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Neutral Citation Number: [2009] EWCA Civ 664

Case No: C1/2009/0073/QBCAF

IN THE SUPREME COURT OF JUDICATURE
COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE QUEEN'S BENCH DIVISON
ADMINISTRATIVE COURT
MR JUSTICE COLLINS
C0/4483/2004

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 07/07/2009

Before :

LADY JUSTICE ARDEN
LORD JUSTICE KEENE
and
LORD JUSTICE SULLIVAN

Between :

SECRETARY OF STATE FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS	**Appellant**
- and -	
GEORGINA DOWNS	**Respondent**

Robert Jay QC & Vikram Sachdeva (instructed by **Treasury Solicitors**) for the **Appellant**
Michael Fordham QC & Emma Dixon (instructed by **Messrs Foresters**) for the **Respondent**

Hearing dates : Monday, 18th, Tuesday, 19th & Wednesday, 20th May 2009

Approved Judgment

Lord Justice Sullivan :

1. Introduction

This is an appeal against the Order dated 15th December 2008 of Collins J. in which he granted the Respondent a Declaration that the Appellant was not acting in compliance with Directive 91/414 EEC ("the Directive") in the respects identified in his judgment [2008] EWHC 2666 (Admin), and ordered the Appellant to reconsider and as necessary amend his policy in accordance with the terms of the judgment.

2. Background

The background to the Respondent's claim is set out in her first Witness Statement dated 22nd October 2006, in which she describes herself as a "full-time pesticides campaigner", and is summarised by Collins J. in paragraphs 1 – 7 of his judgment. The Respondent moved with her parents to her present address in 1983. The house is in the countryside, and since 1984 the adjoining fields have been sprayed with pesticides. She has produced a video (now a dvd) "Pesticide Exposures for People in Agricultural Areas – Part 1, Pesticides in the Air", which shows the tractor-drawn sprayer boom passing within less than a metre of her garden. For many years the Respondent suffered from ill health. In 1991 her condition was so serious that she was hospitalised. On leaving hospital she was determined to discover the cause of her ill health, and concluded that it was the effects of the pesticides to which she had been repeatedly exposed.

3. In 2001 she began her campaign to persuade the Government, and the Appellant in particular, that the United Kingdom's regulatory regime for pesticides was inadequate because, while it protected the operatives who carried out the spraying, it did not properly protect those residents in rural areas who were exposed to the effects of the spraying.

4. In 2003 the Department for Environment, Food and Rural Affairs ("Defra") carried out two consultation exercises, an informal preliminary consultation "to explore the options requiring farmers and growers to notify those in surrounding houses of intended spray operations and maintain a register of pesticide treatments which will be available for public consultation"; and a formal consultation document on "Proposals for the introduction of No-Spray Buffer Zones around residential properties in England and Wales".

5. The Respondent made extensive written submissions in response to these consultations. Her submissions included a second video (now a dvd) entitled "Pesticides Exposures for People in Agricultural Areas – Part 2, The Hidden Costs". On 16th June 2004 the Minister for Rural Affairs and Local Environmental Quality, Alun Michael MP, responded to the consultations:

> "The Government's top priority is to ensure that the safety arrangements we have in place protect the public. The independent scientific advice to me is very clear that the existing system provides full reassurance on that score. For this reason I have decided against the introduction of

> compulsory no-spray 'buffer zones' around agricultural land.
>
> But despite existing advice, there is clearly a perception that current arrangements are inadequate. I have listened to the concerns of campaigners who hold strong views about how crop spraying has affected their health. I believe the time is now right for a fresh and independent appraisal of the basis for risk assessment.
>
> That is why I have asked the Royal Commission on Environmental Pollution to examine the evidence on which the current system is based and the reasons for people's concerns. The Commission, as an independent body, will adopt its own approach to the question. Its conclusions may also inform the way in which Defra, across its work, deals with uncertainty in science and public perceptives on risk."

Defra is advised by an independent committee, the Advisory Committee on Pesticides ("ACP"), Professor Coggon, the then Chairman of the ACP said:

> "The considered view of the ACP, based on all the available evidence, is that current safeguards on crop spraying provide a high degree of protection to health and reassurance to the public. We recognise, however, that some public concern remains.
>
> I therefore wholeheartedly support the Minister's decision to invite the Royal Commission also to look at this area. I and my colleagues on the advisory committee look forward to assisting the Commission in its work and await its findings with interest."

6. The Respondent was dissatisfied with the Appellant's response to the consultations and, acting in person, filed her Claim Form in these proceedings on 16th September 2004. Subsequently, the parties agreed that consideration of her Claim should be stayed pending the report of the Royal Commission on Environmental Pollution ("RCEP") and Defra's response to the report.

7. The RCEP's report "Crop Spraying and the Health of Residents and Bystanders" ("the Report") was published in September 2005. The RCEP made numerous recommendations. It will be necessary to refer to the Report in more detail when considering the grounds of the Respondent's Claim. At this stage it is sufficient to note that the RCEP expressed:

> "serious concerns about the current method of assessing resident and bystander exposure to pesticides." (3.50)[1]

It recommended:

[1] References are to the relevant paragraph numbers in the document.

> "that the current approach for assessing resident and bystander exposure should, with some urgency, be replaced by a computational model which is probabilistic, looks at a wider range of possible exposure routes and more robustly reflects worst case outcomes." (3.53)

8. The RCEP also recommended the introduction of five metre buffer zones alongside residential property and other buildings such as schools and hospitals where people may be adversely affected by crop spray (5.86).

9. The majority of the members of the ACP did not agree with these recommendations. In "A Commentary on the Report Published by the Royal Commission on Environmental Pollution in September 2005", dated 30th December 2005 ("the Commentary") the ACP said that:

> "while there is a need for further empirical data to confirm the adequacy of the current approach to bystander risk assessment, there is no indication of a problem from the data that are currently available " (3.32).

The ACP disagreed with the recommendation that a probabilistic model should be developed, and favoured

> "a simpler approach of the type that is currently employed".

However, the ACP saw

> "merit in further developing the scientific information base for bystander (and other) exposure modelling". (3.34)

10. In summary, the ACP agreed with the RCEP that there were uncertainties in the current risk assessment which warranted further research, some of which was ongoing, but was "unconvinced by the scientific case for a precautionary 5 metre buffer zone..." (3.46)

11. In a response to the Commentary ("the RCEP Response") dated 11th July 2006 the RCEP maintained its position (13). On 20th July 2006 the Government published its response to the Report ("Defra's Response"). The Government's response to the recommendation that the current model for assessing bystander exposure should with some urgency be replaced by a computational model which is probabilistic was as follows:

> "44. The Government believes that the current approvals system for pesticides, which is at the forefront of international standards, provides adequate protection for both spray operators and members of the public. The Royal Commission noted that "*the present approach may be conservative and protective in its treatment of targets...*" and the Government agrees with this.

45. The Royal Commission also noted that they could not agree that "*...this [conservative and protective treatment] has been conclusively or transparently demonstrated for the exposure process*". The Government agrees that the current model for resident and bystander exposure needs to be reviewed against a more transparent model which clearly takes into account a wide range of possible exposure routes, both during and after spraying, and also addresses the changes in spraying practice and equipment that have taken place since the current model was developed.

46. The Government believes that it is important to develop the model using the most appropriate techniques that will provide the best assessment of potential exposure, and be transparent and demonstrably robust to ensure members of the public can have greater confidence in the approvals system. New field trials designed to measure exposures under more testing application conditions had already commenced before the Royal Commission's study concluded.

47. In developing the model Government will be consulting a number of experts, including a representative covering the Royal Commission's interests, on how the model should be developed. Computational probabilistic techniques will be considered as part of this process alongside other methodologies. Techniques and conditions for validating the model will include wind tunnel evaluation, field tests and non-standard conditions. Defra's Chief Scientific Adviser will ensure the development of the model meets acceptable scientific standards."

12. The Government did not consider that the recommended 5 metre buffer zone was:

> "a proportionate response to the level of uncertainty surrounding the model for exposure of residents and bystanders currently used as part of the approvals process." (58)

13. On 25th October 2006 amended grounds for Judicial Review, drafted by Mr Fordham QC and Ms Dixon, were filed. The Respondent's Notice said that her skeleton argument below was "maintained in its entirety". Collins J. summarised the amended grounds in paragraph 6 of his judgment. When making his submissions on behalf of the Respondent Mr Fordham confirmed that Collins J. had accurately summarised the claims as follows:

> "The claim....was against the alleged failure by the defendant to comply with the obligations imposed by the relevant E.C.

> Directive (91/414/EEC) in that the domestic regime did not provide for the necessary protection of public health, in particular the health of those such as the claimant who were residents living near fields which were subjected to crop spraying. Three grounds were relied on. First, it was argued that there was no risk assessment capable of identifying and properly guarding against the effect on residents as opposed to those who might happen at the particular time to be near the field, properly described as bystanders. Secondly, the approach adopted by the defendant that there should be no serious harm to human health was wrong in law: the Directive did not qualify the requirement that the use of pesticides should not result in harm to human health. Thirdly, it was said that the defendant's failure to act on the RCEP's conclusion that a more precautionary approach was needed was erroneous and that at the very least cogent and clear reasons were needed to justify such a failure. There was included a submission that the failure meant that there was a breach of Article 8 of the ECHR in that the interference with the claimant's private life was disproportionate and not justified by Article 8(2)."

14. The Directive

As a first step in deciding whether Defra's current regime for authorising the use of pesticides is in breach of the obligations imposed by the Directive it is necessary to establish precisely what it is that each Member State is required to do in order to comply with the Directive. The Directive:

> "concerns the authorisation, placing on the market, use and control within the Community of plant protection products in commercial form and the placing on the market and control within the community of active substances intended for a use specified in Article 2(1)." (Article 1.1).

"Active substances" are defined in Article 2.4 as:

> "4. '*active substances*'
> substances or micro-organisms, including viruses, having general or specific action:
>
> 4.1. Against harmful organisms; or
>
> 4.2. on plants, parts of plants or plant products;"

"Plant protection products" are:

> "active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user...."

In ordinary language (and in this judgment) plant protection products are the pesticides that farmers and growers spray on the fields and in the orchards.

15. Active substances are not authorised by the Member States. They must be listed in Annex I to the Directive, and the Commission decides in accordance with the procedure established under Article 19 whether they are to be included in Annex I: see Article 6. When deciding whether an active substance should be included in Annex I the Commission is assisted by the Standing Committee on the Food Chain and Animal Health: Article 19.

