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The author asserts her moral rights generally in respect to this Witness Statement.

On behalf of: Claimant
Witness: G.Downs
3rd statement
Date of statement: 4th July 2008

CO/4483/2004

IN THE ADMINISTRATIVE COURT

R (Georgina Downs) v Secretary of State for Environment, Food and Rural Affairs

THIRD WITNESS STATEMENT OF GEORGINA DOWNS

1 I am Georgina Downs, of "Reflections", Runcton Lane, Runcton, Chichester, West Sussex, PO20 1PT and I make this, my third statement, to respond to some of the points made in the Defendant's second Witness Statement, which is included in the further response and evidence lodged by the Defendant in Volume V. Except where otherwise stated, I depose to the truth of the facts contained in this statement from my own knowledge.

2 In §1 of Mr. Hamey's second Witness Statement he has stated, *"..the Claimant contends that, because the approach to risk assessment under the Directive only considers exposure to single active substances "the possibility of increased toxicity due to potentiating or synergistic interactions from mixtures" is not assessed..."* This is not what I said in §8(c) of my second Witness Statement **[IV/7-8]**, as I was referring to the Defendant's approach to bystander exposure assessment and did not mention the Directive in §8(c) at all.

3 In relation to the new document relied upon by the Defendant at **[V/1/1-84]** (an opinion by the European Food Safety Authority's Plant Protection Products and their Residues Panel regarding exposure to two or more pesticide residues in combination in food), I would question the Defendant's assertion that *"The toxicological aspects and conclusions are valid in the context of bystander/resident exposures"* for the following reasons.

a) The exposure scenario for residents is completely different to the pesticide residue levels that are found in food. Residents exposure is long-term, chronic and cumulative and involves exposure to innumerable mixtures of pesticides that can be at high doses and levels, whereas exposure to pesticide residues in food will (normally) be at a low level, far lower than exposure to residents exposed during and after the actual application process, from all exposure factors, and via all exposure routes.

b) In the context of this Judicial Review challenge, it is actually immaterial that there is currently no internationally agreed methodology to assess risks from exposure to two or more agents **[V/1/7],** as the requirement of the Directive is quite clear in relation to the need for Member States to carry out the appropriate assessments for all relevant *humans* that may be exposed to establish that there will be no harmful effect to the health of those humans. Therefore specific and relevant exposure assessments for whoever may be exposed must be undertaken and those assessments have to be realistic for the exposure scenario concerned.[1] As set out in my second Witness Statement the exposure scenario for residents inevitably involves long-term exposure to innumerable mixtures of pesticides as agricultural pesticides are rarely used individually, but are commonly sprayed in mixtures near to residents' homes, children's schools etc. (quite often consisting of 4 or 5 different products mixed together, and as stated in §8(c) of my second Witness Statement, this can include other chemicals such as solvents, surfactants and other co-formulants). Therefore the fact that the Defendant has not included the assessment of mixtures into its exposure assessment model is a significant omission, as to fulfil the requirement of establishing no harmful effect of a pesticide product *"having regard to all normal conditions under which it may be used,"* (Directive, Article 4(1)(b) **[II/126]**) would have to include not only when that product is used on its own, but also when used in combination with any other

[1] As highlighted in footnote 26 of my second Witness Statement**,** Annex 3 §7.3 of Directive 91/414/EEC under the heading of *"Data on exposure,"* states, *"The risks for those in contact with plant protection products….depend on…**the route, the degree and duration of exposure**…"* **[II/272].**

products considering, as said, that the normal conditions of use in relation to agricultural pesticides is that they are commonly sprayed in mixtures. However, as repeatedly stated throughout my second Witness Statement the specific pesticide exposure scenario for residents (as opposed to bystanders) would need to include in the exposure calculations all the exposure factors relevant for residents and via all exposure routes over the long-term, as no exposure assessment or resulting risk assessment for **residents** can be accurate or complete if some of the exposure factors are ignored in the exposure calculations, which they currently are. Therefore it is about all the various exposure factors that are currently missing from the Defendant's current approach (of which exposure to mixtures is just one) as highlighted at §56 of my second Witness Statement **[IV/42-60].**

