RISK ASSESSMENT OF BYSTANDER/RESIDENT EXPOSURE TO PESTICIDES: REFERRAL FROM DEFRA MINISTERS.

(Previous paper TOX/2009/09)

Referral

1. Following the advice from the Court of Appeal, regarding a Judicial Review of the risk assessment of bystander exposure to pesticides, Defra Ministers would be grateful for the initial advice of the Committee on Toxicity, particularly on those aspects of the judgement that might have a wider impact on regulatory toxicology for plant protection products and other substances.

2. A copy of the referral letter from PSD can be found as Annex 1 to TOX/2009/09 (http://cot.food.gov.uk/cotmtgs/cotmeets/cot2009/cotmeet7apr2009/cotagenda papers7apr09)

Background to referral.

3. A case for judicial review of the current consideration of risk to bystanders and residents in the pesticide approval process was brought by Georgina Downs (Case no: CO/4483/2004). The case was heard by Mr Justice Collins in July 2008, and his judgment was handed down in November 2008. A copy of the judgment was circulated to COT members as Annex 2 to TOX/2009/09. COT Members will be aware that the appeal court judgement has been handed down. Defra Ministers have confirmed that they wish to continue the review of policy in this area, but that the precise detail of the referral for advice from the COT will need to be amended in the light of the Appeal Court Decision.

Background to COT consideration of bystander/resident exposure to pesticides

5. The COT has previously considered bystander/resident exposure to pesticides when providing advice to the Advisory Committee on Pesticides (ACP) on the Royal Commission on Environmental Pollution Report ‘Crop Spraying and the health of residents and bystanders’ (September 2005). http://www.rcep.org.uk/cropspraying.htm. The COT/COC comments on the main conclusions of the RCEP report are reproduced below for ease of reference;

6. The Committees considered the recommendations for human health presented in the RCEP report (reproduced in italics below).

i) Regarding 2.65 of the RCEP report; Based on the conclusions from our visits and our understanding of the biological mechanisms with which pesticides interact, it is plausible that there could be a link between resident and bystander pesticide exposure and chronic ill health. We found that we are not able to rule out this possibility. We recommend that a more precautionary approach is taken with passive exposure to pesticides. The existing uncertainties indicate an urgent need for research to investigate the size and nature of the problem and any underlying mechanisms that link pesticide spraying to ill health. The committees did not consider that there was a basis to support the recommendation that there was an urgent need for research. The Committees agreed that recommendations relating to additional precaution in risk assessment above the already precautionary approach used did not have a scientific basis and this was an issue of policy regarding pesticide approvals.

ii) Regarding paragraph 2.66 of the RCEP report; We recommend that a comprehensive systematic review of the literature in this field be conducted that takes account of, and avoids, the shortcomings of the Ontario study. The COT agreed that an epidemiological review of para-occupational exposure to pesticides should be undertaken. The COT agreed a review of the literature on chronic fatigue syndrome and multiple chemical sensitivity should be undertaken. COC members doubted that a comprehensive systematic review would be valuable given the deficiencies in exposure measures in published studies. The COC agreed that geographical studies of cancer incidence linked to potential exposure (possibly to include appropriate biomonitoring data) should be considered.

iii) Regarding paragraph 2.67 of the RCEP report; We recommend that an imaginative systematic approach is taken to apply both well validated as well as novel clinical investigative methods to those with chronic symptoms linked to pesticide spraying such as magnetic resonance
spectroscopy (MRS) and gene and protein profiling The COT agreed that specialist investigations should be aimed at all potential causes of chronic illness such as chronic fatigue syndrome and multiple chemical sensitivity, not just the proposed hypothesis relating to bystander exposure to pesticides.

iv) Regarding paragraph 2.68 of the RCEP report; We recommend that the Health Protection Agency and related organizations within the devolved administrations in Scotland and Wales collect population data on pesticides, their metabolites, and biomarkers of effects that would provide a sound basis for exposure assessment and could also be used to establish a national database for monitoring. The COC considered that appropriate population biomonitoring could be of value in interpreting any studies of cancer and the potential association with exposure to pesticides. The COC noted the role of HPA in coordinating such work in the U.K. The COT concluded that targeted biomonitoring work was more preferable to gain an estimate of potential bystander exposure.

v) Regarding paragraph 2.69 of the RCEP report; We recommend that the private sector and universities be encouraged to develop new animal models that better reflect the chronic disorders experienced by residents and bystanders exposed to pesticide spraying. The COT considered that there was currently no clear rationale for developing animal models to test for poorly-defined end effects such as multiple chemical sensitivity without some mechanistic basis for undertaking such work. The COT considered that there was little value in using in vitro techniques to investigate such chronic ill health effects. (The Committees noted that all pesticides are tested for potential carcinogenicity in rodents)