16. Pesticides are authorised by the Member States. Article 4.1 is of central importance in this case. So far as material, it provides:

> "1. Member States shall ensure that a plant protection product is not authorised unless:
>
> (a) its active substances are listed in Annex I and any conditions laid down therein are fulfilled, and, with regard to the following points (b), (c), (d) and (e), pursuant to the uniform principles provided for in Annex VI, unless:
>
> (b) it is established, in the light of current scientific and technical knowledge and shown from appraisal of the dossier provided for in Annex III, that when used in accordance with Article 3(3), and having regard to all normal conditions under which it may be used and to the consequences of its use:
>
> (i) it is sufficiently effective;
>
> (ii) it has no unacceptable effect on, plants or plant products;
>
> (iii) it does not cause unnecessary suffering and pain to vertebrates to be controlled;
>
> (iv) it has no harmful effect on human or animal health, directly or indirectly (e.g. through drinking water, food or feed) or on groundwater;
>
> (v) it has no unacceptable influence on the environment, having particular regard to the following considerations:
>
> - its fate and distribution in the environment, particularly contamination of water including drinking water and groundwater.

- its impact on non-target species."

17. There are two limbs to Article 4.1. First, the active substances in the pesticides must be listed in Annex I. The second limb requires the Member States to establish that the pesticide has no harmful effect on human health. Does the second limb of Article 4.1 require Member States to establish, "pursuant to the uniform principles provided for in Annex VI" that there is no harmful effect on human health, or does it impose a free-standing, or over-arching, requirement on Member States to establish that the pesticide has no harmful effect on human health? The Appellant's first ground of appeal is that Collins J. erred in rejecting the Appellant's submission that compliance with the uniform principles in Annex VI was sufficient to ensure that there was compliance with the requirements of Article 4.1 (b) (iv) of the Directive.

18. Mr Fordham submitted that Collins J. had not "de-coupled" Article 4 and Annex VI. I do not accept that submission. It seems to me that Collins J. did consider the key question - whether the Appellant had complied with the Directive – on the basis that even if no harm to human health was established by applying the principles in Annex VI, Article 4.1.(b)(iv) nevertheless imposed a more general, or free-standing, obligation upon the Appellant to establish that there would not be such harm:

> "Mr Jay [QC, who appeared on behalf of the Appellant] submitted that compliance with Article VI was sufficient for the purposes of the Directive. That would only be so provided that the compliance adequately covered the risks to bystanders and residents." (paragraph 21 of the judgment, see also paragraphs 51 and 52).

19. In my judgment, the Appellant's submission that the Directive requires Member States to establish that a pesticide has no harmful effect on human health by applying the uniform principles in Annex VI, and that if, applying those principles, authorisation of a pesticide may be granted, the authorisation will be in compliance with Article 4.1, is correct. My reasons for concluding that this is the proper interpretation of the Directive are as follows.

20. The Directive was adopted having regard to Article 43 of the Treaty: to further the objectives of the common agricultural policy. It is a harmonisation measure, intended to reduce barriers to trade in pesticides by requiring the Member States to apply uniform rules on the conditions and procedures for their authorisation. This is evident from the fifth, sixth and seventh recitals:

> "5. Whereas, in view of the hazards, there are rules in most Member States governing the authorisation of plant health products; whereas these rules present differences which constitute barriers not only to trade in plant protection products but also to trade in plant products, and thereby directly affect the establishment and operation of the internal market;
>
> 6. Whereas it is therefore desirable to eliminate such

> barriers by harmonizing the provisions laid down in the Member States;
>
> 7. Whereas uniform rules on the conditions and procedures for the authorization of plant protection products must be applied by the Member States;"

21. Collins J. referred to the ninth and tenth recitals:

> 9. "Whereas the provisions governing authorization must ensure a high standard of protection, which, in particular, must prevent the authorization of plant protection products whose risks to health, groundwater and the environment and human and animal health should take priority over the objective of improving plant production;
>
> 10. Whereas it is necessary, at the time when plant protection products are authorized, to make sure that, when properly applied for the purpose intended, they are sufficiently effective and have no unacceptable effect on plants or plant products, no unacceptable influence on the environment in general and, in particular, no harmful effect on human or animal health or on groundwater;"

22. While the authorisation process must ensure that there is a high standard of protection and give priority to the protection of human health, so that an authorised pesticide will not have a harmful effect on human health, it is clear that these objectives are to be achieved by requiring the Member States to apply the "Uniform Principles" in Annex VI.

23. The sixteenth recital states that:

> "16. Whereas it is in the interests of free movement of plant products as well as of plant protection products that authorization granted by one Member State, and tests carried out with a view to authorization, should be recognized by other Member States, unless certain agricultural, plant health and environmental (including climatic) conditions relevant to the use of the products concerned are not comparable in the regions concerned; whereas to this end there is a need to harmonize the methods of experimentation and control applied by the Member States for the purpose of granting authorization;"

24. This recital is carried into effect by Article 10, which provides for the mutual recognition of authorisations. Where a pesticide has been authorised in a Member State, and an application for authorisation is made in another Member State, the latter must:

> "to the extent that the uniform principles [in Annex VI] have been adopted in accordance with Article 23, where the product contains only active substances listed in Annex I, also authorise the placing of that product on the market in its territory...."

25. The introductory note to the Table of active substances listed in Annex I tells Member States that "for the implementation of the uniform principles of Annex VI" the conclusions of the Standing Committee on Plant Health, set out in the form of specific provisions in the final column of the Table, shall be taken into account. Annex VI contains the "Uniform Principles for Evaluation and Authorisation of Plant Protection Products". The first paragraph in Part A, the Introduction to Annex VI, explains the purpose of the Annex:

> "1. The principles developed in this Annex aim to ensure that evaluations and decisions with regard to authorization of plant protection products, provided they are chemical preparations, results in the implementation of the requirements of Article 4 (1) (b), (c) (d) and (e) of this Directive by all the Member States at the high level of protection of human and animal health and the environment."

26. The "uniform principles" in Annex VI are prescriptive and immensely detailed. Part B of the Annex deals with the "Evaluation" of the dossier which must be submitted in accordance with the very detailed requirements of Annex III. Part C of the Annex deals, again in considerable detail, with "Decision Making".

27. I will consider the detailed requirements in Annex VI in due course, however, it is clear that the "Uniform Principles" are a comprehensive code which, if applied by Member States, will result in compliance with the requirements of Article 4.1, including Article 4.1(b)(iv). If each Member State was free to adopt its own principles or policies for the purpose of establishing that a pesticide has no harmful effect on human health, the underlying purpose of the Directive, harmonisation of authorisation procedures enabling mutual recognition by Member States of each other's authorisations, would be frustrated.

28. This approach to the role of Annex VI is supported by the decision of the European Court of Justice ("ECJ") in European Parliament v Council of the European Union, Case C – 303/94. The ECJ annulled an earlier version of Annex VI because it referred only to "groundwater intended for the production of drinking water", and did not deal with the potential effect of pesticides on all groundwater (whether or not intended for human consumption). The ECJ explained the interrelationship between Article 4.1 and Annex VI in paragraph 27 of its judgment:

> "27. With regard more particularly to the protection of health, groundwater and the environment, Article 4(1)(b) of the basic directive provides that the Member States are not to authorize a plant protection product unless, in accordance with the above mentioned uniform principles, it is established that that product has no harmful effect on human or animal health,

> either directly or indirectly, or on groundwater and has no unacceptable influence on the environment..."

29. The other authority of relevance is a decision of the Court of First Instance ("CFI") in the Kingdom of Sweden v Commission of the European Communities, Case T – 229/04. Sweden challenged the Commission's inclusion pursuant to Article 5 of the Directive of the active substance paraquat in Annex I. In response to Sweden's complaint that the uniform principles in Annex VI had not been applied the Commission argued that it was not required to apply the uniform principles when assessing an active substance under Article 5.

30. The CFI rejected the Commission's argument:

> "160 Article 5(1) of Directive 91/414 provides that, for an active substance to be included in Annex I to that directive, it must be possible to expect that, in the light of current scientific and technical knowledge, use of plant protection products containing that active substance, consequent on application consistent with good plant protection practice, will not have any harmful effects on human health as provided for in Article 4(1)(b)(iv) and (v) of that directive.
>
> 161 It follows from that provision, interpreted in combination with the precautionary principle, that, in the domain of human health, the existence of solid evidence which, while not resolving scientific uncertainty, may reasonably raise doubts as to the safety of a substance, justifies, in principle, the refusal to include that substance in Annex I to Directive 91/414. The precautionary principle is designed to prevent potential risks. By contrast, purely hypothetical risks, based on mere hypotheses that have not been scientifically confirmed, cannot be accepted (Case T-392/02 *Solvay Pharmaceuticals v Council* [2003] ECR II-4555, paragraph 129).
>
> 162 In order to determine whether the requirements laid down in Article 5(1) of Directive 91/414 have been fulfilled in regard to human health, that provision refers back to Article 4(1)(b)(iv) of the directive which provides, in essence, that it must be established that a plant protection product has no harmful effect on human health, directly or indirectly, or on groundwater.
>
> 163 It should be pointed out, however, that it can be seen from Article 4(1)(a) of Directive 91/414 that in order to fulfil the requirements laid down in Article 4(1)(b) of that directive, the uniform principles provided for in Annex VI must be applied. Moreover, the second recital in the preamble to Directive 97/57, fixing the content of Annex VI, states that that annex must lay down uniform principles to ensure the application of the requirements of Article 4(1)(b), (c), (d) and

> (e) of Directive 91/414 in a uniform manner and as stringently as is sought by the directive.
>
> 164 It follows that Article 4(1)(b)(iv) of Directive 91/414, to which Article 5(1)(b) of that directive expressly refers, requires compliance with the uniform principles laid down in Annex VI."

31. Collins J. referred to the existence of "solid evidence" in a number of passages in his judgment: see paragraphs 23, 27, 40 and 47. The Appellant contends that Collins J. erred in substituting his own evaluation of the available evidence for that of the Appellant. Later in this judgment I will consider whether that criticism of the judgment is justified. For the moment, it is sufficient to note the CFI's view in paragraph 163 of its judgment:

> "that in order to fulfil the requirements laid down in Article 4 (1) (b) of [the Directive], the uniform principles provided for in Annex VI must be applied."

This echoes the judgment of the ECJ in the European Parliament case, that a plant protection product is not to be authorised under Article 4(1)(b)

> "unless in accordance with the aforementioned uniform principles, it is established that the product has no harmful effect on human health...." (paragraph 27).

32. It follows that for the Respondent to succeed in her claim that Defra's authorisation regime fails to comply with the obligations imposed by the Directive, she must establish that the current regime is not in accordance with the "uniform principles" in Annex VI.