4 In relation to §3 of Mr. Hamey's second statement. The statement that I made that *"none of the measures would make any difference in relation to the exposure of either bystanders, or the more extensive exposure of residents, (as opposed to operators, who would gain protection)"* was specially in relation to the statement made by Jayne Wilder, ACP Secretariat, in a letter dated 30th November 2007 where she stated regarding the outcome of the PSD's adverse data review that, "*the outcome of the review was that conditions of approval were amended in early 2004 in order to ensure that estimated operator and bystander exposure were within the AOEL. The changes to approval were a change in container design to wide-necked containers, gloves and coveralls required when handling contaminated surfaces, application only from closed cab tractors, and a reduction in dose rates."* **[IV/662-3].** Therefore my statement was directly in relation to this statement as clearly indicated in §32(a) of my second Witness Statement **[IV/28-30]**. In relation to Mr. Hamey's statement that I was wrong to conclude that only dermal absorption was considered in the adverse data review of Dithianon Flowable, I went by the only document that was released to me following an FOI request regarding the adverse data review of dithianon and stated in §32(a) of my second Witness Statement that it would *appear* from that PSD

file note that the adverse data review was only in relation to dermal exposure[2] and did not include a review related to inhalation or oral exposure. This was a perfectly reasonable assumption to make in the absence of any further documentation, as I had not been provided with the file note that Mr. Hamey has now set forth at exhibit PYH 2 **[V/2/85-94]**.

5 In relation to Mr. Hamey's statement in §5 of his second Witness Statement that the adverse data review included two other products (Barclay Cluster and Topas D 275 SC) in addition to Dithianon Flowable, again, I must reiterate that the conclusion I made was perfectly reasonable in the absence of any further documentation, as I had only been provided with information relating to just the one product, Dithianon Flowable. Therefore I was not provided with any of the documents now set forth by Mr. Hamey at exhibits PYH 4, 5, 6 and 7 **[V/103-114]** despite my FOI request having been for information regarding the adverse data review of dithianon (and thus concerning all related products).

6 In relation to §9 of Mr. Hamey's second Witness Statement again if I had been provided with all the relevant information regarding the adverse data review of dithianon in response to my FOI request then I would have seen that the remaining three products that Mr. Hamey refers to were not included in the adverse data review.

7 In relation to Mr. Hamey's comments in §10 of his second Witness Statement, regarding what I said in §32(b) of my second Witness Statement **[IV/31]**, table 7, example 7, of the July 2003 PSD paper at **[I/265]** clearly shows that the AOEL was exceeded by 1.66 times for the child 24 hour inhalation exposure, (at 166% of the AOEL). It does not indicate in that specific table anywhere that it was in fact the ADI, as it says the AOEL, and therefore as I was going by the results in that table when I made the statement in §32(b) of my second Witness Statement then I was quite correct in doing so. If it was in fact an error in the table, which should have indicated

[2] Eg. in the PSD file note under "*Data Protection*" it states, *"A new **dermal** absorption study has been considered and this was requested as a result of the ACP's concerns regarding bystander exposure. It has been used to make a regulatory decision therefore should receive five years protection."* **[IV/674]**.

that it was the ADI not the AOEL, then the table itself should have said that to make that clear.

8 Also in relation to §10 of Mr. Hamey's second Witness Statement. I did not say in §32(b) of my second Witness Statement that, *"following the review the European Commission made a formal decision that trifluralin is not to be included on Annex 1 to the Directive…"* I just stated correctly that Trifluralin is no longer to be included as an active substance in Annex I to the Directive. I did not mention any review and I also didn't say that the decision was necessarily based on *"bystander exposure risks,"* I just made the correct statement that it had been withdrawn at the behest of the European Commission and that the Defendant, had taken no action as a result of the estimates in the July 2003 PSD paper, (where it was estimated that the AOEL would be exceeded, many times over). This was all factually correct information and statements.

9 In relation to Mr. Hamey's comments in §11 of his second Witness Statement[3], I reiterate that the suggestion of Mr Hamey that since the January and July 2003 PSD papers that the Defendant has adopted into its assessment of *bystanders* 24-hour air exposure, and exposure of children to residues via skin contact and hand-and object-to-mouth activities in neighbouring gardens, was definitely not borne out by the existing material before the Court.[4] In fact quite the opposite, as can be seen from the information set out §§37 to 55 of my second Witness Statement **[IV/34-42]**, the confirmation of what the bystander risk assessment entails has been repeatedly made by the Defendant, PSD and ACP (ie. dermal and inhalation exposure to spraydrift at 8 metres at the time of the application only, from a single pass of a sprayer, for 5 minutes exposure (which the Defendant and the PSD have previously asserted is then assumed to be at that level, (only for 5 minutes each day), over just a 3 month period (or less)). Therefore based on the continued statements made by the Defendant there was no evidence to support Mr. Hamey's suggestion that the assessment had been

[3] In which Mr. Hamey incorrectly refers to §37 of my second Witness Statement which should in fact be §38. **[IV/34-35]**.
[4] The evidence in the Defendant's bundle, Volume III, did not support the suggestion that the Defendant had made any change to the current bystander exposure assessment.

modified in any way and no material had been set forth by the Defendant setting out any revised exposure model.

