



**INTERDEPARTMENTAL GROUP
ON
HEALTH RISK FROM CHEMICALS**

**STEERING COMMITTEE
*Ninth Meeting***

AGREED MINUTES

Minutes of the meeting held on 19th January 2006 at the
Medical Research Council, 20 Park Crescent, London

Present:	Dr Vyra Navaratnam	Home Office
	Dr Ian Dewhurst	PSD
	Mrs Elanor Ball	HSE
	Prof Iain Purchase	Manchester University
	Ms Alison Gowers	EA
	Dr Robin Fielder (Chair)	HPA
	Dr Simon Dyer	DH
	Prof Michael Moore	NERC
	Dr Jane Stratford	Defra
	Mr Nick Tomlinson	FSA
	Mr Lenroy Wallace	DTI
	Dr Heike Weber	MRC
	Prof Len Levy (Secretariat)	IEH
	Ms Kathryn James (Secretariat)	IEH
	Ms Jo Franklin (Secretariat)	IEH

Apologies:

Dr David Harper	DH
Mr Henry Stemplewski	MHRA
Dr Gabriela Pastori	BBSRC
Mr Andrew Browning	VMD

Action

1. Welcome

- 1.1 The Chair welcomed all Members to the ninth meeting of the IGHRC Steering Committee, including Mrs Ball who deputised for Dr Fairhurst and Dr Navaratnam who deputised for Mr Buckley. Dr Fielder acted as Chair in Dr Harper's absence as he had been called away on priority business.

The Chair introduced himself as the Health Protection Agency's official representative on the Steering Committee. As there were some new members, the Chair requested brief round-table introductions.

2. Minutes from the Previous Meeting and Matters Arising (IGHRC/SC/min/01/05)

- 2.1 The minutes were accepted by the Committee as a true reflection of the meeting.

Action

2.2 Dr Navaratnam referred to item 3.4 of the minutes and asked if this was due to a deadline for animal tests. Members agreed that it was.

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

3.1 Ms James updated the Steering Committee on the actions from the last Steering Committee meeting in January 2005. All actions have been completed.

3.2 Action 3.4: The proposed skin sensitisers' workshop was not progressed over the past year due to a perceived lack of interest but it was suggested that HSE should keep abreast of IPCS's involvement in this area. Mrs Ball reported that Peter Evans of the HSE has said there is a similar workshop due to be run by the IPCS in Berlin. She would keep IGHRC informed of events.

3.3 Action 4.1: A response has been received from the ABPI with anonymised contributions from the pharmaceutical industry and was tabled for the Committee's information.

3.4 Dr Stratford asked if the invoice to DEFRA had been sent out for the financial year Sept 05-Sept 06 as she had not seen one. She asked if this could be sent before the end of February. Ms James replied that this was dependent on the novation agreement transaction, which is ongoing, but she would chase Cranfield accounts department to progress the invoices.

Secretariat to ensure invoices are sent out ASAP

3.5 Prof Purchase enquired as to whether Prof Andy Renwick had published a peer-review paper relating to his 2003 study on Human Variation in Toxicodynamics. The Secretariat confirmed that a cursory search had not located anything in Sept 2005 but they will check again.

Secretariat to check Prof Renwick's recent publications.

4. Report update from Prof Purchase on the activities and work programme of the IGHRC

4.1 The Route-to-route guidance document was discussed under item 5.

4.2 The Chemical Mixtures brain-storming Workshop in February 2005 kick-started a guidance document which has been prepared using an external consultant, Dr Karin Fletcher. Transferring the knowledge base to someone who is not part of the initial workshop was found to be difficult and so a Chemical Mixtures Steering Group (Tim Marrs, Alan Boobis, John Groten, Caroline Harris, Ian Dewhurst, Alison Gowers and Elanor Ball) volunteered to give Dr Fletcher guidance when writing the draft document. The Group met with Dr Fletcher on 21 Nov 2005 to discuss the first draft document and provide a clear steer on the production of a 'final' draft by the end of Jan 2006. This draft will be discussed at the next Executive Committee (EC) meeting on 21 Feb 2006. Specific thanks were recorded to Mrs Ball for her contribution to this work and in particular, to the development of the flow diagram.

EC to approve draft Chemical Mixtures guidance document at the EC meeting in Feb 2006.

4.3 Prof Purchase informed the Committee that the Environment Agency has taken the lead on the Exposure Modelling guidance document. Ms Grosso has produced a template document for circulation to the EC members for completion by 24 Feb 2006. This information provided by each Department /Agency will form the basis of the document.

Action

4.4 Two training courses have been held over the past year. The course held at HSL in March 2005 was *Probabilistic Modelling of Exposures in Risk Assessment*. The two-day course was expensive to run and was attended by a limited number of people but it received very good feedback and achieved its aim of enhancing the skills of already experienced modellers. Bob Scott on behalf of LGC on behalf of DTI led the *Understanding Chemical Exposure Assessment* course. This was inexpensive, easy to organise and was well received by participants. This was discussed further under agenda item 6.