33. The Directive is transposed into domestic law by the Plant Protection Products Regulations 2005 ("the Regulations"). As Collins J. observed in paragraph 8 of his judgment, the Regulations reproduce the language of the Directive and import the Annexes. It is, therefore, unnecessary to refer to the text of the Regulations since they add nothing to the Directive. The Appellant contends that Defra complies with the Regulations, and therefore with the uniform principles in Annex VI of the Directive when authorising pesticides. In what respects does the Respondent contend that the Appellant is failing to comply with the "uniform principles"?

34. Although the Respondent criticises the current approvals regime on numerous grounds, which she has explained in great detail, principally in her second Witness Statement dated 29th April 2008, Mr Fordham, when asked to identify the respects in which it was contended that there was non-compliance with Annex VI, submitted that there was non-compliance in the following respects:

(1) Defra's "Bystander exposure" model was not a "suitable calculation model" for the purposes of paragraph 7.2.2 in Annex III of the Directive in relation to residents.
(2) Defra's authorisation process does not take account of "local effects", even though they are, he submitted, within the scope

of the Directive as shown by paragraph 2(c) in Part A of Annex VI, and paragraph 1(b) in the General Principles governing Evaluation in Part B of Annex VI. Paragraph 2 in Part B states that the specific principles of evaluation are to be applied without prejudice to the general principles.

(3) Although Defra, through the ACP, receives reports (including the Health and Safety Executive's Pesticides Incident Appraisal Panel (PIAP's) reports) of incidents involving pesticides where harm has been caused to human health, or where doubts have been raised as to the safety of pesticides under the regime which presently exists (see paragraph 161 of the Kingdom of Sweden case above), it does nothing about them, contrary to the provisions of Articles 4.5 and 4.6, 7 and 11 of the Directive.

I will deal with these three criticisms of the authorisation process in turn.

35. The bystander exposure model

Paragraph 2.4.1.1 in Part B of Annex VI requires Member States to evaluate operator exposure to the active substance and/or to toxicologically relevant compounds in the pesticide. An acceptable operator exposure level ("AOEL") must be determined:

> "The acceptable operator exposure level is the maximum amount of active substance to which the operator may be exposed without any adverse health effects. The AOEL is expressed as milligrams of the chemical per kilogram body weight of the operator. The AOEL is based on the highest level at which no adverse effect is observed in tests in the most relevant animal species or, if appropriate data are available, in humans."

36. Moving from evaluation to decision making, paragraph 2.4 in Part C of Annex VI deals with "Impact on human or animal health". Paragraph 2.4.1.1 provides:

> "2.4.1.1 No authorization shall be granted if the extent of operator exposure in handling and using the plant protection product under the proposed conditions of use, including dose and application method, exceeds the AOEL."

37. The AOEL is intended to protect the health of operators. It is not suggested by the Respondent that the Appellant fails to comply with the Directive in either establishing the AOEL in the evaluation and authorisation process, or in refusing authorisation if the extent of operator exposure would exceed it.

38. Annex VI does not require Member States to establish a separate acceptable exposure level for residents (an"AREL" in addition to the AOEL). Instead Annex VI requires Member States to address the health of residents (who fall within the

definition of "bystanders" in the Annex) by reference to the AOEL. Thus, at the evaluation stage, paragraph 2.4.1.4 in Part B of Annex VI requires that:

> "2.4.1.4. Member States shall evaluate the possibility of exposure of other humans (bystanders or workers exposed after the application of the plant protection product) or animals to the active substance and/or to other toxicologically relevant compounds in the plant protection product under the proposed conditions of use.
>
> This evaluation will take into consideration the following information:
>
> (i) the toxicological and metabolism studies on the active substance as provided for in Annex II and the results of the evaluation thereof, including the acceptable operator exposure level;
>
> (ii) the toxicological studies provided for in Annex III, including where appropriate dermal absorption studies;
>
> (iii) other relevant information on the plant protection product as provided for in Annex III such as:
>
> - re-entry periods, necessary waiting periods or other precautions to protect humans and animals...."

This is reflected in paragraph 2.4.1.4 in Part C of Annex VI which directs Members States that when making decisions on authorisation:

> "Waiting and re-entry safety periods or other precautions must be such that the exposure of bystanders or workers exposed after the application of the plant protection product does not exceed the AOEL levels established for the active substance or toxicologically relevant compound(s) in the plant protection product nor any limit values established for those compounds in accordance with the Community provisions referred to in point 2.4.1.1."

39. Paragraph 2.5 in Part C of Annex VI deals with "Influence on the environment". Again, the AOEL is used as the benchmark in paragraph 2.5.1.4:

> "No authorization shall be granted if the airborne concentration of the active substance under the proposed conditions of use is such that either the AOEL or the limit values for operators,

bystanders or workers as referred to in Part C, point 2.4.1, are exceeded."

40. Defra does evaluate the possibility of residents' exposure to pesticides, its evaluation does take into account the AOEL, and it does ensure that residents' exposure, as estimated in accordance with its bystander exposure model, does not exceed the AOEL. The Respondent contends that there is, nevertheless, a failure to comply with the Directive because the bystander exposure model used by Defra to estimate residents' exposure is "not fit for purpose", or as Mr Fordham put it: "the model is truly hopeless".

41. Annex III sets out in great detail the information that must be included in the dossier that must be submitted for the authorisation of a pesticide. Part 7 lists the various toxicological tests that must be carried out. Paragraphs 7.2.1 – 7.2.1.2 and 7.2.3 – 7.2.3.2 deal with the estimation and measurement of operator exposure and worker exposure. Bystander exposure is dealt with in paragraph 7.2.2:

> "*Bystander exposure*
>
> Bystanders can be exposed during the application of plant protection products. Sufficient information and data must be reported to provide a basis for the selection of appropriate conditions of use, including the exclusion of bystanders from treatment areas and separation distances.
>
> Aim of the estimation
>
> An estimation shall be made, using where available a suitable calculation model in order to permit an evaluation of the bystander exposure likely to arise under the proposed conditions of use.
>
> Circumstances in which required
>
> An estimation of bystander exposure must always be completed.
>
> Estimation conditions
>
> An estimation of bystander exposure must be made for each type of application method. The estimation shall be made with the assumption that bystanders do not use any personal protective equipment.
>
> Measurement of bystander exposure may be required when estimates indicate a cause for concern."

42. Under the current authorisation process the dossier submitted under Annex III does include an estimation of likely residents' exposure, and in making the estimation Defra does use a "calculation model": the "bystander exposure model". Mr Fordham submitted that there was a failure to comply with the Directive because

Defra's bystander exposure model was not "a suitable calculation model for residents."

43. He further submitted that the Court was entitled to form its own view of the suitability of the model, and that since the Court was considering whether there was compliance with a European Community Directive its jurisdiction was not limited to a review on Wednesbury grounds of the Appellant's conclusion that the model is suitable. The Court should consider whether there was a "manifest error" in the Appellant's conclusion. In my judgment, it is unnecessary on the facts of this case to try to identify the position on the spectrum where "manifest error" ends and "Wednesbury unreasonableness" begins. In a case such as this, involving complex questions of highly technical scientific judgment, the "manifest error" hurdle is a high one. In Commission of the European Communities v Cambridge Healthcare Supplies Ltd., Case C-471/OOP(R), the ECJ said, in the context of directives dealing with the authorisation of medicinal products:

> "96. In principle, such assessments are subject to limited judicial review. According to the Court's case-law, where a Community authority is called upon, in the performance of its duties, to make complex assessments, it enjoys a wide measure of discretion, the exercise of which is subject to a limited judicial review in the course of which the Community judicature may not substitute its assessment of the facts for the assessment made by the authority concerned. Thus, in such cases, the Community judicature must restrict itself to examining the accuracy of the findings of fact and law made by the authority concerned and to verifying, in particular, that the action taken by that authority is not vitiated by a manifest error or a misuse of powers and that it did not clearly exceed the bounds of its discretion."

44. In paragraphs 56-62 of her second Witness Statement the Respondent explains in great detail why she considers that the current bystander exposure model "does not and cannot assess residents' exposure". Her criticisms of the model are numerous, paragraph 56 alone extends to over 18 closely typed pages, and any attempt to summarise them would not do justice to her case.

45. However, what is of particular significance for present purposes is that although the Respondent has further developed her evidence and arguments for the purposes of this legal challenge, she was able to, and did, present her criticisms of the current model to the RCEP. The RCEP's response to those criticisms was, in turn, considered by the ACP. The Appellant was then able to reach a conclusion as to the suitability, or otherwise, of the model having regard to the differing views expressed by those two expert bodies. Paragraph 6 in the Introduction to Annex VI advises the competent authorities of the Member States that their judgments during the evaluation and decision-making process:

> "must be based on scientific principles, preferably recognised at international level... and be made with the benefit of expert advice."

46. The RCEP's views, unmoderated by the ACP's comments, must, realistically, be the high water mark of the Respondent's case. Although the Respondent is a most effective campaigner, and has developed a very considerable expertise in and knowledge of pesticides, she has no formal scientific or medical qualifications. For my part I can see no possible basis for going further than the RCEP's conclusions, insofar as they were critical of the current model. I have briefly referred to the RCEP's views when describing the "Background" to the Claim (paragraphs 7 and 8 above). In paragraph 3.39 of the Report the RCEP said that the current model represented "a pragmatic approach to a complicated problem", and that the assessment was "probably conservative and protective in the majority of situations". However, it was also satisfied that the model suffered from a number of "serious shortcomings" which it then listed, and discussed in the Report.

47. For convenience, I set out below paragraphs 3.43, 3.44, 3.50, 3.53 and 3.56 of the Report:

> "3.43 The ACP in its July 2003 discussion concluded in the paper: *Final Minutes of the 301st Meeting of the Advisory Committee on Pesticides* held on 10 July 2003:
>
> > 3.1.3 Members felt that the paper provided a good review of the information available, and that the models used were appropriate and could be identified as worst-case scenarios.
> >
> > 3.1.4 A range of issues arising from the paper were discussed by members. It was agreed that the approach currently used to assess bystander risks is generally protective with the possible exception of soil fumigants. Further data were identified as necessary to complete the assessment for dithianon and trifluralin.
>
> 3.44 We consider that the present approach may be conservative and protective in its treatment of targets, but in view of the absence of any attempt to model the complexity of bystander exposure and the probability of extreme values, we cannot agree that this has been conclusively or transparently demonstrated for the exposure process. We cannot therefore support the ACP's unequivocal conclusion above.
>
> 3.50 We have serious concerns about the current method of assessing resident and bystander exposure to pesticides. Although uncertainty factors are built into the AOEL, they are there to cover issues related to

toxicology and do not address the variability of exposure or the uncertainties in exposure assessment.