10 The material Mr. Hamey has now set forth at exhibits PYH 14-23 **[V/252-306]** still does not appear to support his suggestion that 24-hour air exposure, and exposure of children to residues via skin contact and hand-and object-to-mouth activities in neighbouring gardens, is now part of the standard criteria that is required in the *bystander* exposure (and risk) assessment for the following reasons.

a) It is only for 6 pesticides and their related products and does not appear to be for all pesticides and related products approved for use since consideration of the July 2003 PSD paper.[5] It should also be noted that in relation to the 6 pesticides given as examples, 2 appear to be no longer approved in the UK[6] (products containing Ethaboxam and Triadimoenol) and the remainder (products containing Amisulbrom, Fluopicolide Mandipropamid, Spirodiclofen) have approvals only for 1 product each[7]. Therefore this supports the assumption that the examples provided are highly unlikely to be for all pesticides and related products approved since consideration of the July 2003 PSD paper, as no other documentation has been set forth by the Defendant to demonstrate that 24-hour air exposure, and exposure of children to residues via skin contact and hand-and object-to-mouth activities in neighbouring gardens has also been assessed in addition to the existing 5 mins (or less[8]) 8 metre bystander model.

b) In addition to that at a) §83 of the Defendant's skeleton states, "*The Defendant's position is that these judgements have in the main been vindicated by the further data which came out of the January and July 2003 papers, and to the extent that*

[5] Also Mr. Hamey has not been specific about the date from which he says that the 24-hour exposures and toddler exposures were included. He says *"later assessments*" in §11 but doesn't give a start date. The earliest exhibited is July 2005 which is a very long time after the 2003 PSD papers.
[6] According to the PSD database of approved products as searched for on 26th June 2008.
[7] According to the PSD database of approved products as searched for on 26th June 2008.
[8] It should be noted that page 298 of Volume V regarding orchard (and knapsack sprayers) states, "*As these spray drift data have no inhalation exposure values, inhalation exposure is calculated from the UK POEM estimate for BAA application to vines (but assuming 1 minutes exposure instead of 6 hours):"* so for that calculation it has bystander exposure just for one minute. (NB. 6 hours is the inhalation exposure assumed under the UK POEM model for operators).

refinements have proved to be necessary these have been carried out…" It then refers to exhibits 14 – 23 of volume V. However, the wording here is quite carefully worded in that it is only where *"refinements have proved to be necessary these have been carried out*" (and in the related footnote 13 of the Defendant's skeleton that, *"the refinements which are being referred to are not to the 1983/87 model itself (this remains untouched) but constitute a series of additional assessments based on 24-hour data and children exposure)"* which again would appear to support the assumption that the additional exposure estimates are i) not part of the standard criteria that is required in the *bystander* exposure assessment and that ii) that the further "*assessments"* were not for all pesticides and related products approved since consideration of the July 2003 PSD paper. **Therefore it is not established that these 2 additional exposure factors have been part of the standard requirement in the bystander exposure assessment for all pesticide products since the consideration of the July 2003 PSD paper.**

11 In relation to Mr. Hamey's comments in §12 of his second Witness Statement, although the Defendant has considered these other two additional exposure factors (among many which the Defendant has not considered), it is apparent from the exhibits 14 – 23 of volume V that the Defendant just considers the three exposure factors (5 mins at 8m to spraydrift only; 24-hour inhalation value; and toddler playing (which excludes inhalation altogether)) individually on their own and does not combine them together in the exposure calculations[9] (and also does not include the fact that each exposure is likely to involve mixtures of pesticides per application, as pesticides are commonly used in mixtures rather than individually). Therefore it could be seen to be unsurprising that no product has been refused authorization solely on

[9] §104(v) of the Defendant's skeleton argument states, *"As Paul Hamey has explained (see paragraph 5 of his second witness statement), the Defendant's assessments now taken into account exposures to children via skin contact and hand to mouth activities in neighbouring gardens"* and §115 of the Defendant's skeleton states, *"As Paul Hamey has reiterated in his second witness statement (paragraphs 11-12, and exhibits PYH 13-24), post-July 2003 assessments have taken into account the Californian and German data, as well as potential exposure to children." "Taken into account"* does not mean that they have been included in the exposure calculations along with the existing exposure estimates for the standard model (5 mins (or less) at 8 metres etc.)

the basis of the additional assessments on their own (last sentence of §12 of Mr. Hamey's second Witness Statement).

12 In any event it still misses the further fundamental point that even if the Defendant has considered the 2 additional *limited* exposure factors for a few pesticides it is not all exposure factors and via all exposure routes in totality that it needs to be in relation to the specific exposure scenario for residents, as highlighted in §56 of my second Witness Statement **[IV/42-60]**).

