

Freedom of Information Act 2000 (Section 50) Environmental Information Regulations 2004

Decision Notice

Date: 10 December 2009

Public Authority: Veterinary Medicines Directorate
(an executive agency of the Department for Environment,
Food and Rural Affairs)

Address: Nobel House
17 Smith Square
London, SW1P 3JR

Complainant: Anglers Conservation Association

Address: Eastwood House
6, Rainbow Street
Leominster
Herefordshire, HR6 8DQ

Summary Decision

The complainant, on 14 October 2005, requested from the Veterinary Medicines Directorate ("the VMD") copies of the Environmental Risk Assessments carried out by the VMD as part of the marketing authorisation process for cypermethrin sheep dips. The Commissioner is satisfied that the information which was withheld from disclosure by the VMD relates to information on emissions. The Commissioner's decision is that VMD was not entitled to refuse to provide the withheld information on the basis that it was exempt under regulations 12(5)(e), 12(5)(c) and 12(4)(e) of the EIR. The Commissioner is satisfied that some of the withheld information was exempt under regulation 13 of the EIR but that other information was wrongly withheld under this exemption.

The Commissioner's Role

1. The Environmental Information Regulations (EIR) were made on 21 December 2004, pursuant to the EU Directive on Public Access to Environmental Information (Council Directive 2003/4/EC). Regulation 18 provides that the EIR shall be enforced by the Information Commissioner (the "Commissioner"). In effect, the enforcement provisions of Part 4 of the Freedom of Information Act 2000 (the "Act") are imported into the EIR.
2. This Notice sets out the Commissioner's decision in respect of the complainant's request of 14 October 2005.

Background

3. Cypermethrin is a synthetic pyrethroid, that is, a synthetic chemical compound, used as an insecticide and indicated for use against sheep scab and the treatment of ticks and blowfly. A number of other products are authorised for some or all of these indications. These include three organophosphorous sheep dips for treatment of all sheep ectoparasites, eleven injectable products for the treatment of sheep scab and one dip and five pour on products for the treatment of ticks and blowfly.¹
4. In July 2005 the Environment Agency (the EA) presented a report to the Veterinary Medicines Directorate (the VMD) on incidents of sheep dip pollution in Wales. Between January 2004 and August 2005 the EA had investigated thirty two sheep dip incidents causing major or significant ecosystem damage. The twelve most serious of these incidents arose from routine use of cypermethrin dips.²
5. Veterinary medicinal products may not be placed on the market unless a marketing authorisation has been granted.³
6. As part of the process of application for marketing authorisation veterinary medicinal products are subject to environmental risk assessment (ERA) by the VMD.
7. On 22 February 2006, following advice from the VMD, the Minister for Environment, Food and Rural Affairs suspended the marketing authorisations for three sheep dip products which contain cypermethrin as the active ingredient.⁴
8. In March 2006 the VMD issued the following statement:

“Following evidence that the use of cypermethrin sheep dips is causing environmental pollution in watercourses, ministers have decided to suspend their marketing authorisations. The suspensions will continue while the manufacturers provide further assessment of the environmental risks presented by these products and make recommendations for risk management strategies to reduce the risk to the environment. Once the VMD has received this information we will assess whether the additional controls proposed will enable farmers to use these products in a manner that is acceptable for the environment. The Stakeholder Group that the VMD and the Environment Agency jointly set up will consider the proposed controls.”⁵

¹ PQ 3885 The Duke of Montrose 14 February 2006 (HL4473)

² HC Deb 14 March 2006 cc2903-4 W

³ At the time of the request, under regulation 3 of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (as amended); at the time of writing, under regulation 4 of the Veterinary Medicines Regulations 2008; under regulation 4 of the Veterinary Medicines Regulations 2009 which come into force on 12 October 2009.

⁴ <http://www.vmd.gov.uk/General/sheepdip/suspension.htm>

⁵ <http://www.vmd.gov.uk/General/Sheepdip/statement.pdf>

9. Suspension of the cypermethrin sheep dip marketing authorisations remains in place as the Government is not satisfied that the cypermethrin sheep dip products can be used without presenting a significant risk of polluting the environment.
10. The decision on the future of the cypermethrin sheep dips will be based on the evidence received from research projects jointly funded by the VMD and the EA, the Pollution Reduction Plan⁶, the manufacturers and other stakeholders. No timescale has been set for the completion of this process.