3.53 We recommend that the current approach for assessing resident and bystander exposure should, with some urgency, be replaced by a computational model which is probabilistic, looks at a wider range of possible exposure routes and more robustly reflects worst-case outcomes. The model should be rigorously validated by wind tunnel and field tests designed for the purpose, including non-standard conditions to test the sensitivity of the model predictions. As a first step, whoever takes ownership of the creation of relevant data should undertake a through review of the relevant experimental work that already exists.

3.56 In the short term, whilst the new probabilistic model is being developed and introduced, we recommend that all actual spraying practice be brought into line with the aspirations of the Green Code recommendations (chapter 5) including giving proper regard to the importance of optimal timing of the application and therefore efficacy of the pesticide. This will require appropriate monitoring arrangements and sanctions for non-compliance. These short-term practical measures must contain provisions for recording relevant data."

48. Pausing there, before considering the ACP's response to the Report, the fact that a model has been criticised by an expert body such as the RCEP does not necessarily mean that it is not "a suitable calculation model" for the purposes of paragraph 7.2.2 of Annex III. It will be noted that while paragraph 7.2.2 requires an estimation of bystander exposure, it does not require that a model must be used. A suitable calculation model must be used if one is available. Suitability is a relative concept, and a decision as to whether a model is suitable must take into account what is available in the "real world". An existing model is not unsuitable merely because, if an "ideal" model was to be devised in a hypothetical world, it would give a better estimate of residents' exposure.

49. I would readily accept Mr Fordham's submission that use of an unsuitable model could not be justified under paragraph 7.2.2 merely because no other model was available. In those circumstances an estimation would have to be made without the assistance of a model. However, it is one thing to say that an existing model has defects, and that research should be undertaken to devise a replacement model which would remedy some, or all, of those defects, it is quite another thing to say that an existing model is so defective that it is not a suitable model for the purposes of paragraph 7.2.2 of Annex VI.

50. The RCEP did not consider whether the defects of the current model were such that it was not "suitable" for the purpose of paragraph 7.2.2. That is not surprising, since it was not asked to do so. Reading the Report as a whole, and in particular the

passages set out in paragraph 46 above, I do not consider that the Report leads to the conclusion that the current model is so defective that it is not a suitable model for the purposes of paragraph 7.2.2. Rather, the Report supports the view that an improved model should be devised, and that while that is being done the current model, despite its defects, continues to be suitable, provided extra precautions are taken: see paragraph 3.56. If the RCEP had concluded that the current model was unsuitable, in the sense that it materially underestimated residents' exposure, then I have no doubt that the RCEP would have recommended either that its use should immediately cease, or that modifications should be made to the exposure calculations to eliminate any risk of underestimation, in the short term, pending the development of a replacement model.

51. When considering whether there was a "manifest error" in the Appellant's approach to the suitability of the current model the views of the RCEP do not stand alone. The ACP's views must also be considered. The RCEP was established in 1970 as an independent body to provide authoritative advice on environmental issues. Its members "have a wide range of expertise and experience in natural and social sciences, medicine, engineering, law, economics and business" (see "About the Royal Commission on Environmental Pollution" at the beginning of the Report).

52. By contrast, the expertise of the membership of the ACP is, given that committee's much narrower remit, heavily weighted towards those branches of science that have particular relevance to the evaluation of pesticides, e.g. toxicology. I have summarised the ACP's response to the RCEP's criticisms of the current model in paragraphs 9 and 10 above. Putting the matter as shortly as possible: the ACP did not accept the RCEP's criticisms of the model, and while it accepted that there was a need for more empirical data to confirm the adequacy of the model, it did not accept that it was unsuitable. It favoured an improved version of the current model rather than a probabilistic exposure model: see paragraphs 3.32 and 3.34 of the Commentary.

53. The Appellant was entitled to have regard to the ACP's views when considering what should be the Government's response to the RCEP's criticisms of the current model. Given that eminent scientists could not reach agreement as to whether there were significant shortcomings in the existing model, but were agreed that an improved model should be devised, even though they were not agreed as to whether it should be a probabilistic model, it is impossible to conclude that there is any error, much less a "manifest error" in the Government's conclusions which are, in effect, that while the current approvals system is "suitable" for the purposes of paragraph 7.2.2 because it is "at the forefront of international standards and provides adequate protection for both spray operators and members of the public" (paragraph 44, Defra's Response), it should be reviewed against a "more transparent model" which is not currently available, but which should be developed (paragraphs 45-46, Defra's Response).

54. Although I have set out my reasons at some length, I realise that the Respondent will vigorously disagree with my conclusion that there is no manifest error in the Appellant's view that the current model does comply with paragraph 7.2.2 of Annex VI. However, I believe that the proposition that there is no manifest error in the Appellant's approach to the bystander evaluation model is supported by the facts that: (a) there is no challenge to the Appellant's contention that Defra's current

approval system is "at the forefront of international standards"; (b) it is not submitted on behalf of the Respondent that any of the other Member States uses a more suitable (or as the Respondent would say, less unsuitable) bystander exposure model, or that any such model is even available for use by the Member States; (c) in these circumstances there is, unsurprisingly, no evidence that any of the other Member States decline to recognise under Article 10 authorisations of pesticides by the United Kingdom on the ground that Defra's current bystander model is so deficient that the United Kingdom's authorisation process does not comply with the "uniform principles" in Annex VI.

55. Local Effects
In this context, the "local effects" of exposure to pesticides, such as eye or skin irritation, are to be distinguished from the chronic and/or systemic effects of long-term exposure. There is not necessarily a clear divide between local and systemic effects. A systemic effect may be secondary to a local effect, e.g. if a substance causes skin irritation when it is splashed on to the skin, the irritation will be a local effect. If the substance is not washed off it may be absorbed into the body through the skin, and absorption in sufficient quantities may result in a systemic effect.

56. There was much discussion before us as to whether the local effects of exposure to pesticides were, or were not, within the scope of the Directive. Local effects – skin irritation and sensitisation and eye irritation – are referred to in Annex III to the Directive, and certain tests are prescribed. In that sense, local effects are "within the scope of the Directive". However, such a general proposition is of little assistance. The question needs to be more focussed. It is not whether local effects are "within the scope" of the Directive, but what, if anything, do the "uniform principles" in Annex VI require Member States to do about local effects, whether upon operators or residents, when authorising pesticides under the Directive?

57. Both Annex II and Annex III require their respective dossiers to contain sufficient information "on acute toxicity, irritation and sensitisation of the active substance". Various tests are prescribed: Oral, Percutaneous, Inhalation, Skin irritation, Eye irritation and Skin sensitisation. All of these tests are carried out on the active substance (Annex II) or the pesticide (Annex III) and must be carried out in accordance with the test methods prescribed in various Directives which are concerned to ensure a uniform approach to the classification, packaging and labelling of dangerous products (paragraphs 5.2 in Part A of Annex II and 7.1 in Annex III).

58. When estimating operator exposure, two estimations are made. The first estimate assumes that the operator is not using any personal protective equipment. Where appropriate, a second estimate is made incorporating the assumption that the operator will be using effective and readily available protective equipment, and taking account of any protective measures specified on the label (paragraph 7.2.1.1 Annex III).

59. These provisions are consistent with the advice in paragraph 2.10 of the Commission's draft "Guidance for the Setting and Application of Acceptable Operator Exposure Levels (AOELs)" cited in paragraph 51 of the judgment of Collins J., that, as a matter of general principle, No Observed Adverse Effect Levels ("NOAEL") for local effects are not considered relevant to setting an AOEL, and

that in general such effects should be addressed by hazard symbols, risks and safety phrases on the product label, and appropriate risk management such as suitable protective equipment. Collins J. was referred to an earlier draft of the guidance document. In the current draft guidance (revision 10) there appears to be some inconsistency between the advice in paragraph 2.10, which remains the same, and the advice in paragraph 1.7 that:

> "This document does not attempt to address the derivation of acceptable exposure levels for local effects (e.g. irritation and sensitisation) produced by exposure to plant protection products. For professional operators, it is envisaged that such effects will normally be addressed by classification and labelling and the use of appropriate personal protective equipment. However, the potential for acute local effects to occur in workers, amateur operators, bystanders and residents should be considered, for example if the spray dilution is classifiable as an irritant, and appropriate risk management measures taken. If local effects are produced in inhalation studies, these should be taken into account to ensure a systemic AOEL is adequately protective for the local effects."

60. However, the guidance does not prescribe how the potential for acute local effects should be considered. The introduction to the document explains that:

> "It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Annex II, III and VI of [the Directive]..."

61. The Respondent makes the point that while precautions such as hazard symbols, risks and safety phrases on labels, and protective clothing may well be sufficient to protect operatives, they are of no assistance to residents who are exposed to the effects of the spraying carried out by those operatives. Collins J. accepted that "bystanders cannot benefit from warnings or protective clothing" (paragraph 52 of the judgment). So do I, but the question is not whether residents, as well as operatives, should be given some form of protection against local effects, but what, if any, steps are Member States legally required to take under Annex VI?

62. Mr Fordham referred to paragraph 2 in Part A of Annex VI, which states that in evaluating applications and granting authorisations Members States shall ensure that the dossier complies with Annex III, taking into account the Annex II data concerning the active substance, and also:

> "(c) take into consideration other relevant technical or scientific information they reasonably possess with regard to the.... potentially adverse effects of the plant protection product, its components or its residues."

63. Paragraph 1 in Part B of Annex VI sets out the "General Principles" for evaluation. Having regard to current scientific and technical knowledge Member States "shall

evaluate the information referred to in Part A, point 2" (which includes the "other technical or scientific information" referred to in paragraph 2(c)) and:

> "(b) identify the hazards arising, assess their significance and make a judgment on the likely risks to humans.... "

Mr Fordham pointed out that the "Specific Principles" in Part B of Annex VI, none of which requires an assessment of the "local impact" of pesticides on residents, must be implemented by the Member States "without prejudice to the general principles" referred to above (see paragraph 2 in Part B).

64. I do not consider that it is possible to elevate these, very general, principles, or the advice in paragraph 1.7 of the Commission's draft guidance, into an obligation to evaluate the local effects upon residents of exposure to pesticides, and in all cases to take them into account at the authorisation stage in Annex VI. The obligation is limited to a requirement to take "relevant technical or scientific information" about local effects into consideration if such information is reasonably available. Defra does ensure that the dossier complies with Annex III and does take into account the Annex II data concerning the active substances. Although the Annex II and Annex III dossiers will include the results of the eye irritation and skin irritation and sensitisation tests, these tests will have been carried out either on the active substances or on the pesticide in its concentrated form, the form in which it will be handled by operators. The Annex III dossier will not contain the results of any such tests on the local effects of the diluted pesticide, in the form in which residents may be exposed to it.