13 Also in relation to §12 Mr. Hamey states *"I accept that misunderstandings may have arisen in this respect…"* and in §116 of the Defendant's skeleton it states, *"It is accepted that misunderstandings may have arisen for two reasons. First, the use of the adverb transparently could be misinterpreted, and perhaps has been. Secondly, there may be a distinction here between the conventional model, derived from MAFF's 1983 and 1987 experiments, which remains unchanged as a model, and the Defendant's overall approach to bystander/residents risk assessment, which has been broadened to take into account further evaluations."*

14 I have to stress that there is no misunderstanding here, as the evidence is quite clear considering the continued statements made by the Defendant, the ACP and PSD (as set out in §38 to §55 of my second Witness Statement at **[IV/34-42]**) that the Defendant has not "*changed*" its bystander exposure assessment model subsequent to the January and July 2003 PSD papers, (considered by the ACP), to include in the exposure calculations for that model any other exposure factors or exposure routes. Rather, as can be seen from the information set out in the aforementioned paragraphs of my second Witness Statement, the confirmation of what the bystander risk assessment entails has been repeatedly made by the Defendant, PSD and ACP (ie. maximum 24 hour exposure as equal to five minutes' exposure to spraydrift at eight metres from a single pass of a sprayer and via inhalation and dermal absorption only). Secondly, the continuous statements made by the Defendant, the ACP and PSD are very clear in that the exposure assessment and risk assessment is still related to the existing bystander assessment model. There was no mention of any changes made to

either the exposure assessment (or the risk assessment) until Mr. Hamey's first Witness Statement in these proceedings. For example, Professor Coggon's statement at §43 of my second Witness Statement **[IV/36]** is quite clear in that any additional exposure factors are ignored in the exposure calculations. In response specifically to §116 of the Defendant's skeleton, many of the aforementioned statements made by the Defendant, the ACP and PSD are clear in that they refer to the assessment of risks (and/or exposure) for bystanders as being "*satisfactory"* and repeatedly confirm that the risk assessment approach had not "*changed*". (This is also confirmed in the RCEP report, as §3.38 refers to the outcome of the two PSD papers in 2003 and states, *"The ACP consideration of these papers is reflected in two documents headed 'Advice to Ministers'"* that "***did not result in any changes in pesticides approved for use or policy."*** **[II/504]**). **The evidence does not demonstrate that any other exposure factors are now included in the exposure calculations (as a standard requirement) regarding the exposure assessment for *bystanders*.** In particular, the material provided shows that while two additional exposure factors have sometimes been considered, the Defendant has, wrongly, calculated each factor in isolation and has failed to calculate the exposure factors together.

15 In §13 of his second Witness Statement Mr. Hamey states, "*the Defendant does not believe that the provision of information about a pesticide, either before or after an individual's exposure to it, would in itself guarantee to reduce that individual's exposure, much less protect public health."* However, this statement and position is impossible to reconcile with the fact that in certain respects (eg. use of sulphuric acid), a proper legal obligation of prior notice is imposed in the public interest and for the protection of health.

16 In §14 of his second Witness Statement Mr. Hamey refers to the 3rd party access to information service that was already referred to in my second Witness Statement (footnote 261 at **[IV/129]** in which I pointed out that this is not a mandatory requirement and is merely subject to a farmer/pesticide user providing the PSD (that will be acting as the 3rd party) with the information voluntarily and thus no penalty or enforcement can be applied when the information is not forthcoming. Also again, this

is not direct access for residents, which it needs to be, and in any event, the 3rd party process is not in relation to immediate access either, as there will be a time-lag between a request going in and the disclosure of the information (if the enquirer actually gets it that is, as there will be no mandatory obligation for the farmer/pesticide user to provide it). This is completely unacceptable when someone suffers immediate acute effects and needs to have the information on what chemicals they have been exposed to immediately without any delay.

17 In §14 of his second Witness Statement Mr. Hamey also refers to the industry-led voluntary approach and the publication of its two guidance leaflets for farmers and spray operators. However, as I pointed out in my second Witness Statement aside from the *severe limitations* of these leaflets (as indicated at §175 of my second Witness Statement **[IV/124]**) they simply are not going to make any difference, as voluntary measures have existed for decades, have not worked and are completely unacceptable in this situation.

18 In relation to Mr. Hamey's comments in §15 of his second Witness Statement regarding the EC Regulation currently under negotiation it should be pointed out that this European Regulation is still a long way off and so it could still be years before it comes into force. Therefore the Defendant cannot rely on that for its continued inaction in this area, aside from the critical fact that the Defendant has previously given an undertaking for mandatory not voluntary access to information and prior notification for residents (see §89 of the Claimant's skeleton argument) which was a stated commitment that was never carried through.