4.5 The Awareness Day on *Chemical risk assessments on health effects: current practice within the UK Government* is approaching. This will be held in York on 16 March 2006 and is being organised by Dr Dewhurst. Flyers were distributed to Members to take back to their respective Departments and Agencies to recruit attendees. Ms James confirmed that registration had just begun.

Members to take away flyers and promote the Awareness Day within their Department /Agency

4.6 Other activities include the PBPK Club Project. This item was discussed in depth by the EC in June 2005, when it was agreed that IGHRC would not go ahead with funding a training course on the PBPK Club Project. A letter was sent to Dr Loizou at HSL explaining the reasons for this decision, and stating that the EC would be keen to endorse and bring to the awareness of government personnel any course that HSL runs in connection with the PBPK Club Project.

Members supported the decision not to proceed in funding this activity.

4.7 Prof Purchase reported the view of the EC that the ABPI's response to the request for access to toxicodynamic data had not been encouraging and that they saw little merit in pursuing the ABPI further. However, the EC had noted that the Committee should wait for the consultative document from the COT Working Group on Variability and Uncertainty, before taking a fresh look at this area. Mr Tomlinson informed the Committee that the COT report would be published in the next few weeks.

Secretariat to alert the EC to the draft COT report on toxicology and variability for relevance to toxicodynamic research.

Prof Purchase also suggested that it could be possible to encourage one of the companies, e.g. ILCE, to take it up as a project.

Prof Levy added that he had good contacts with ILSI HESI in Washington if Members wanted him to approach them on behalf of IGHRC, but Mr Tomlinson was of the opinion that if the ABPI are not interested, it was unlikely that IGHRC would get support from elsewhere.

4.8 There is currently a lot of cross-Government activity on nanotechnology, including a House of Lords Select Committee so it was suggested that the IGHRC should maintain a watching brief rather than be actively involved in this area.

Members to keep a watching brief in nanotechnology

4.9 The current programme of work (until Sept 2006) includes two guidance documents on Exposure Modelling and Chemical Mixtures, and one Awareness Day due to run in March 2006.

5. Guidance Document: Guidelines on Route-to-Route Extrapolation of Toxicity Data

5.1 Ms James thanked Dr Fielder and Dr Philippa Edwards for taking the lead in writing the document. The latest version is currently with a technical editor but is

Dr Fielder to sign-off the route-to-route document on behalf of the Committee.

Action

not expected to need too much further work before it is ready for sign-off. Ms James asked Members for their comments. Dr Stratford noted it was a useful document.

The Committee agreed Dr Fielder should sign-off the final edited document on their behalf.

6. Repeat of previous IGHRC training courses

- 6.1 This item was discussed after item 10 since it depended on the outcome of discussions from items 7 and 10. Prof Levy introduced this item and reminded members that the IGHRC courses are available to Government department members free of charge and that they only pay for their own travel and accommodation. Robin Fielder asked the Committee to prioritise which courses they considered worthy of repetition. It was noted that the *Presenting and publishing transparent risk assessments* and the *Probabilistic modelling of exposures* courses run in 2004-2005 received particularly good feedback from participants.
- 6.2 Prof Levy commented that the *Probabilistic modelling* course was an intense course intended for those already advanced in using probabilistic techniques. The cost (£21,544) reflected the resources required to run a two-day computer-based course. It was agreed that demand within Government departments for re-running the three two-day courses is limited as there have been few new starters since they were run before. Of the three, there would be the greatest interest in the *Understanding chemical exposure assessment* and the *Presenting and publishing transparent risk assessments* courses. However, if the *Probabilistic modelling* course is re-run, Ms Gowers suggested the Secretariat speak to Ms Albania Grosso for detailed feedback on areas for improvement. It was also suggested the course should be simplified for a less-specialist audience.
- Ms Gowers noted that she attended the *Presenting and publishing transparent risk assessments* course and found it useful. However, she suggested amending the title of the course to better reflect the content (e.g. how to do chemical risk assessments) to avoid misleading potential attendees.
- 6.3 Several Members agreed that there would be great demand for a new IGHRC course on Epidemiology for scientists currently working in the field of chemical risk assessment. Risk assessors are often toxicologists by training and have little epidemiological experience. Prof Levy agreed to contact Dr Lesley Rushton, a former colleague, who ran a similar course at IEH to progress this.
- 6.4 It was proposed that IGHRC could initiate a short course on the UK's implementation of the EU REACH regulations due in 2007 but it was acknowledged that there is a lot of activity on REACH within Government at present and that an IGHRC course on REACH would be premature at this stage.
- 6.5 Prof Moore suggested PBPK as an increasingly important area for course development in the future.