65. The PIAP Reports

Paragraphs 1(c) in Part A and 1(b) in Part B of Annex VI require Defra to consider, and evaluate "other relevant technical or scientific information" and identify the hazards arising. Defra contends that it does consider and evaluate such material, in particular the PIAP reports (see paragraph 34(3) above). The Respondent accepts that the ACP considers such reports, but contends that Defra "does nothing about them".

66. There is no doubt that the ACP does consider "other relevant technical and scientific information", including the PIAP reports. The Report refers to the two papers produced by the Pesticides Safety Directorate ("PSD", at that time an executive agency of Defra, and since 1st April 2008 part of the HSE) for the ACP as part of its review of the bystander exposure model in 2003: see paragraphs 3.32-3.38 of the Report.

67. The PIAP process was criticised by the RCEP (see paragraph 2.85 of the Report) but the ACP does consider annual summaries of the PIAP Reports. In paragraphs 3.31 and 3.32 of the Commentary the ACP said:

> "3.31 A useful further check, therefore, on the adequacy of risk assessment comes from data on acute pesticide poisoning. Reporting of minor incidents to the enforcement authorities, as monitored by the Pesticide Incidents Appraisal Panel (PIAP), is known to be incomplete, and it is often difficult to determine

whether the illnesses reported have arisen from toxicity, through non-toxic effects of exposure, or coincidentally and unrelated to pesticides. More severe poisoning episodes, of sufficient severity to warrant hospital admission, should, however, be more reliably recorded. Hospital Episode Statistics data for England indicate that each year there are approximately 200 admissions to hospital nationally for accidental pesticide poisoning (ACP 16 (300/2003), and preliminary findings from a more detailed investigation of such admissions in adults aged 16-69 years, show that the health effects are usually not serious, and very rarely if ever arise from bystander exposure to agricultural pesticides. Exposures from mishaps in users (either at work or in the home), and from unsatisfactory storage, figure much more frequently. A similar pattern is apparent in follow-up enquiries about pesticide poisoning to the National Poisons Information Service (ACP 22 (315/2005), ACP11 (316 (2005)).

3.32 Overall, therefore, while there is a need for further empirical data to confirm the adequacy of the current approach to bystander risk assessment, there is no indication of a problem from the data that are currently available."

68. The Government's response to the RCEP's recommendation that PIAP should be replaced by a new system of national reporting and monitoring for ill health associated with pesticide spraying is contained in paragraphs 37 and 38 of Defra's Response:

"37. The Pesticide Incident Appraisal Panel (PIAP) contributes to the post-approval monitoring of pesticides by examining the evidence obtained by Health and Safety Executive inspectors investigating complaints of ill health allegedly arising from exposure to pesticides. PIAP's primary function is to identify trends in ill health that may be associated with pesticide usage. The Government recognises that PIAP was not developed to assess causality in individual cases.

38. The Government considers that any changes to PIAP, including the development of new mechanisms, will need to be integrated with any wider changes to the regulatory and policy structure for pesticides proposed as part of the implementation of the recommendations of the Hampton review *Reducing administrative burdens: effective inspection and enforcement.* The Government will await the outcome of discussions on these wider issues before considering any potential implementation of changes to PIAP."

69. Mr Fordham's submission that Defra "does nothing" about the PIAP Reports is, in reality, another manifestation of the Respondent's disagreement with ACP's conclusion in paragraph 3.32 of the Commentary that the other "technical and scientific information" that is currently available, which includes the PIAP Reports, does not indicate a problem with the current approach to bystander risk assessment. The real complaint is not that Defra and the ACP do not consider the PIAP Reports and other relevant information, but that, having considered such material they have not been persuaded that there is "solid evidence" which "while not resolving scientific uncertainty reasonably raises doubts" as to the safety of the pesticides which have been authorised under Defra's current approvals process. Whether there is evidence which reasonably raises such doubts, or whether the risks are "purely hypothetical...based on mere hypotheses which have not been scientifically confirmed" (see the test in paragraph 161 of The Kingdom of Sweden case) is pre-eminently a matter for Defra to decide, with the benefit of the ACP's expert scientific advice.

70. Mr Fordham also referred to Articles 4.5 and 4.6 which empower Member States to review authorisations at any time if there are "indications" that any of the requirements for authorisation are no longer satisfied, and require them to cancel an authorisation if it is "established" that those requirements are no longer satisfied. Since Defra would review an authorisation if it was persuaded that there were indications that the requirements for authorisation were no longer satisfied, and would cancel the authorisation if it concluded that the requirements were no longer satisfied, the Respondent's contention that the Appellant does not act in compliance with the Directive in this respect is, in reality, another way of putting her challenge to the Appellant's conclusions that there are no such indications, and that there is, therefore no basis for concluding that the requirements for authorisations generally (the claim is a generic one and does not relate to any specific authorisation) are no longer satisfied.

71. The other articles referred to by Mr Fordham, Articles 7 and 11, are of no assistance to the Respondent. Article 7 requires Member States when granting authorisations to require the holders to notify "the competent authority" of all new information on the potentially dangerous effects of any pesticide. The authorisations granted by Defra do include such a requirement. Article 11 provides that:

> "1. Where a Member State has valid reasons to consider that a product which it has authorized or is bound to authorize under Article 10 constitutes a risk to human or animal health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.
>
> 2. A decision shall be taken on the matter within three months in accordance with the procedure laid down in Article 19."

72. Mr Jay told us upon instructions that there had been occasions when the Appellant had exercised the powers conferred by Article 11 in respect of particular pesticides which had been authorised by other Member States and which Defra was bound to

authorise under Article 10, but which, in Defra's view, nevertheless constituted a risk to human health. While the Respondent considers that there are "valid reasons" to consider that the pesticides which have been authorised by Defra constitute such a risk, Defra, on the basis of the ACP's advice, does not agree, and for the reasons set out above, the Respondent has not established that there is a "manifest error" in its approach.

73. "Solid Evidence"

Collins J. said that he would not have been able to find in the Respondent's favour if the only matter she relied on in challenging the Appellant had been the fact that the Government had accepted the ACP's advice in preference to that of the RCEP (paragraph 39, Judgment). However, he said that that was not all that was relied upon:

> "It is not however all by any means. There is in my judgment solid evidence produced by the claimant that residents have suffered harm to their health (her own ill health is an example) or, at the very least, doubts have reasonably been raised as to the safety of pesticides under the regime which presently exists: see the *Sweden* case at paragraph 161. It is clear that the precautionary principle must apply." (paragraph 40, Judgment).

74. In paragraph 46 of the Judgment Collins J. referred to chronic long term illnesses and said:

> "I recognise that it is not easy to attribute a particular cause to many chronic illnesses and a view that a cause has been identified may be wrong. But there is evidence that some long term illnesses may be attributable to pesticide exposure."

75. He continued in paragraph 47:

> "But there is much more positive evidence that local effects are attributable to exposure. The dvd makes it clear that those effects do in many cases amount to more than merely transient and trifling harm. I appreciate that the dvds have been presented to and considered by the ACP and they have not changed their approach. Had they appreciated that the evidence was solid and that the conditions come within the scope of the Directive inasmuch as they constituted harm to human health, a different approach ought in my view to have been adopted. There has in my judgment been both a failure to have regard to material considerations and a failure to apply the Directive properly. It is in the context relevant to note that the view that local effects need not be taken into account, albeit apparently in the European Commission Guidance, cannot be justified. The reason for their exclusion is, it seems, because packet warnings can deal with them. But, as I have said, that cannot possibly help bystanders. In any event, there is sufficient material to

> raise a real doubt as to long term harm in some cases. They may be rare, but it is to be noted that in the *Sweden* case one study was regarded as sufficient to require paraquat to be removed from Annex I."

76. In my judgment, Collins J. in these passages was substituting his own evaluation of the available evidence for that of the Appellant. Whether the evidence does reasonably raise doubts as to the safety of those pesticides that have been authorised by Defra under the current approvals process, or whether it amounts to no more than "hypotheses that have not been scientifically confirmed" is, in the first instance, for Defra to decide, having taken advice from the ACP. While the Appellant's decisions in this respect are not immune from judicial review, the hurdle of "manifest error" in such a highly technical field is a formidable one: see paragraph 42 above. The Respondent is not able to surmount that hurdle.

77. Apart from the dvds, the PIAP reports and the Respondent's evidence about her own health, Collins J. did not identify the evidence which he found to be persuasive. He acknowledged that the dvds and the PIAP reports had been considered by the ACP. Indeed, with the possible exception of a letter dated 13th April 2004 from a Dr Myhill to the Respondent's GP relating to the Respondent's own health (which was served only after the hearing before Collins J. had concluded) all of the material relied on by Collins J. had been considered by both the RCEP in preparing the Report, and the ACP in preparing its Commentary on the Report.

78. I have already referred to the ACP's views, and in particular to its conclusion in paragraph 3.32 of the Commentary (paragraph 9 above). It did not accept that there was "solid evidence". In paragraph 4.31 of the Commentary, responding to a recommendation from the RCEP that there should be a system of surveillance operated by the Health Protection Agency, the ACP said:

> "4.31 However, while appropriate investigation is important in the clinical management of individual patients with suspected chronic pesticide toxicity, we think it unlikely that the registration of such cases would usefully contribute to the assessment of risks, since there is no valid method by which chronic diseases can be attributed to pesticide exposure in the individual case. At best, a reporting scheme for suspected chronic effects of pesticide exposure would provide an index of perceptions about risk in the medical profession and general public, and perhaps have some therapeutic value in responding to the needs of patients to have their concerns recognised." (emphasis added)

The ACP agreed that the PIAP system required improvement, but added:

> "We can see little scientific value, however, in a reporting scheme for illness that people believe is a chronic effect of exposure to pesticides, since it is rarely if ever possible to make a meaningful attribution to pesticides in the individual case. At best, such a system would provide information about the types of illness that people believe are an effect of pesticide

exposure, and about levels of concern in the community." (emphasis added) (6.17).