19 It should be noted that there are a lot of points that Mr. Hamey's second witness statement does *not* answer. I will not attempt to list these exhaustively, but for example on Ground 2 Mr. Hamey does not come back to dispute all the evidence I set forth in my second Witness Statement (at **[IV/68-95]**) to demonstrate that adverse effects, including acute *local* effects can be, and are, caused by pesticides in the dilute spray solution form. Neither does Mr. Hamey come back on the point that there has been a clear change of position that '*non-serious'* effects (as previously stated by the

Defendant) are in fact, according to the Defendant, in reference to the acceptance of '*local'* effects in operators. In fact it is noticeable that Mr. Hamey does not respond at all to any of the evidence I set forth in my 2nd Witness Statement in relation to Ground 2. **[IV/64-111]**.

20 Nor has the Defendant made any attempt to respond to the finding of the July 2003 PSD paper that numerous other pesticides (aside from Dithianon and Trifluralin which Mr. Hamey has commented on in his second Witness Statement) had been shown to exceed the AOEL and on the Defendant's own figures (see eg. the seven examples set out in my second witness statement, footnote 41 at **[IV/26-27]**).

21 I would also like to take the opportunity in this third Witness Statement to respond to a few specific points relating to the Defendant's skeleton argument. It should be noted that there are a number of factual inaccuracies in the Defendant's skeleton. I will not go through them all as there are too many, but I will correct the most important.

22 Footnote 1 of the Defendant's skeleton tries to say that my amended grounds dated 25th October 2006 were late. This is completely incorrect as the amended Grounds and the accompanying file bundle Volume II were submitted to the court and served on the Defendant prior to the deadline for re-activation of the time-limits following the agreed stay I had with the Defendant in the relevant Consent Order. (See the Cover Sheet to the amended Grounds in Volume II **[II/1]** that clearly shows the deadline date being 26th October 2006).

23 §8 of the Defendant's skeleton states, *"The Defendant has used the phrase "no serious harm" as synonym for minor skin and eye irritation (acceptable)…"* However, as I said at §69 of my second Witness Statement **[IV/67]** this stated position in §8 is completely contradicted by the fact that Professor David Coggon, Chairman of the Advisory Committee on Pesticides from 2000 to 2005 has publicly stated that approval for a particular pesticide was withdrawn in the mid 1990s

"*because it was shown to cause skin rashes and eye irritation*"[10] and thus was withdrawn solely on the basis of *local* (irritant) effects).

24 §58 of the Defendant's skeleton states, *"The only difference between operators and bystanders is the key practical difference that operators are routinely exposed to the concentrate and bystanders are only exposed to the dilution."* However, it should be pointed out that when the water evaporates from pesticides sprayed in the dilute form a *concentrated* pesticide particle or droplet is left so it is not quite right to say that bystanders are *only* exposed to the diluted pesticide. Also there are a number of key practical differences between operators and residents, such as the fact that residents can be present 24 hours a day, 7 days a week, for many decades; and that residents do not use protective clothing or have access to air-conditioned cabs to reduce exposure.

25 §77 of the Defendant's skeleton states, *"It is also noteworthy that the RCEP made the point that on average arable crops are sprayed five times a year and orchard crops thirteen times a year (see paragraph 3.4 at **[II/493]**), which rather vindicates the Defendant's position that it is both conservative and protective to assume spraying every day for three months: this does not happen in the real world…"* First of all it should be pointed out that this is rather misleading, as it is only for 5 minutes (or less) each day for over (usually) at most just a 3 month period (although it appears that this can in fact be less than 3 months, see footnote 71 of my second Witness Statement at **[IV/42]**). Secondly, as pointed out in §56h of my second Witness Statement **[IV/55-57]**, spraying can take place in the locality to residents' homes numerous times a week for a number of months per year. For example, last year, my family and I experienced approximately 20 spraying applications near our home over a period of about three months some of which were only one day apart. In just the last 2 weeks we have had about 6 spraying applications in the field adjoining our property, so the averages given in the RCEP report can in no way to be taken as the definitive.[11]

[10] *Outlooks on Pest Management*, June 2006, **[IV/764]**.
[11] Although as I have repeatedly stated, in relation to a residents specific exposure scenario it is about all exposure factors and via all exposure routes in totality. See §56 of my 2nd Witness Statement **[IV/42-60]**.

(Also as I pointed out in §56h of my second Witness Statement **[IV/55-57]**, I have received reports from residents where their houses are surrounded on three or even on all four sides by sprayed fields, all of which may be sprayed on any given day, (whether it be the same day or on subsequent days), repeatedly, throughout every year).

26 §90 of the Defendant's skeleton states, *"Thirdly, the point is made by the Claimant, possibly more than once, that the Defendant's risk assessment is deficient because it ignores (i) long-term and repeated exposure, (ii) exposure from a multitude of factors and via all routes, and (iii) exposures from mixtures of pesticides (see, for example, paragraph 29 of the Claimant's Skeleton Argument)."* This is made factually incorrect by not having the words *"in the exposure calculations"* following the word "*ignores*" as underlined above, as I have repeatedly made the factually correct statement that various exposure factors and routes are ignored in the exposure calculations (as confirmed by Professor Coggon in his statement as highlighted at §43 of my second Witness Statement **[IV/36]**).