The Request

11. The complainant's request was made to the VMD on 14 October 2005. The Commissioner notes that the VMD is an executive agency of the Department for Environment, Food and Rural Affairs (Defra), responsible to Defra and acting on behalf of Defra in this matter. For ease of reference the public authority shall be referred to as the VMD in this Decision Notice.
12. The complainant wrote:

"I would be grateful if you would indicate whether the ERAs as detailed in [the VMD] presentation are available to me under the Freedom of Information Act, or the Environmental Information Regulations. If so, I would be grateful for copies of the same and, of course, if not would be happy to receive your reasoning why such documents may not be available to me."
13. The VMD wrote to the complainant on 25 October 2005 advising:

"If you wish to see a copy of the environmental risk assessments prepared as part of this process you should make an application under the Freedom of Information Act or Environmental Information Regulations."
14. The complainant responded to VMD on 27 October 2005:

"...the request made in my letter of 14 October 2005 was indeed made under the Freedom of Information Act and/or Environmental Information Regulations and I would be grateful if you could please treat the letter of 14 October 2005 as that request as it clearly states, "I would be grateful for copies of the same"."
15. The VMD replied to the complainant on 4 November 2005 stating that it hoped to provide the complainant with a response by 12 December 2005.
16. The VMD wrote again to the complainant on 12 December 2005 stating that it was unable to provide a response to the request of 14 October 2005 as it was *"still consulting on this issue."* This letter crossed with a request from the complainant dated 15 December 2005 requesting the VMD's full response.

⁶ <http://www.vmd.gov.uk/General/Sheepdip/PRP.pdf>

17. On 21 December 2005 the VMD advised that it required further time to “consult the companies involved.”
18. On 4 January 2006 the complainant asked the VMD to “point out under what statute or regulatory instrument you believe you are entitled to consult third parties as to an information request made ...on 14 October 2005.”
19. The VMD returned to the complainant on 10 January 2006 referring to paragraphs 40 – 45 of the Code of Practice under regulation 16 of the EIR⁷ on consultation with third parties and confirming that consultees do not have a veto on disclosure.
20. On 20 January 2006 the VMD wrote to the complainant advising that its consultations had raised significant and complex public interest issues and that the VMD would be unable to provide the complainant with a response to his request of 14 October 2005 until 17 February 2006.
21. On 23 January 2006 the complaint wrote to the VMD asking that the VMD consider that letter a formal complaint over the conduct of the VMD in respect of this request.
22. On 13 February 2006 the VMD provided the complainant with details of the outcome of its review of its response to the complainant’s request for information. This review was carried out in response to the complainant’s formal complaint of 23 January 2006. The VMD stated that it was satisfied that the request had been handled correctly.
23. On 17 February 2006 the VMD wrote to the complainant in response to his request for information of 14 October 2005. The VMD stated that there were three sheep dip products on the market containing cypermethrin. These are identified by the VMD as Ecofleece, Robust and Auriplak.
24. The VMD advised that Auriplak is based on an ‘informed consent’ application with Ecofleece as the parent holder of the marketing authorisation and so a separate ERA was not necessary for Auriplak.
25. The VMD provided copies of the ERAs for Ecofleece and Robust. However, information had been redacted from these documents.
26. The VMD advised that the withheld information fell under the exception in regulation 12(5)(d) of the EIR (the confidentiality of the proceedings of a public authority where such confidentiality is provided by law) and some of the information fell under the exception under regulation 12(5)(e) of the EIR (commercial confidentiality).

⁷ SI 2004 No3391 - Code of Practice on the discharge of the obligations by Public Authorities under the Environmental Information Regulations 2004. Issued under Regulation 16 of the Environmental Information Regulations 2004.