79. Having considered the evidence in some detail in the Report the RCEP did not go as far as Collins J. appears to have done in paragraphs 46 and 47 of his judgment. In paragraph 2.9 of the Report the RCEP said that "the evidence from the residents and bystanders visited identified a series of well defined acute symptoms immediately following pesticide spraying. These include upper and lower respiratory tract irritation, eye irritation, skin rashes and, in susceptible subjects asthma attacks." Other "less closely defined" acute symptoms were referred to, and in paragraph 2.9 the RCEP said that:

> "Residents and bystanders attributed a range of chronic health effects to crop spraying, some of which followed and some of which were unconnected with acute symptoms."
>
> In respect of chronic ill health the RCEP said this, in paragraph 2.65 of the Report:"
>
> "2.65 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 bystander pesticide exposure and chronic ill health. We find 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." (emphasis added)

80. The RCEP did not conclude that the evidence showed that local effects were attributable to exposure. It said in paragraph 6.4 of the Report that there was no dispute that some people who had been exposed to pesticides had become ill. The issue was causality on which the RCEP said:

> "On the evidence we have received we cannot draw firm conclusions on causality, but we are persuaded that it is possible that some cases of ill health could, on further investigation be shown to be due to complex effects following exposure to pesticides."

This conclusion is reflected in the guarded terms in which it dealt with the ill health effects attributed to pesticide exposure when dealing with the PIAP system.

Having criticised the deficiencies of the system, the RCEP said:

> "2.85 ... We believe that this system needs to be radically reformed, by the introduction of detailed clinical investigation, and extended to cover chronic cases. This is critical for an adequate understanding of the ill health effects attributed to pesticide exposure. To

> ascertain whether pesticides are indeed the cause of these adverse health effects it is important, not only that the numbers should be properly recorded through well-designed proactive surveillance methods, but also that a proactive investigative service should examine reported cases, where possible using modern laboratory methods such as imaging." (emphasis added)

81. Thus, in respect of both chronic and local effects the RCEP was not saying that they were caused by bystander exposure to pesticides, rather it was saying that the possibility could not be ruled out and that more research was required to ascertain whether pesticides were the cause of such effects. The RCEP's "Conclusions and Recommendations" in Chapter 6 of the Report included, in respect of health issues, the following paragraphs:

> "There is no dispute that some people who have been exposed to pesticides have become ill. The dispute has concerned the causality and underlying basis for these illnesses. On the evidence that we have received we cannot draw firm conclusions on causality. But we are persuaded that it is possible that some cases of ill health could, on further investigation, be shown to be due to complex effects following exposure to pesticides. (6.4)
>
> 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 find 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." (6.20)

82. The Government's response to the recommendation in paragraph 6.20 of the Report is contained in paragraphs 17 and 18 of Defra's Response:

> "In its conclusions the Royal Commission states that "*There is no dispute that some people who have been exposed to pesticides have become ill. The dispute has concerned the causality and underlying basis for these illnesses. On the evidence that we have received we cannot draw firm conclusions on causality.* The Government accepts that if a resident or bystander were to accidentally receive a high exposure to certain pesticides then some acute adverse effects might occur. One of the aims of the precautionary measures set out in the PPP Code is to avoid such circumstances occurring. The Government agrees with the Royal Commission that the evidence does not allow a firm conclusion to be drawn on

causality in relation to chronic ill health.

> The Government believes that being unable to rule out the possibility of a link cannot be considered a basis to support the recommendation of an urgent need for research into any potential chronic ill health effects from pesticide exposure of resident and bystanders. Similarly there is no scientific basis for additional precaution beyond the already precautionary approach currently adopted."

83. In paragraph 65 of his judgment Collins J. said that:

> "the medical tests carried out on the Claimant provide very powerful reasons for concluding that there has been the necessary cause and effect."

84. Although the letter from Dr Myhill dated 13th April 2004 was not served until after the hearing before Collins J. had concluded, in substance the information contained in the letter about certain tests on blood and fat samples taken from the Respondent was not new. The Respondent had referred to the results of the tests in paragraph 48 of her first witness statement. While it is not clear whether the letter dated 13th April 2004 was produced to the RCEP, Dr Myhill is listed in Appendix C to the Report as one of the individuals who either submitted evidence to, or provided information for, the purposes of the RCEP's study; and in paragraph 2.57 of her evidence to the RCEP the Respondent referred to Dr Myhill and said that she:

> "utilises fat biopsies to test for pesticide levels and to prove definite exposure in people suffering from suspected pesticide related ill health."

85. The RCEP considered the evidence relating to "Pesticide Spraying and Health" in detail in Chapter 2 of the Report. If it had concluded that Dr Myhill's views were persuasive, and if in particular it had concluded that there were "powerful reasons for concluding that there has been the necessary cause and effect", it would surely have said so.

86. For the sake of completeness, I should mention the fact that Mr Hamey, of the Chemicals Regulation Directorate (which was created on 1st April 2009 as a result of the merging of the PSD with another division which dealt with "biocides" within the HSE), makes it clear in his third Witness Statement dated 18th May 2009 that the Appellant takes issue with many aspects of Dr Myhill's letter dated 13th April 2004. In her sixth Witness Statement dated 5th June 2009 the Respondent set out in some detail her response to Mr Hamey's third Witness Statement.

87. The exhibits to the Respondent's sixth Witness Statement included a letter dated 29th May 2009 from Dr Myhill responding to some of the points made by Mr Hamey, and a Note dated 27th May 2009 from Professor Hooper, Professor Emeritus of Medicinal Chemistry at Sunderland University. Professor Hooper has:

> "No doubt that [the Respondent's] chronic ill health is due to her exposures to mixtures of agricultural pesticides of various

> classes, particularly OPs, carbamates and pyrethroids. There is a considerable body of scientific evidence to support her case."

88. I note, however, that Professor Hooper was also one of the individuals who submitted evidence to, or provided information for the purposes of, the RCEP's study. The references at the end of his Note dated 27th May 2009 all pre-date the commencement of the RCEP's study in 2004. A number of the references are concerned with the "Gulf War Syndrome", a topic that was specifically considered in Appendix I to the Report. One of the research papers referred to in the Note, by Mackness and Others, published in Biochemical and Biophysical Research Communications (2000) 276, is listed among the references to Appendix I in the Report.

89. In his submission to the RCEP Professor Hooper was not dealing with the Respondent's individual health, but if there was a consensus in the scientific community that there was "a considerable body of scientific evidence" to support the Respondent's case that her ill health, or the ill health of others was due to exposure to pesticides, then setting aside the ACP's views entirely, it is inconceivable that the RCEP would have expressed its conclusions in Chapters 2 and 6 of the Report in such guarded terms (paragraphs 77-80 above).

90. In its response to the Commentary the RCEP said in paragraph 12:

> "We appreciate the fact that the approach taken by the ACP is in line with approaches taken more widely in risk assessment in other areas such as food safety and at EU and international level. Nevertheless we remain concerned that these approaches underestimate the full range of variability in the population. We are also concerned that the two ten fold safety factors may be used to suggest that there is a degree of security in respect of weaknesses elsewhere in the risk assessment process such as the exposure assessment. We do not set out to criticise the ACP or suggest that UK practice is in anyway less rigorous that elsewhere. Indeed we recommend that the UK Government also presses the EU Commission to reassess its analysis in line with the recommendation of one of its own Committees in 2002. We note that the ACP supports our recommendation."

91. The Report, the Commentary and the RCEP's Response all make it clear that there is no consensus in the scientific community that there is "solid evidence" as found by Collins J. In Defra's response the Appellant did not accept that there was such evidence (paragraph 81 above). Collins J. was not entitled to substitute his own view for that of the Appellant, and in the absence of such a scientific consensus, had Collins J. applied the "manifest error" test, he would have been bound to conclude that there was no manifest error in the Appellant's approach to the issue of causality.

92. <u>"Serious Harm"</u>

I can deal quite shortly with the Respondent's second ground of challenge before Collins J. It is common ground that the question for the purposes of Article 4.1(b)

(iv) is not whether a pesticide has no serious harmful effect on human health, but whether it has no harmful effect. There is a clear distinction between "no harmful effect" in sub-paragraph 4.1 (b) (iv), and "no unacceptable effect", or "no unacceptable influence" on plants or the environment respectively, in sub-paragraphs 4. (b) (iii) and (v).

93. In "A Guide to Pesticide Regulation in the UK and the role of the Advisory Committee on Pesticides" ("the Guide") published by Defra and the HSE in 2005 it was said that the legislative framework had been designed with the aim that:

> "b) no-one should develop any serious illness through the use of pesticides" (emphasis added)."

The reference to "serious" illness was repeated in the section of the Guide dealing with "Reviews of pesticides that are already approved" which said that the aim of the regulatory process was:

> "that nobody should be made seriously ill through the use of a pesticide in an approved manner..."

94. Mr Norman Baker MP, the then Liberal Democrat Shadow Environment Secretary wrote to Defra on 4th January 2006 seeking clarification of what was said to be a "reconstruction" of the language used in the legislation by Professor Coggon:

> " In my view the word 'serious' appears incompatible with the precise and definite language used in both the EU Directive 91/414/EEC and the UK PPP Regulations 2005, regarding the unconditional degree of priority required to be given for the protection of human health. The UK legislation clearly states the Secretary of State shall not approve a plant protection product unless it has been satisfied that it **"has no harmful effect directly or indirectly on human or animal health..."**
>
> I would be grateful, therefore, for clarification as to whether Professor Coggon had the authorisation of any Minister prior to reconstructing and thus reinterpreting the language used in the legislation to include the word 'serious' and if you will now review the use of this word in the context referred to."

95. The reply dated 16th February 2006, from Lord Bach, the Minister for Sustainable Farming and Food said that:

> "You asked for clarification in relation to Miss Downs' first question concerning the interpretation of the language used in the legislation about the harmful effects of pesticides. I can confirm that no-one has "reconstructed" or "reinterpreted" the wording of this legislation. I believe that Professor Coggon the former Chairman of the ACP has, on several occasions, explained to Miss Downs that our interpretation of the legislation is that which has consistently been applied in the UK and throughout the European Community.

> As Professor Coggon has explained, in residents and bystanders a "serious" adverse effect is anything other than transient minor irritant symptoms (of the same sort that might be produced when visiting the local swimming pool). Discomfort associated with unpleasant odours would not be considered serious. In workers and operators a small risk of skin sensitisation may be considered acceptable.
>
> To reiterate; any symptom or health effect more serious than those described above would be classed as "serious". This is the interpretation adopted throughout the European Community.
>
> I trust that this matter has now been clarified to your, and Miss Downs' satisfaction."