27 In relation to §100 of the Defendant's skeleton it should be noted that the ACP made more than just two recommendations to the Defendant as a result of the ACP Open Meeting (eg. the ACP recommended further work in relation to harvest dust and oral exposure in addition to the two recommendations that the Defendant has detailed).

28 §107 of the Defendant's skeleton states, *"As regards 24-hour inhalation exposure, care needs to be taken to differentiate between the arable and the orchard data. Looking at the arable data first **[I/261-265]**, there is only one example of the AOEL being exceeded, namely in relation to the estimation for child exposure to the active substance trifluralin (see **[I/265]**)."*

29 This is not correct and needs to be clarified for the Court's information. In relation to the 24 hour inhalation exposure there are actually **25 examples** (involving 4 different products) where the AOEL was shown to be exceeded as highlighted in §23a of my second Witness Statement **[IV/23]** (when counting each individual date that the exceedances were listed in relation to both adults and children). These all relate to

arable crops (as lettuce is an outdoor vegetable crop that involves ground boom sprayers, and thus comes under the arable heading, as can be seen stated in the July 2003 PSD paper at **[I/254]**).

30 §107 of the Defendant's skeleton goes on to state, *"Looking next at the orchard data [I/266-267], there are a greater number of examples of the AOEL being exceeded…"* It is not clear what products the Defendant is referring to here as there do not appear to be any products exceeding the AOEL in relation to 24 hour inhalation exposure for the *orchard* examples.

31 It is important to point out to the court that in total there were **82 examples** in the July 2003 PSD paper of the AOEL being exceeded (when counting each individual date that the exceedances were listed and for each time) involving 15 pesticide products (and 10 actual pesticides). The breakdown for this consists of:- 40 examples where the AOEL was exceeded at 1 metre and/or in some cases at 8 metres (ie under the current exposure assessment) **[IV/16-22]**, 25 examples where the AOEL was exceeded for 24 hour inhalation **[IV/22-23]**, and 17 examples where the AOEL was exceeded for hand-to-mouth-object-to-mouth exposure (see §24 and footnote 39 at **[IV/24]**.

32 Despite the 40 examples where the AOEL was estimated to be exceeded at 1 metre and/or in some cases at 8 metres there has been no change to the existing bystander model of 5 mins (or less) at 8 metres.

33 It also is important to note that many of the estimated exceedances of the AOEL in the July 2003 PSD paper were extremely high and in some cases an "*order of magnitude*" over the AOEL and therefore not just a small degree over, although it is clear from the Directive requirements that the AOEL must not be exceeded at all.

34 In *Sweden v Commission* one of the reasons for Paraquat being withdrawn was that evidence showed that the AOEL was exceeded for operators at 118% of the AOEL (1.18 times above the AOEL) which is far, far less of an exceedance than many of those estimated in the July 2003 PSD paper.

35 See §182 of the Judgment of *Sweden v Commission*[12] that states, *"Since the Guatemalan study attests to an exposure level greater than the AOEL based on a use of paraquat under the proposed conditions, the requirement posed in point C 2.4.1.1 of Annex VI, which prohibits any exceeding of the AOEL, is not fulfilled. But, for the reasons set forth in points 162 to 168 above, the criteria of Annex VI are to be applied within the framework of the evaluation of an active substance by virtue of Article 5, para. 1, sub b) of the same directive. Consequently, the criticized directive fails to comply with the requirement to protect human health as it appears in Article 5, para. 1, sub b) of Directive 91/414.* ***The complaint drawn from an exposure of the operator greater than the AOEL must therefore be admitted."***

36 §186 of the Judgment[13] states, "*In light of the preceding, one should admit the complaints drawn, respectively, from an exposure greater than the AOEL [Acceptable Operator Exposure Level] and from the insufficiently probative nature of the case to admit the entering of paraquat in Annex I of Directive 91/414."*

37 Therefore in *Sweden v Commission* the exceedance of 118% of the AOEL was enough for the ECJ to rule that it was not in line with the strict requirement of the Directive for the protection of *operators* health.

38 In relation to the findings of the July 2003 PSD paper §111 of the Defendant's skeleton states, *"…products identified in this paper as constituting a cause for concern have been subject to adverse data reviews and further evaluations."*

39 This is not correct, as the adverse data review was only in relation to Dithianon and nothing else, as I highlighted at §28 and footnote 41 of my second Witness Statement **[IV/25-27]** that for a number of the pesticides that were estimated to exceed the AOEL, and in some case many times over, there is no evidence that any further data

[12] As taken from an "*unofficial*" translation, as there is currently no official English translation available from the ECJ.
[13] Ibid.

reviews or evaluations were carried out. The Defendant has not set forth any evidence before the court to support the statement in §111 of the Defendant's skeleton.