27. The VMD advised that it recognised the strong public interest in having access to information about the impact of approved products on the environment. The VMD stated its view that the public interest was met by the release of the “*substantial amount of data and comment*” that it was releasing to the complainant.
28. The VMD also stated that it considered that the information on which the ERAs were based was supplied to it by the respective companies on the basis of a clear understanding that it would be treated in confidence.
29. The VMD referred to regulation 14 of the Marketing Authorisation for Veterinary Medicinal Products Regulations 1994 (regulation 14) which specifically prohibited the release of such information. The VMD acknowledged that this provision had been repealed but confirmed that it felt that there was an expectation of confidence which had to be considered in weighing the public interest.⁸
30. The Commissioner notes that Regulation 14 was in force at the time of the creation of the documents of which the withheld information is comprised, however the provision was repealed following consultation by the VMD in preparation for the full implementation of the Freedom of Information Act. The majority of consultees supported the revocation of regulation 14 upon the implementation of the Act.⁹
31. Further, the VMD advised the complainant that certain of the withheld information related to such matters as product formulation and as such disclosure would cause commercial harm to the companies concerned. In view of this the VMD considered that the harm likely to arise from releasing this information outweighs the public interest in disclosure.
32. The VMD advised that the information provided to the complainant continued to be covered by the Copyright, Designs and Patents Act 1988.
33. On 7 March 2006 the complainant wrote to the VMD making representations and requesting a review of the VMD’s decision. The complainant also asked what information had been redacted under which of the exceptions referred to in its letter of 17 February 2006.
34. The complainant also requested copies of certain documents referred to within the information provided by the VMD and requested an explanation of some of the content of the information provided by the VMD.
35. The VMD and the complainant continued in correspondence regarding the disclosure of information regarding the authorisation of cypermethrin products and on 28 June 2006 the VMD wrote to the complainant setting out the result of

⁸ Regulation 14 of the Marketing Authorisation for Veterinary Medicinal Products Regulations 1994 stated: “*Except in the performance of his duty, no person shall disclose—*

(a) any information in respect of any manufacturing process or trade secret obtained by him in premises which he has entered by virtue of these Regulations, or

(b) any information obtained by him or furnished to him in pursuance of these Regulations.”

This regulation was repealed by the Marketing Authorisations for Veterinary Medicinal Products (Revocation of Confidentiality Provision) Regulations 2004

⁹ Explanatory memorandum to the Marketing Authorisations for Veterinary Medicinal Products (Revocation of Confidentiality Provision) Regulations 2004- www.opsi.gov.uk/si/em2004/uksiem_20043193_en.pdf

its review of its application of the exceptions. The VMD provided a detailed analysis of its application of the exceptions to the withheld information and now sought to rely on the exceptions under regulations 12(4)(e), 12(5)(e) and 13 of the EIR.

36. The Commissioner is satisfied that this letter of 28 June 2006 represents the VMD's reconsideration of its decision as set out in its letter of 17 February 2006.

The Investigation

Scope of the case

37. The complainant wrote to the Commissioner on 11 October 2006 requesting that he investigate the VMD's handling of the complainant's request of 14 October 2005. The Commissioner accepted the complainant's request as a valid complaint under section 50 of the Act and has considered the conduct of this matter by the VMD in response to the complainant's request for information and its decision in relation to that recorded information relevant to the request.

38. The complainant identified the scope of his complaint as follow:

"The massive and repeat delays in breach of the EIR in responding the ACA's information request of 14th October 2005 and the subsequent decision of the VMD's own internal review dated 13th February 2006...is the first element of the complaint now brought to the ICO.

The second element of this complaint to the ICO concerns the application by the VMD of redactions under the exceptions provided for by the EIR in relation to all the information so far disclosed by the VMD ..."

39. Accordingly, the Commissioner has identified as the subject information of this complaint, that information which forms part of the ERAs prepared as part of application for marketing authorisations for sheep dip products containing synthetic pyrethroids such as cypermethrin which was not disclosed to the complainant in response to its request of 14 October 2005 (hereinafter 'the withheld information').
40. In his request for an investigation the complainant assisted the Commissioner in his investigation by providing detailed and considered submissions in support of his position that the information should properly have been disclosed by the VMD.

Chronology

41. The Commissioner wrote to the VMD on 17 December 2007 requesting a copy of the withheld information.
42. On 28 January 2008 the VMD provided the Commissioner with a copy of the withheld information.
43. On 31 January 2008 the Commissioner requested that the VMD provide the Commissioner with its full submissions in support of its decision to withhold the information, requesting that the VMD explain why each element of the information was considered to be excepted under the EIR and, where the qualified exceptions were relied upon, the VMD's view of the balance of the public interest.
44. The VMD responded to the Commissioner on 11 March 2008 providing details of its consideration of the application of the exceptions. The VMD confirmed that it sought to rely upon the exceptions under regulations 12(5)(e), 12(5)(c), 12(4)(e) and 13 of the EIR. The VMD also detailed its consideration of the public interest in maintaining these exceptions and the public interest in disclosing the information. The VMD advised that it considered that, in all the circumstances of the case, the public interest in maintaining the exceptions applied, outweighed the public interest in disclosure of the information.
45. Following discussions between the Commissioner and the VMD, on 8 April 2009 the VMD advised the Commissioner that it considered that certain aspects of the withheld information to which it had previously applied the exception under regulation 12(5)(e) of the EIR (commercial confidentiality) also fell under the exception under 12(5)(c) of the EIR (intellectual property rights).
46. The Commissioner has considered the withheld information and the submissions of the VMD and of the complainant.