96. In an article "Bystander Exposure: Does the Current Regulatory Approach Provide Adequate Protection?" Professor Coggon who, it should be remembered is a scientist not a legal draftsman, explained what he meant by "seriously ill":

> "A major aim of pesticide regulation is that no-one should be made seriously ill through toxic effects of pesticides when they are used in accordance with the conditions of their approval. Ideally, there would be no adverse effects whatsoever, but achieving this would lead to major inconsistencies with other areas of risk management. For example, it would be unreasonable to ban a product because it caused occasional skin sensitisation in operators, when occupational exposure to other, more potent skin sensitisers such as epoxy adhesives is permitted. Similarly, unpleasant smells and minor and transient eye irritation may be tolerated, as they are when produced by, for example, the occasional bonfire. Nevertheless, regulatory controls on pesticides are more stringent than for almost all other industrial products."

97. As Collins J. said:

> "the use of the adverb 'seriously' is unfortunate, but the examples being given are likely to be categorised as merely transient and trifling." (paragraph 48 of the judgment)

Before Collins J. both parties had accepted that any harm to human health which could properly be regarded as "more than merely transient or trifling" fell within a "harmful effect on human health" for the purposes of the Directive: see paragraph 24 of the judgment.

98. The question is not whether the advice in the Guide was wrong, it is whether, looking at the whole of the evidence, the Respondent has established that the Appellant was applying the wrong test when authorising the use of pesticides under the Directive. In

the light of the explanations from both Defra and Professor Coggon there is no substance in this ground of challenge, and it does not appear that it was accepted by Collins J., who said in paragraph 53 of the judgment:

> i. " As I have said, the word serious should not have been used. It suggests an erroneous approach. However although it should be removed from any guidance, if the approach is and has always been as Professor Coggon suggested in the article quoted in paragraph 48, it may not in itself have resulted in an erroneous decision. However, since the defendant accepts that harm will be material if more than merely trifling and transient, he must make his decisions on that basis."

99. Failure to accept the RCEP's recommendations

The Appellant asked the RCEP to undertake a "fresh and independent appraisal" of the scientific evidence on which the regulatory system was based: see the written Ministerial Statement reproduced in Appendix A to the Report (paragraph 5 above). Mr Fordham submitted that in these particular circumstances, where a Minister had requested an expert body to carry out an independent review, it would be Wednesbury unreasonable for that Minister to reject the conclusions of the expert body by merely asserting that he adhered to the views expressed by Government prior to the review. The Minister had to have "clear and compelling" reasons for departing from the recommendations of such a review, and in the present case the Appellant had no such reasons for not accepting the RCEP's recommendations in the Report.

100. During the course of his oral submissions Mr Fordham accepted that where there were differences of opinion between the RCEP and the ACP it could not be said that it was unreasonable for the Minister to prefer the views of the latter. However, he submitted that the unreasonableness of the Appellant's approach to the recommendations in the Report was demonstrated by the fact that in three respects the Appellant had refused to accept the RCEP's recommendations even though they were supported by the ACP. The three recommendations are concerned with (a) the imposition of statutory obligations in place of the current Code of Practice (the PPP Code, also referred to as the "Green Code"); (b) access by residents to farmers' and growers' records of spraying operations, and (c) giving residents prior notification of what substances are to be sprayed, where and when.

101. The RCEP's recommendations, in respect of these three matters, followed by the Government's response in each case, are set out in the following passages in Defra's response:

> *i.* "72. ***6.38 We believe that adherence to some of the recommended conditions under the Green Code [PPP Code] should become statutory duties. These include maximum wind speed, spraying practice as specified on the label, boom height and vehicle speed***
>
> 1. ***Further research on refining the resident and bystander exposure model should lead to***

recommendations for revised spraying conditions for all factors relevant to minimising exposure, and thus to a revision of the statutory obligations. (5.73-5.74)

73. The Code of Practice (PPP Code) for using plant protection products has a special position in law. As it is a statutory code, if a spray operator, be they a farmer or commercial contractor, follows the advice in the code they will be doing enough to keep within the law. They may also be able to work in a different way from the code so long as that way is equally as safe. A court would find someone guilty of a breach of pesticide law if they have not followed the code and cannot show, when asked, that they have still kept within the law. This potentially allows farmers to adapt their practice to local circumstances including the needs of local residents. It also means that farmers can adopt practices that go beyond the PPP Code, or which result in improved efficacy, for example using more dilute pesticide than recommended on the label, and therefore potentially reduce pesticide use overall.

74. The Government believes that the current statutory status of the PPP Code is sufficient and that making adherence to some of the recommended conditions statutory duties would not be beneficial. Doing so could lead to the reduction in some local best practice and potentially an increase in the level of risk associated with bystander and resident exposure.

75. The Government recognises that further research on refining the resident and bystander exposure model could lead to a greater understanding of the conditions and factors which minimise the potential for such exposure. The Government will keep the advice in the PPP Code under review both in the light of the Royal Commission's report and future research on resident and bystander exposure. If such research indicates that modification of the advice is required this will be considered along with the legal status of such advice."

ii. "109. ***6.51 We recommend that records of which pesticides, and when and where they have been used,***

should be directly available from the persons responsible for crop spraying upon request to any resident and bystander and to researchers investigating the health effects of resident and bystander exposure. (5.84)

110. In 2004, Alun Michael the then Minister for Rural Affairs and Local Environment Quality, made a commitment to introduce new legal measures to require farmers and growers to keep records of pesticides used on crops and to make those records available to the public via a third party. Since that time this commitment has been superseded by new European legislation (EC Regulation 852/2004 on the Hygiene of Foodstuffs, EC Regulation 183/2005 on the Hygiene of Feed for Livestock). Under this legislation farmers and spray operators are now legally required to keep a record of their spraying activity and these records can be made available through a suitable mechanism.

111. In the case of acute exposure where a resident or bystander has come into immediate contact with a pesticide as it is being sprayed, the Government believes it is highly unlikely that a spray operator would not be prepared to immediately inform the affected person or a doctor of what was being sprayed. The Government does not feel that a statutory requirement of disclosure is necessary for this situation as it is already covered in the PPP Code. The PPP Code states that "*If a [spray operator] or people they are working with or near feel unwell as result of being exposed to pesticides, they should think about getting medical attention (depending on the nature and severity of the symptoms)*" it further recommends that "*information on the pesticide involved, labels, data sheets and possible cause of contamination should be sent with the patient*". Government will review the wording of the PPP Code to determine whether this advice needs further clarification for the specific context of acute exposure of a resident or bystander.

112. More generally the Government agrees that residents and bystanders concerned about both acute and longer term chronic exposure should have access to information relating to pesticide use. The Government believes that most farmers would be willing to engage in a dialogue with residents, to address their concerns and provide them with appropriate information if requested, and that a statutory requirement is not necessary or appropriate. The Government is not aware

of an existing scheme where one individual can demand this type of information directly from another and they are required by law to supply it.

113. The Government does recognise that there may be circumstances where such a dialogue is not appropriate or possible and that in these cases the use of a third party is most appropriate. Such a mechanism would allow records to be requested, on a case-by-case basis, and supplied in an appropriate format and timescale to meet the requirements of both the farmer and the requester. The availability of a third party will also help prevent vexatious requests for information.

114. The Government will consider a pilot approach using a central bureau, to accept inquiries and gather data from farmers. Information would be requested on a case-by-case basis in order to minimise the overall burden. The level of demand for such information and, therefore, the burden which would potentially be placed upon farmers and spray operators is not known. A pilot approach would allow an accurate assessment of the level of demand and the potential administrative burden as well as the opportunity to explore some of the practical issues before any decision is made on a long-term approach."

iii. "115. *6.52* ***We recommend that the residents living next to fields that are to be sprayed be given prior notification of what substances are to be sprayed, where and when. The results of the pilot study in this area announced by the government should be treated as an exercise to determine how best to provide information, not as an opportunity to re-examine the principle of doing so, which should be accepted (5.79).***

116. The Government recognises that notification can assist residents to make informed decisions regarding their behaviour in relation to pesticide spraying, should they wish to do so.

117. The Government considers that where a resident expresses concern about a farmer's use of pesticides it is good practice to give information about the pesticide and the reason for using it. It is also good practice to tell people who occupy land, premises or houses close to the area being sprayed. This is reflected in the guidance within the PPP Code.

118. A pilot study on prior notification was

announced in 2004 by Alun Michael the then Minister for Rural Affairs and Local Environment Quality. The results of this study indicated that when residents' awareness had been raised through an introductory letter 75% expressed an interest in notification of spraying and that this dropped to 8% when some action was required on their part, for example a phone call, to obtain such information. Based on these findings there is no economic justification for requiring all adjacent residents to be notified in advance of all spraying events relative to a more targeted local approach. Provision of information does not guarantee any precautionary action will be taken by the recipient, Government would need to take other measures to ensure any health risks were addressed and therefore, the need for full notification can not be justified as a protective measure.

119. Application of pesticides in accordance with best practice and greatest efficacy requires quite specific weather conditions which can change rapidly on a day-to-day or even an hour by hour basis meaning that planned spraying is often cancelled or the decision to spray is made at the last minute. If a resident is notified in advance of spraying there is a risk that they may decide to take action as a result of this notification but that the spraying itself may be cancelled. This could lead to residents taking action on many more occasions than necessary. Similarly having made the effort to notify residents there is a risk that a farmer may feel constrained to spray in less than optimum conditions reducing the efficacy of the pesticide and potentially needing to increase the overall amount of pesticides used.

120. The Government believes that the above situations are best addressed through dialogue between the farmer and a resident so that both parties can understand the implications of notification, can consider alternative approaches which may satisfy the resident's concerns and if the resident would still like to be notified identify the most suitable means and timing of doing this.

121. The Government believes that making prior notification to all residents of every spraying event a statutory requirement would be highly bureaucratic and potentially reduce the ability of farmers to engage in such local best practice. The Government is committed to working with the various organisations representing the full range of stakeholders to identify how greater

> dialogue between farmers and residents can be encouraged and to develop ways in which farmers can be supported in providing information to residents. We will also examine the language in the PPP Code to determine if this can be amended to further encourage such local best practice."

102. I have set out the Government's response to these recommendations in full because it is clear that the Appellant gave a very full and detailed explanation as to why the three recommendations were not accepted. The Respondent's submission that the reasons given by the Appellant are not "clear and compelling" is, in reality, no more than an expression of her disagreement with those reasons. In each case, the Green Code, access to information, and prior notification, the key question was whether the issue was better dealt with by way of "good practice" as set out in the Code of Practice or by the imposition of statutory obligations.