40 §132 of the Defendant's skeleton states, *"The Defendant does not ignore chronic or systemic effects. These are directly relevant to the setting of the AOEL, and equally relevant to individual assessments of plant protection products."*

41 This needs to be clarified, as the Defendant has changed the context of the statements that I made in relation to chronic effects. I did not say that animal testing does not cover chronic effects in general or that chronic effects in general are not considered when setting an AOEL. What I actually said in §152 of my second Witness Statement **[IV/111]** (which I am presuming is the paragraph that the Defendant is referring to) is that by the Government allowing acute effects to be considered *acceptable* (ie. acceptable to be suffered) and the ACP stating that the risk of certain symptoms should be regarded as acceptable, **[II/633]**) this is then also allowing the risk of chronic effects, because the risk of chronic effects developing can increase when acute effects repeatedly occur as a result of long-term (*"continuous"*) exposures.

42 §132 of the Defendant's skeleton goes on to state that, "*Chronic or systemic effects raise a separate issue altogether from local effects, and should not be placed in the same bracket."*

43 However, as I said at §§70 and 71 of my second Witness Statement **[IV/67-68]**, it is clear from the statement made by Ian Dewhurst (who is the PSD's principal specialist in toxicology) in his oral evidence to the RCEP that the word *"serious"* was actually brought in to cover *any* effect which cannot be dealt with by animal models (eg. acute *systemic* effects such as headaches, nausea, aching limbs, pain, dizziness, tingling sensations etc.) and which is thus *accepted* by the Defendant in the approval and use of a pesticide, in direct contradiction of the Directive requirement that pesticides should have *no harmful effect* on the health of humans (including residents, bystanders and operators). And in contradiction of the Defendant's previous position that it was only '*transient minor irritant symptoms'* which were accepted – see eg **[II/730]**.

44 Therefore the evidence before the court shows that the Defendant, ACP and PSD have clearly continued to allow acute effects, (and not just local irritant effects, but seemingly *all* other acute effects, including systemic effects such as headaches, nausea etc.) to *occur* in residents and bystanders without taking any action to protect residents health. (See in particular §127-§152 of my second Witness Statement at: **[IV/99-111]**). Therefore it does not raise a separate issue altogether from local effects, and is completely appropriate to include *in the same bracket* considering the Defendant is considering a variety of different adverse effects as being *non-serious* (and which is of course the point in challenge in Ground 2 of this Judicial Review). It should be reiterated that as stated in §95 of my first Witness Statement **[II/16]**, I have confirmed with European Commission officials that *"no harmful effect*" means any adverse effect (whether it be acute or chronic), as they stated that **any acute effects, however minor, are not acceptable.**

45 In relation to the Defendant's comments at §133 of its skeleton argument regarding local effects, I reiterate that just because the AOEL does not cover local effects does not mean that such effects can simply be ignored. On the contrary, in order to meet the Directive duty to ensure that there will be *no harmful effect* to human health, the Defendant is required to take *other* measures (such as risk management measures) to protect residents, bystanders and operators from such effects. (See §123-§126 of my second Witness Statement at **[IV/97-99]**.

46 §158 of the Defendant's skeleton incorrectly states that the Claimant's skeleton argument "*seeks to reformulate"* the third Ground. It can be seen that this is not correct in relation to the Defendant's sub-headings (1) to (4) as all these points were included in the Claimant's Grounds document dated 25th October 2006 – eg. see §41 and §43 **[II/21]** and footnote 54 **[II/27]** of the Claimant's Grounds document that covers that referred to in sub-heading (1) at §158 of the Defendant's skeleton; see §42, §43, **[II/21]** §47 **[II/26]** and §51 **[II/30]** of the Claimant's Grounds document that covers that referred to in sub-heading (2) at §158 of the Defendant's skeleton; and see §42 to §51 **[II/21-30]** of the Claimant's Grounds document that covers that referred to in sub-heading (4) at §158 of the Defendant's skeleton.

47 In relation to sub-heading (3) of §158 of the Defendant's skeleton in relation to the Human Rights point, this was again made in the Claimant's Grounds document, eg. at §2 **[II/3]** and §18 **[II/11-12]**. However, it should be noted that just because the Human Rights point in the Claimant's skeleton (at Part VI) is in the section that follows that related to Ground 3, it by no means should be interpreted as meaning that the Human Rights point is only related to Ground 3, as it is related to any and all of the 3 Grounds involved in this Judicial Review challenge, as previously set out at §2 and §18 of the Claimant's Grounds document.