Members to consider possible repeat of the *Presenting and publishing transparent risk assessments* and *Understanding chemical exposure assessment*.

Secretariat to seek feedback from Albania Grosso should the *Probabilistic modelling* course be re-run in the future and simplify course content.

Secretariat to amend the title of the *Presenting and publishing transparent risk assessments* course, should it be re-run in the future.

Prof Levy/Secretariat to contact Dr Rushton about a new course on *Epidemiology for risk assessors*.

Members to discuss IGHRC involvement with REACH at the brainstorming session in June 2006.

Action

7. Financial Statement Oct 2004–Sept 2005 and projected income and expenditure to Sept 2006.

7.1 Ms James introduced this item. Finances are currently healthy, with a balance of £142,277 at the end of Year 2. This sum will be transferred to Cranfield University’s accounts department when the contract between all parties has been agreed and novated. Projected expenditure for Year 3 of the programme is £148,475. This estimated sum is dependent on the Steering Committee’s decision to repeat training courses, which in turn is dependent on the Committee’s decision on the future of IGHRC beyond 2007. Unallocated funds for phase II are therefore estimated to be at least £88,359.

Secretariat to amend income in light of DEFRA’s withdrawal of funding and notify the Cranfield accounts department.

7.2 Mr Wallace noted that running the IGHRC with a continual surplus of funds is not in line with principles of Government accountancy.

7.3 Dr Stratford referred the Committee to footnote ‘a’ of the table on point 5 of paper IGHRC/SC/04/06 and informed the Committee that Defra have reviewed funding for the third year of phase II and would not be contributing any further payments.

Secretariat to invoice contributing agencies and depts for the period Sept 2005 to Sept 2006.

7.4 Representatives requested that they are invoiced for contributions due for Year 3 (Sept 2005-Sept 2006) as quickly as possible.

8. New Location of IGHRC Secretariat

8.1 Prof Levy updated members on the successful move of IEH to Silsoe campus at Cranfield University from Leicester on 1 November 2005.

Five members of staff transferred: Prof Len Levy, Dr Paul Harrison, Mr Phil Holmes and Ms Kathryn James and Mr Bob Harris. New IEH staff include a senior toxicologist, Dr Huijun Zhu, who came from Imperial College; an environmental chemist, Ms Louise Assem, who will soon complete her PhD on metabolism of estrogenic compounds in fish (due to start 23 Jan 2006); and Ms Jo Franklin, who has been appointed in an administrative role and will be spending a good proportion of her time working on the Secretariat. IEH are also looking to recruit an information scientist.

8.2 The IGHRC Website has been transferred as agreed and is now hosted by Cranfield University. The website is an important forum for IGHRC to publish and promote its activities and documents. Prof Levy reported that some documents have received a large number of hits from around the world.

Secretariat to maintain and update IGHRC website.

8.3 The Silsoe campus is due to close and move to Cranfield’s main campus sometime towards the end of this year. No interruption to IGHRC activities is foreseen.

Secretariat to notify Committees of new contact address.

9. Evaluation of IGHRC Phase II activities

9.1 Prof Levy introduced this item and drew the Committee’s attention to the evaluation carried out by Dr Sue Barlow in early 2004. Although the independent evaluation of phase I was seen as useful, the value of an independent phase II evaluation was questioned. This was because the three recommendations on page 8 of the previous report have already been addressed, each IGHRC guidance document is extensively peer-reviewed and workshops/courses/training days are evaluated on the day by participants.

Action

The main role of an independent evaluation would be to steer the direction of the next three-year phase of IGHRC. Therefore, item 10 needed to be decided before this could be discussed. An evaluation would however, be useful in assessing value for money and whether Phase II met its remit, especially for auditing purposes.

9.2 The point was made that there should only be an evaluation if it is warranted and not just because there is money available to do so. Prof Purchase suggested that if Dr Barlow was commissioned again, she would need less time (a few days) than was required for the Phase I evaluation because she now has the background information on IGHRC.

9.3 It was decided that it was more important to have a programme of future work that all members feel is relevant than to be evaluated externally. Prof Levy added that Secretariat's final report of Phase II is required in any case. The Committee agreed that a new evaluation would not be commissioned but the report of phase II should include an evaluative element.

Secretariat to incorporate evaluation into the final summary report of Phase II.

10. The future of IGHRC

10.1 Prof Levy introduced this item to discuss the future of IGHRC beyond the end of phase II in Sept 2006. The three options discussed were to terminate activities at the end of Sept 2006 and refund surplus funds to the departments/agencies; extend IGHRC for a further year using the surplus funds from phase II; or start a new phase III with an agreed programme of work and level of resource.

Secretariat to arrange meeting with the SC to decide on the programme of work for IGHRC from Sept 2006 to Sept 2007.