103. Statutory Codes of Practice are found in many administrative contexts: Social Services, Mental Health, Homelessness etc. Whether a particular provision or provisions should be included in primary or delegated legislation, in a Statutory Code of Practice, or in non-statutory policy guidance, is pre-eminently a matter of political judgment. The more usual criticism of Governments is that they seek to persuade Parliament to enact too much, not too little, primary legislation, and that they make far too many, rather than too few, regulations under delegated legislation. The Respondent vigorously disagrees with the Government's view that the imposition of statutory duties in these three respects would not be appropriate, but that is a very far cry from establishing Wednesbury unreasonableness, however intensive the process of judicial review.

104. Article 8

Collins J. dealt briefly with this aspect of the Respondent's case because he considered that it added nothing to her claim: either the Appellant's approach was in compliance with the Directive, in which case any interference with the Respondent's Article 8 rights would be in accordance with the law; or if the Appellant's approach was not in compliance with Article 8, reliance on the Article was not needed because the Respondent had a domestic remedy in respect of the Appellant's failure to comply with the Directive: (see paragraph 67 of the judgment). Given Collins J.'s view that there was a failure to comply with the Directive his conclusion that Article 8 added nothing to the claim is readily understandable.

105. If the Appellant's approach does comply with the Directive, is the Respondent nevertheless entitled to succeed on her Article 8 claim?
It is common ground that:

i. "severe environmental pollution may affect individuals' well being and prevent them from enjoying their homes in such a way as to affect their private and family life adversely, without, however, seriously endangering their health." Lopez Ostra v Spain 20 EHRR 277, paragraph 51.

b. However, in that case, as in Fadeyeva v Russia (2007) 45 EHRR 10 it had been established that (a) the environmental pollution had had a severe impact on the complainant's quality of life; and (b) the responsible authorities had failed to take appropriate legal steps to deal with the pollution. In Guerra v Italy 26 EHRR 357:

   i. "it was not disputed that the inhabitants of Macedonia were at risk from the factory in question and that the state authorities had in their possession information which would have enabled the inhabitants to assess this risk and take steps to avert it": see McGinley and Egan v United Kingdom 27 EHRR 1, paragraph 99.

c. The complainants in McGinley, who had been stationed on or near Christmas Island at the time of nuclear tests there in 1958, sought access to documents in the Government's possession relating to the tests. The ECtHR held that in these circumstances there was a positive obligation under Article 8 to disclose the documents:

   i. "Where a Government engages in hazardous activities, such as those in issue in the present case, which might have hidden adverse consequences on the health of those involved in such activities, respect for private and family life under Article 8 requires that an effective and accessible procedure be established which enables such persons to seek all relevant and appropriate information." (101)

106. Mr Fordham relied upon the Guerra and McGinley decisions in support of his submission that there was a failure to comply with Article 8 because, in the absence of a statutory entitlement to access to spraying records and to prior notice of spraying the Respondent was unable to assess the risks and to take steps to avert them. However, McGinley is clearly distinguishable because (a) the activity in question, the spraying of pesticides, is undertaken by third parties, not the Government; (b) there is a dispute as to whether that activity, if it is carried out in accordance with the uniform principles in the Directive, is hazardous; and (c) the records are held by, and prior notice would have to be given by, third parties, not the Government. In Guerra, while the factory was not operated by the State, there was no dispute: (a) that it was hazardous (in that it placed certain inhabitants of Macedonia at risk); and (b) that the state authorities had the relevant information in their possession.

107. Even though the state authorities in Lopez Ostra and Fadeyeva had not complied with, or had failed to enforce, the relevant legal provisions dealing with the pollution in those cases, I would accept Mr Fordham's submission that the mere fact of the Appellant's compliance with the Directive would not necessarily be a sufficient answer to the Respondent's Article 8 claim. It is possible to envisage circumstances in which severe environmental pollution might infringe on individual complainants' Article 8 rights even though the state authorities had complied with all relevant legal requirements. If the pollution was not caused directly by the state, it would have to be demonstrated that there was a failure properly to regulate the third party responsible for the pollution. Whoever is responsible for the activity that is complained of, the mere possibility of

harm to the complainant is not sufficient for the purposes of Article 8. In Asselbourg v Luxembourg (2912/95) (Dec) June 29, 1999, the applicants complained of a violation of their Article 8 rights as a result of the environmental impact of a steelworks. The ECtHR considered:

> i. "that the mere mention of the pollution risks inherent in the production of steel from scrap iron is not enough to justify the applicants' assertion that they are the victims of a violation of the Convention. They must be able to assert, arguably and in a detailed manner, that for lack of adequate precautions taken by the authorities the degree of probability of the occurrence of damage is such that it can be considered to constitute a violation, on condition that the consequences of the act complained of are not too remote."

b. The Court rejected the application as inadmissible.

108. The Respondent genuinely believes that her own, and her family's health problems have been caused by their exposure to pesticide spraying. However, that is not enough for the purposes of her Article 8 claim. In the absence of evidence to support an argument that there is a sufficient degree of probability of a causal link between the pesticide spraying and her health problems the Respondent is not able to establish that there has been a breach of Article 8 (see "Solid Evidence" above).

109. I realise that, for the purpose of deciding whether or not there was compliance with the Directive, the question was not whether this Court considered that there was "solid evidence", but whether the Appellant was in manifest error in concluding that there was not such evidence. On the premise that in an Article 8 case the Court is entitled to form its own view as to whether, by reason of severe environmental pollution, there has been an interference with the individual's right to respect for his private and family life, home and correspondence, under Article 8.1, I can see no evidential basis for going further than the RCEP's conclusions on causality in respect of both chronic illnesses and local effects. While the possibility that some or all of the Respondent's medical conditions may be due to pesticide spraying cannot be ruled out, that possibility is not a sufficient foundation for an Article 8 claim. Moreover, even if the probability of a causal link had been established in respect of certain local effects, such as skin or eye irritation, it must be questionable whether they would fall within the description of "severe environmental pollution" in the Lopez Ostra and Guerra decisions.

110. I realise that the Respondent's concerns for the purposes of Article 8 are not limited to the health problems of herself and her family. She complains of the effect of pesticide spraying on the quality of her home life generally. The spray drifting over her garden, the noxious fumes of some of the sprays, the need to keep windows shut in the summer, etc. These general effects are described in great detail, principally in her first witness statement and the first dvd.

111. However, if causality is not sufficiently established in respect of the medical effects of spraying, I do not consider that these general effects on the Respondent's family fall within the ECtHR's description of "severe environmental pollution". In saying this, I do not intend to minimise the problems experienced by the Respondent, but she has

made her claim as an individual, not in a representative capacity. In Lopez Ostra and Guerra and Fadeyera the pollution came from a particular source and affected a wide area containing a considerable number of people. It was therefore entirely reasonable to expect the state authorities to have taken action to prevent, or at least minimise, the widespread pollution from that particular source.

112. There is no doubt that some, the Respondent would say very many, individuals are adversely affected by pesticide spraying: spray drifts across their gardens forcing them to close their windows etc. (see the dvds). The fact that a particular farmer or grower sprays pesticides on his fields or orchards in such a manner as to cause a nuisance to his neighbours does not mean that the state authority is in breach of its obligations under Article 8. Where spray drift does cause damage or nuisance, e.g. by harming plants or animals on adjoining land, or by reason of fumes etc., the legal system does afford a remedy to those individuals who are adversely affected. Just as the obligation under Article 2 of the Convention to protect life does not impose an obligation on Governments to guarantee the safety of their citizens, but merely requires them to put in place an effective criminal justice system; so Article 8 does not impose an obligation on the Government to guarantee that no individual's enjoyment of his private and family life, or his home will be disturbed by the activities of third parties. The Government's obligation in respect of pesticides is to put in place an effective regulatory framework. That it has done: the Directive is such a framework, and Defra's current regulatory process is in accordance with the Directive. However effective the framework, particular cases of nuisance or other harm may occur. If they do, the legal system provides redress for the individuals concerned.

113. The extent to which, and the means by which, potentially harmful effects in the environmental field should be regulated by the state was considered by the Grand Chamber of the ECJ in Hatton v United Kingdom (2003) 37 EHRR 28. The case was concerned with the night flying regime at Heathrow. Having stated that an issue may arise under Article 8 "where an individual is directly and seriously affected by noise or other pollution (paragraph 96), the Court said:

i. "97. At the same time, the Court reiterates the fundamentally subsidiary role of the Convention. The national authorities have direct democratic legitimation and are, as the Court has held on many occasions, in principle better placed than an international court to evaluate local needs and conditions. In matters of general policy, on which opinions within a democratic society may reasonably differ widely, the role of the domestic policy maker should be given special weight.

98. Article 8 may apply in environmental cases whether the pollution is directly caused by the State or whether State responsibility arises from the failure properly to regulate private industry. Whether the case is analysed in terms of a positive duty on the State to take reasonable and appropriate measures to secure the applicants' rights under para.1 of Art.8 or in terms of an interference by a public authority to be justified in

> accordance with para.2, the applicable principles are broadly similar. In both contexts regard must be had to the fair balance that has to be struck between the competing interests of the individual and of the community as a whole; and in both contexts the State enjoys a certain margin of appreciation in determining the steps to be taken to ensure compliance with the Convention. Furthermore, even in relation to the positive obligations flowing from the first paragraph of Art.8, in striking the required balance the aims mentioned in the second paragraph may be of a certain relevance.
>
> 99. The Court considers that in a case such as the present, involving State decisions affecting environmental issues, there are two aspects to the inquiry which may be carried out by the Court. First, the Court may assess the substantive merits of the Government's decision, to ensure that it is compatible with Art.8. Secondly, it may scrutinise the decision-making process to ensure that due weight has been accorded to the interests of the individual.
>
> 100. In relation to the substantive aspect, the Court has held that the State must be allowed a wide margin of appreciation. In *Powell and Rayner*, for example, it asserted that it was "certainly not for the Commission or the Court to substitute for the assessment of the national authorities any other assessment of what might be the best policy in this difficult social and technical sphere", namely the regulation of excessive aircraft noise and the means of redress to be provided to the individual within the domestic legal system. The Court continued that "this is an area where the Contracting States are to be recognised as enjoying a wide margin of appreciation"."

114. The regulatory framework for pesticides undoubtedly falls within a "difficult social and technical sphere" in which a balance must be struck between "the competing interests of the individual and of the community as a whole". The Appellant was entitled to conclude that that balance was struck by compliance with the terms of the Directive which ensures, through the application by all Member States of the uniform principles in Annex VI, that priority is given to the protection of human health. For these reasons the Respondent's Article 8 claim must fail.

115. Conclusion

I would allow the appeal.

116. Lord Justice Keene

I agree.

117. Lady Justice Arden

I also agree.