48 §178 of the Defendant's skeleton states, *"The RCEP was not able to identify any new evidence of a causal link between exposure to pesticides and ill-health in rural residents. DEFRA draws a distinction between anecdotal report and scientific evidence."*

49 As I have pointed out previously in my first Witness Statement (eg. see §67 and §68 of that statement **[II/12**) this is not correct, as where the RCEP referred to the *plausibility* of a link between resident and bystander exposure and ill-health, it actually states that it is in relation to *chronic ill-health*. (See paras §2.65 **[II/482]** and §6.20 of RCEP report **[II/556]).** The RCEP fully accepted that acute effects can be, and are, caused by pesticides from crop-spraying. (See §68 of my first Witness Statement **[II/12]** and §112 of my second Witness Statement **[IV/90**) as well as §2.9 of the RCEP report itself at **[II/465]**. Therefore the Defendant's statement is inaccurate in that it leaves out the word "*chronic*" in its statement at §178 of its skeleton argument.

50 Exactly the same point applies to the Defendant's statement at §179 of its skeleton argument that states, *"Thus the RCEP's key conclusion was that, while that was no evidence of a causal link, the scientific uncertainties were sufficient to make such a link "plausible", and that additional interim precautionary measures should therefore be deployed until such time as the uncertainties were or could be addressed."* Again the Defendant's statement is factually incorrect due to the omission of the reference to "*chronic ill health*" in the context of the statement.

51 §179 of the Defendant's skeleton argument goes on to state, *"However the RCEP provided no compelling scientific rationale behind the recommended precautionary measures, nor any assessment of the likely resulting benefits to human health."*

52 In relation to this last bit underlined it is important to reiterate what I previously pointed out in my second Witness Statement (at §194 and footnote 277 **[IV/134-135]**) that DEFRA itself recognised that implementing all the RCEP recommendations would have benefits, **including health benefits**, for the public, particularly residents living near farmland. (This was also highlighted in §97 of the Claimant's skeleton).

53 In relation to the Human Rights point §199 of the Defendant's skeleton states, *"In this case the Claimant has no convincing evidence of a probability of damage to health or quality of life due to inadequate precautions by the authorities, or that the consequences of the acts complained of would not be too remote, given the current state of scientific knowledge."*

54 This statement is somewhat ambiguous, as it is not clear whether this is a reference to me personally or in relation to residents more generally. If related to me personally then I would like to point out that as stated in my first Witness Statement at §48 **[II/9]** and in the Claimant's skeleton at footnote 197, in relation to my own personal health problems, I have received medical advice to the effect that *"the most important aspect is to avoid ongoing exposure"* to pesticides. In whichever context the Defendant meant this statement to be in there are a number of reasons why it is not correct.

(a) As set out in my second Witness Statement and the Claimant's skeleton in the case of pesticide spraying, the health risk has already been accepted – even by the ACP, which has taken the view that a *"small risk"* of *"minor transient symptoms"* is *"acceptable"* **[II/633]**; and the Defendant, PSD and ACP are well aware that acute effects in residents and bystanders can be, and are, caused by pesticides from exposure to crop spraying, as the same types of symptoms have continued to be reported again and again, year in year out (eg. the examples detailed in the FOD reports which are assessed by PIAP as being

"*confirmed*" or "*likely*") and the Defendant has simply decided to accept them as *non-serious* effects (see under Ground 2 in my second Witness Statement).

(b) In addition, as I have stated previously by the Government allowing acute effects to be considered acceptable (and the ACP stating that the risk of certain symptoms should be regarded as acceptable, **[II/633]**) this is then also allowing the risk of chronic effects, because the risk of chronic effects[14] developing can increase when acute effects repeatedly occur as a result of long-term (*"continuous"*) exposures. (See §86 of my second Witness Statement **[IV/78-79]** and §104 of the Claimant's skeleton)).

55 Not only are both matters raised in a) and b) in direct contradiction of the Directive requirement that pesticides should have *no harmful effect* on human health, they also have to be in direct violation of Article 8 of the ECHR.

56 §205 of the Defendant's skeleton argument states, *"…it is denied that "bystanders" have "other status" within the meaning of article 14; and that any different treatment is not objectively justified."*

57 §108 of the Claimant's skeleton was quite clear in its argument in that "*residents*" have been unjustifiably treated less favourably, within the ambit of their Article 8 rights, than operators. Therefore it was referring to residents as opposed to bystanders, as residents and bystanders are two separate exposure groups.

I believe that the facts stated in this witness statement are true.

Signed:

Georgina Downs

Date:

[14] It should also be noted that once someone is suffering from chronic long-term health problems (like myself and many other residents who contact me) then they fall into the bracket of a *vulnerable group* where any further exposure to pesticides (irrespective of whether pesticides was the cause of their pre-existing health problems or not) can be deleterious.