Analysis

Environmental Information

47. The Commissioner is satisfied that all of the withheld information is environmental information and falls to be considered under the EIR for the following reasons.
48. Section 39 of the Act states that information is exempt information if the public authority holding it is obliged, by regulations under section 74 of the Act, to make the information available to the public in accordance with those regulations or would be so obliged but for any exemption under those regulations. The regulations under section 74 of the Act are the EIR. Information falls to be considered under the EIR if that information is environmental information. Environmental information is defined in regulation 2 of the EIR.

49. Regulation 2 of the EIR states:

“environmental information” has the same meaning as in Article 2(1) of the Directive, namely any information in written, visual, aural, electronic or any other material form on –

(a) the state of the elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites including wetlands, coastal and marine areas, biological diversity and its components, including genetically modified organisms, and the interaction among these elements;

(b) factors, such as substances, energy, noise, radiation or waste, including radioactive waste, emissions, discharges and other releases into the environment, affecting or likely to affect the elements of the environment referred to in (a);

(c) measures (including administrative measures), such as policies, legislation, plans, programmes, environmental agreements, and activities affecting or likely to affect the elements and factors referred to in (a) and (b) as well as measures or activities designed to protect those elements;

(d) reports on the implementation of environmental legislation;

(e) cost-benefit and other economic analyses and assumptions used within the framework of the measures and activities referred to in (c) ; and

(f) the state of human health and safety, including the contamination of the food chain, where relevant, conditions of human life, cultural sites and built structures inasmuch as they are or may be affected by the state of elements of the environment referred to in (b) and (c);

50. The Commissioner has considered the withheld information and is satisfied that the withheld information is environmental information as defined by regulation 2 of the EIR.

51. The Commissioner is satisfied that the withheld information is environmental information under regulation 2(1)(a) of the EIR, in that it is information on the state of the elements of the environment such as water, soil, land and biological diversity and its components. This is because the information concerns the regulation, use, and nature of cypermethrin sheep dip and its actual and potential environmental impact, as described at paragraphs 3 - 6 above.

52. The Commissioner is also satisfied that the withheld information is environmental information under regulation 2(1)(b) of the EIR, in that it is information on factors, such as substances, emissions, discharges or other releases into the environment, affecting or likely to affect the elements of the environment referred to in regulation 2(1)(a) of the EIR.

53. Further, the Commissioner is satisfied that the withheld information is environmental information under regulation 2(1)(c) of the EIR, in that it is information on measures and activities affecting or likely to affect the elements and factors referred to in regulations 2(1)(a) and (b) of the EIR.

Exceptions

54. Regulation 12(1) of the EIR states that a public authority may refuse to disclose requested environmental information if an exception to disclosure under regulations 12(4) or 12(5) is engaged and, in all the circumstances of the case, the public interest in maintaining the exception outweighs the public interest in disclosing the information.
55. Regulation 12(2) of the EIR requires that a public authority apply a presumption in favour of disclosure.
56. Regulation 12(9) of the EIR states that, to the extent that the information to be disclosed relates to information on emissions, a public authority shall not be entitled to refuse to disclose that information under an exception referred to in paragraphs 12(5)(d) to 12(5)(g).