An extensive discussion on the benefits of IGHRC to each Department/Agency and IGHRC's wider-ranging impacts followed. Representatives from Defra and the DTI said that IGHRC was less relevant to the work of their departments and they had benefited indirectly only. For example, the DTI found the DH contributions to guidance documents useful. Some members felt that the IGHRC was duplicating work going on elsewhere. However, representatives from the EA, HPA and HSE have found the IGHRC forum useful for fostering cross departmental dialogue, and highlighted that the guidance documents have supplemented advice to Government Departments. Dr Dewhurst added that unlike other scientific Committees, IGHRC is an important catalyst for projects, progresses recommendations from meetings and gets things done. Dr Navaratnam declared the Home Office's position to remain involved as non-contributors, at the Steering Committee level.

Secretariat to investigate running a course on *Understanding epidemiology and its role in chemical risk assessments*.

As an 'outsider' to IGHRC, Prof Levy gave the view that IGHRC is a useful platform for cross-department/agency activity and communication but Dr Stratford re-assured him this is being done elsewhere at both a structural and technical level. Prof Levy added that as a professional, he has found the guidance documents are taken seriously at an international level. For example, Dr John Groten from Denmark has said that the Chemical Mixtures document will be ahead of its time and that the UK is a leader on this important issue within Europe. IGHRC and its publications boost the UK's reputation and give the UK more authority in an international arena of chemical risk assessment.

The point was also raised that it would be a shame for IGHRC to be disbanded only to have to re-invent it again since it is likely there will be a need for such a forum in the future. Prof Purchase made a suggestion for a skeletal IGHRC, which obtains money to carry out specific work and thus grows bigger and smaller by demand but Dr Dyer thought this was not practical in terms of DH funding.

Action

Having identified a consensus for the need for IGHRC, the decision to commit financially to another three years could only be made if a full programme of work is in place. Consequently, there was much discussion on possible future IGHRC activities (see section 6 as well as below).

The introduction of the REACH legislation in to the UK in 2007 will have an effect throughout this field and related areas such as COSHH. The possibility of IGHRC involvement e.g. in running courses on its wide-ranging implications or developing a UK scientific position on REACH was discussed. However, other groups are in place to do this such as Dr Stratford's dedicated REACH team at Defra and the Whitehall Steering Group on REACH. Dr Fielder made the point that REACH is regulatory dealing with specific chemical substances, whereas IGHRC addresses other important niche areas such as chemical mixtures. It was agreed that IGHRC involvement in REACH should be discussed at the next Steering Committee meeting, since the UK's regulatory position should be clearer in one year's time.

Dr Stratford to give information on the timetable for the introduction of REACH to the Steering Committee but further discussion to occur at the 10th SC meeting.

Most support came out for the option to continue for one year and then re-assess. A brainstorming meeting will be arranged in mid-2006 to discuss the future remit and activities for IGHRC for the period Sept 2006 to Sept 2007 and beyond. However, some broader areas for IGHRC involvement suggested by Members were:

Secretariat to arrange a brainstorming session for the Steering Committee mid-2006 to discuss the future activities and remit of the IGHRC until Sept 2007.

- Risk management options relating to health risk assessments for chemicals.
- Health risk assessments for chemicals with an ecological focus, such as wildlife e.g. using wildlife as surrogate markers for humans. Prof Moore noted that the forerunning organisation RATSC had wildlife in their remit.

Members to bring ideas for an IGHRC with a broader remit and programme of activity to the brainstorming session in mid-2006.

It was agreed that surplus funds from Phase II would be used to fund an extra year of the Programme for Sept 2006 to Sept 2007. Members agreed to fund the remaining third year of Phase II (except Defra).

- 10.2 A re-evaluation of the future of IGHRC will therefore occur at the 10th Steering Committee meeting in January 2007. Dr Fielder asked the Secretariat to draw up a programme of work to September 2007.

Secretariat to draw up work programme to Sept 2007.

11. Any other business/date of next meeting

- 11.1 It was agreed to extend the deadline for registration of participants to the IGHRC Awareness Day on Chemical Risk Assessments within UK Government to 14th February 2006.

Secretariat/Members to note the amended deadline and publicise accordingly.

- 11.2 Mr Wallace noted that the novation document that had been circulated was not the most up-to-date version and had not incorporated specific requested changes from the DTI. The Contract Accounts department at Cranfield University will re-issue the correct version of the novation agreement to SC members as a matter of urgency. It was noted that this is also delaying invoicing of IGHRC funds for Sept 2005 to Sept 2006.

Secretariat to prompt Cranfield Uni. Accounts dept to re-issue contract documentation for final agreement and sign-off ASAP.

- 11|3 Date of next meeting – to be arranged.

- 11.4 The meeting closed at 3.00 pm.