suggested that, as the proposed guidance on the *in vitro* method for skin absorption and the work on assessing exposure to the skin are two separate issues, but both are important in risk assessment from dermal contact, the activity should be re-named under the general heading "risk assessment from skin contact". Dr Fairhurst suggested that a UK-based document on methodologies for skin absorption may assist the OECD review of guidelines, although this approach differs from previous IGHRC

Secretariat to change title of Section 4.3.3.

documents as it avoids publication and delivers first to an international organisation. Dr Dewhurst urged that no decisions are made in this regard till February, when the expected OECD comment is due; Dr Dewhurst will report at the next Executive Committee meeting.

#### Action

Secreatraiat to remove reference to "nanomaterials"

Dr Fielder and Dr Dewhurst requested that reference to nanomaterials in Section 4.3.3 be removed.

5.6 Prof Moore suggested that stem cell research be included in the watching brief (Section 4.4) due to evidence that stem cells cultured from individuals exposed to certain chemicals are, as a result, desensitised to the chemical.

Secretariat to add stem cell research to watching brief.

## 6. <u>Financial Statement Oct 2006–Sept 2007 and projected income and expenditure to Sept 2008.</u>

- Dr Harrison introduced this item. The total funding income for Phase 2 was £279,605 plus carry forward from Phase 1 of £71,289 (total = £350,894). Total expenditure for Phase 2 (including £52,502 for additional year 4) was £225,616 plus an estimated £8-10,000 still to be realised = c. £233,000. The balance to be carried forward to Phase 3 is £126,278 less the estimated £8-10,000 costs still to be realised =c. £117,000. The forecast expenditure for Phase 3 is £271,000, which, minus the £117,000 estimated carry-over, gives a total of £154,000 to be sought from funders. The Chair sought a commitment in principle to fund the whole of Phase 3.
- Dr Fairhurst questioned the size of the carry over and how much per year would be expected from the "major" contributors. Prof Levy explained that the carry-over from Phase 1 resulted from limited expenditure on research as previously forecast whilst the Phase 2 underspend is partly a result of savings made by keeping publications "inhouse". Dr Harrison suggested that contributions from each "major" contributor would be under £20,000 with further contributions by "minor" contributors. Another alternative suggested payment plan was the use of unallocated Phase 3 funds before further commitment is sought from contributing members; Dr Harper pointed out that there is the risk that activities are initiated but not completed without a prior payment commitment. Financial contributions could be one-off payments or three annual instalments.

Secretariat to write to each contributor regarding payment value, mechanisms of payment and detailed Phase 3 budget.

### 7. Any Other Business

7.1 Dr Fairhurst raised the issue of the IPCS Programme and suggested that the next Steering Committee meeting include a discussion of IPCS work, overlap with government departments and agencies, and linkages with the IGHRC.

Secretariat to include IPCS item in next agenda

7.2 Ms Gowers requested that it be determined as soon as possible which department/agency leads on which IGHRC activity to permit sufficient warning for the allocation of time and resources.

EC members to determine lead and inform Secretariat.

7.3 Dr Harper reminded all Steering Committee members to read the *Final Report and Future Plan* carefully and send comments to the Secretariat.

All SC members

### **Action**

7.4 The next Steering Committee meeting was proposed to be held in October 2008, although Dr Harper warned that an earlier meeting may be necessary to discuss financial issues if a commitment from all parties is not forthcoming.

Secretariat to arrange the next SC meeting

7.5 The meeting closed at 2.30 pm.