Regulation 12(9) - Emissions

57. The Commissioner has considered whether the withheld information relates to information on emissions.
58. The withheld information is comprised of that information redacted from the requested ERAs for sheep dip products containing the synthetic pyrethroid, cypermethrin.
59. Following dipping of sheep in cypermethrin sheep dip, residues of the chemical remain in the dipped sheep's fleece and may enter the wider environment through drips, sheep walking through watercourses, through product misuse, and the scouring and processing of fleeces.¹⁰ In addition spent dip is disposed of to land subject to Environment Agency authorisation under the Groundwater Regulations 1998¹¹.
60. No definition of the term 'emissions' is provided by the EIR, the Directive¹² which it implements or by the Aarhus Convention.¹³ Neither is there a definition of 'emissions' within the Aarhus Convention Implementation Guide.¹⁴
61. The Commissioner notes the definition of 'emissions' in the European Directive on Integrated Pollution Prevention and Control (the IPPC directive).¹⁵

¹⁰ ADAS 2007: The Environmental Impact of Livestock Production. Report for Defra FFG.

www.defra.gov.uk/farm/livestock/pdf/envimpacts-livestock.pdf

¹¹ <http://www.opsi.gov.uk/si/si1998/19982746.htm>

¹² Council Directive 2003/4/EC(d)

¹³ Convention on Access to Information, Public Participation in decision making and Access to Justice in Environmental Matters

¹⁴ The Aarhus Convention: An Implementation Guide. <http://www.unece.org/env/pp/acig.pdf>

¹⁵ Directive 2008/1/EC codifying Council Directive 96/61/EC and amendments thereto

This defines 'emissions' as:

“direct or indirect release of substances, vibrations, heat or noise from individual or diffuse sources in the installation into the air, water or land.”

62. Whilst the Commissioner notes that the IPPC directive applies only to emissions from certain industrial installations and therefore is not applicable in the instant case, the Commissioner considers that the IPPC directive's definition of 'emissions' is a useful extrinsic aid to construction in this instance. The Commissioner notes that the IPPC directive includes within its definition of 'emissions' both the 'direct' and 'indirect' release of substances 'from diffuse sources.'
63. Further, the Commissioner confirms his view, previously expressed¹⁶, that the inclusion of the phrase 'relates to information on emissions' in regulation 12(9) means that the application of that regulation is not limited to cases where information falls within the definition of environmental information by virtue of regulation 2(1)(b) (emissions). Regulation 12(9) will also apply to information which is environmental information under regulation 2(1)(c) of the EIR (activities) where such activities affect or are likely to affect emissions.
64. The Commissioner is satisfied that, even where certain of the withheld information does not directly relate to emissions, all of the withheld information is used within an approval process, and therefore forms part of an activity, which is likely to affect emissions and, in turn, the elements of the environment.
65. Further, the Commissioner has considered the wording of the EIR, the Directive and the Aarhus Convention and is satisfied that the application of regulation 12(9) is not restricted to emissions which have already taken place and may include past, current and future emissions.
66. The Commissioner has also considered the decision of the Information Tribunal in the case of OFCOM v ICO & T-Mobile.¹⁷ The Tribunal stated:

“It is conceivable that those drafting the Directive did intend the word "emissions" to have a narrower meaning for the purposes of regulation 12(5)(e) than would normally be applied to it.

However, no guidance appears in the Directive to assist us in deciding whether it should be interpreted in that way. The 16th recital suggests that the grounds for refusal to disclose should be interpreted in a restrictive way. It follows that any exception to such a ground should be given a broad interpretation.

Against that background we believe that we should only apply the more restrictive meaning if we are given clear guidance to that effect. We do not believe that we are provided with such guidance by the Implementation Guide...

¹⁶ FER0085500

¹⁷ EA/2006/0078

... we conclude that "emissions" in both sub paragraph (b) of the definition of environmental information and regulation 12(9) should be given its plain and natural meaning and not the artificially narrow one set out in the IPPC Directive."¹⁸

67. In considering the 'plain and natural' meaning of the word 'emission' the Commissioner has considered the definitions in the Oxford English Dictionary of the words 'emission' and 'emit'. It defines the word 'emission' as 'something emitted', and the verb 'emit' as (inter alia) to "give off, send out from oneself or itself, (something imponderable, as light, sound, scent, flames, etc.)"
68. In this case, the withheld information is information relating to the potential environmental risk posed by the cypermethrin products. The Commissioner is satisfied that the manner in which these products may enter the wider environment, to pose any such risk as may be identified within the ERAs, is necessarily by 'emission'. Accordingly, the withheld information, held in the context of considering the impact of any such emission, 'relates to information on emissions'.
69. Therefore, for the reasons set out above, the Commissioner is satisfied that regulation 12(9) is applicable to the withheld information in this instance.