Introduction to current review

7. The ACP considered additional information provided by CRD at its 30 June 2009 meeting. At that meeting ACP members suggested that it might be helpful to form a joint short-life working group with COT members to take these issues forward. Information presented in ACP 9 (338/2009) has been appended to this draft discussion paper set out in the order provided to the ACP. A number of the data requests were submitted by the ACP but are included in the COT discussion paper so that both committees have access to the same information. This comprises Annexes 2-11 of this draft discussion paper. Annexes 2, 5 and 6 have been published along with this draft discussion document on the COT internet site. Annex 7 contains in part published documents which can be obtained by an inter library loan. Annexes 10 and 11 are published documents which can be obtained via inter library loan or via the web, http://www.pesticides.gov.uk/approvals.asp?id=1875 (link to costs analysis of possible changes in pesticides practices) or from ADAS (in respect of Annex 11). Annexes 3,4 and 9 are prepublication documents which will been published in due course. Annex 8 contains medical in confidence information and has not been published on the COT
internet site. In addition the chair of the COT has written to Ms Downs requesting a written document with additional information (Annex 12 not published on COT internet site). The COT has been asked specific questions with regard to Annexes 5-9 which present relevant toxicological information regarding the questions asked by COT at the April 2009 meeting.

8. The COT is asked to comment on the additional information specifically focusing on Annexes 5-9 which were specifically requested by the COT. The COT have not been specifically requested to provide advice on Annexes 2-4, 10, 11. It is hoped that sufficient information has been provided for the chair of COT to respond to CRD with a further letter outlining COT views.

Overview of submitted information


The ACP asked for an update on the BREAM project at the 336th meeting in April 2009. This is the detailed routine annual report from the contractor which includes the period after the discussions at the 327th meeting, in September 2007. The next annual report will cover the period up to 19 June 2009. In meantime the contractor has provided a summary of the current status (see the next item).


The contractor has produced this short accessible summary for the ACP to explain the current state of the project.


The COT asked for information on whether or not diluted products demonstrate a potential for irritation or sensitisation, at their meeting in April 2009. What COT members views on the proposed strategy?

Comparison of AOEL, ADI and ARfD values ACP 9/5 (338/2009) (Annex 6)

The COT, at their meeting in April 2009, asked for information on existing AOELs and ADIs, they also indicated a need for an acute exposure assessment against an alternative reference dose. The secretariat suggest that one possible interpretation of these data is that the higher the ratio of AOEL/ADI the higher the priority for review. Similarly the lower the ratio of ARfD/AOEL the higher the priority for review. Do COT members agree? What conclusions can be reached with regard to this evaluation of reference doses.
Information on duration of use ACP 9/6 (338/2009). (Annex 7)
The COT asked for information on duration of exposure, at their meeting in April 2009. This paper provides some usage data to give an indication of the potential for exposure in the absence of direct measurements of residues in air. What are COT members views of the submitted information?

Additional information from PIAP on confirmed cases 1998-2008 ACP 9/7 (338/2009). (Annex 8)
This paper presents further data on acute health effects in bystanders considered by PIAP as confirmed or likely to be related to pesticide exposure. The COT asked for this, at their meeting in April 2009. What are COT members views of the limited information that is available?

Review of biological monitoring exposure studies reported in the open literature ACP 9/8 (338/2009). (Annex 9)
This is a working draft paper that was considered by the Medical and Toxicology Panel in May 2009, MTP 3 (35/2009). Changes proposed by the Panel have yet to be incorporated into an updated draft. The COT asked for this, at their meeting in April 2009. What conclusions can COT reach on the interim information provided?

The German authorities published this document setting out their approach to bystander and resident risk assessment in 2008. Apart from information on CRD’s website this is the only other guidance that CRD are aware of.

The ACP asked to see this at the 336th meeting in April 2009.

Submitted information from Ms Downs

9. The COT chair wrote to Ms Downs in respect of a submission to COT on the 27 May 2009 (Annex 12). A copy of the submitted documents from Ms Downs has been appended as Annex 13. The various materials were submitted by Ms Downs for COT members consideration, but due to confidentiality the documents themselves have not been placed on the COT internet site. Members will wish to note that Ms Downs has submitted an Executive Summary of Witness Statement No2, which is appended in Annex 13 just after the relevant witness statement. Do COT members have any comments?
COT discussion

10. The COT is asked whether the additional information provided fulfils the requests made at the April 2009 COT meeting. Can the COT update its views on bystander/resident risk assessment of exposure to pesticides?

Secretariat September 2009

Annexes

Annex 1. Letter from COT chair to CRD (pesticides) outlining COT discussions of April 2009.

Annex 2. Definitions of bystander/resident ACP 9/1 (338/2009)
Annex 3. BREAM SID4 Annual/Interim Project Report for Period 19/06/07 – 18/06/08 ACP 9/2 (338/2009)


Annex 13. Submission from Ms Downs (received 25 August 2009)