Regulation 12(5)(e) - commercial confidentiality

70. As the Commissioner finds that the withheld information relates to information on emissions under regulation 12(9) of the EIR, the Commissioner is satisfied that the exception under regulation 12(5)(e) may not be applied to the withheld information.
71. Accordingly, the Commissioner is satisfied that the exception under regulation 12(5)(e) is not engaged and that the VMD acted in error when it refused to disclose the withheld information on the grounds that it was excepted from disclosure under regulation 12(5)(e) of the EIR.

Regulation 12(5)(c) - intellectual property rights

72. The VMD has advised the Commissioner that it considers that certain of the withheld information to which it has applied the exception under regulation 12(5)(e) of the EIR (commercial confidentiality) also falls under the exception under 12(5)(c) of the EIR (intellectual property rights).
73. Regulation 12(5)(c) states that,

*"a public authority may refuse to disclose information to the extent that its disclosure would adversely affect –
(c) intellectual property rights"*

¹⁸ EA/2006/0078, para 25.

Intellectual property and adverse affect

74. The Commissioner notes that Article 2, paragraph viii of the World Intellectual Property Convention (WIPO) Convention (1967)¹⁹, states that 'Intellectual Property' includes:

"... the rights relating to – literary, artistic and scientific works ... protection against unfair competition and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields".

75. The Commissioner has considered the meaning of 'adverse affect' and the purpose of the intellectual property rights exception. The Commissioner notes that that recital 16 to the Directive provides that disclosure of information should be the general rule and that the exceptions setting out "*grounds for refusal should be interpreted in a restrictive way*" so that "*the public interest served by the disclosure should be weighed against the interest served by the refusal*". The implementation guide to the Aarhus Convention, upon which the Directive is based, supports this view, advising that that "*adversely affect means that the disclosure would have a negative impact on the relevant interest*".
76. The Commissioner is satisfied that the exception under regulation 12(5)(c) of the EIR is intended to protect the interests of the holder of an intellectual property right and is not intended to protect intellectual property rights in principle.
77. Accordingly, in order to engage the exception, it is necessary to demonstrate that an adverse affect to the intellectual property rights of the right holder would arise as a result of disclosure of the withheld information.

Is the information the subject of an intellectual property right?

78. The Commissioner has considered whether the withheld information is the subject of an intellectual property right.
79. This information is identified in Annex 2 is described by the VMD as "*formulation details*" and the "*method to degrade cypermethrin dip.*"
80. In response to the Commissioner's request for submissions in support of its application of the exceptions applied, the VMD wrote to the Commissioner on 8 April 2009 advising that the withheld information described, engaged the exception under regulation 12(5)(c) in addition to the exception under regulation 12(5)(e).
81. The VMD stated that that the information at issue was provided to the VMD in order that the VMD could assess the safety, quality and efficacy of a product before it is marketed, see paragraph 4 above.
82. The VMD further stated that the data required to be submitted to the VMD in support of an application for a marketing authorisation²⁰ are often expensive to

¹⁹ Convention establishing the World Intellectual Property Organisation – signed at Stockholm on July 14 1967 and as amended

- produce and commonly include intellectual property and commercially confidential information. The VMD advised that the information provided as part of this process is supplied under a bond of trust with the VMD who ensures that none of this intellectual property and commercially confidential information is made available in such a way that competitors can gain an advantage from it.
83. The VMD advised that placing the formulation in the public domain would help a competitor to develop an application for a marketing authorisation with reduced or possibly none of the research and development costs incurred by the holder of the intellectual property right.
84. The VMD further advised that the Veterinary Medicines Regulations 2008 provides ten years data protection which means that a generic product may not be marketed in that period and that companies are not obliged to release their intellectual property rights or commercial secrets after ten years and normally remain concerned about disclosure after that period.
85. The VMD advised that whether or not the company takes out patent protection on some or all of the information supplied is not known by the regulator nor is it relevant to the regulatory process.
86. The Commissioner notes that EC Directive 2001/82²¹, implemented in the UK by the Veterinary Medicines Regulations 2008 (the VMR)²², requires all veterinary medicinal products in the EU to be licensed for sale by the issue of a marketing authorisation.
87. Regulation 4 of the VMR states:
- “(1) It is an offence to place a veterinary medicinal product on the market unless that product has been granted a marketing authorisation by the Secretary of State or the Agency.*
- (2) Any person who certifies data in relation to an application for a marketing authorisation or in relation to an existing marketing authorisation and who knows that those data are false, or does not believe that they are accurate, is guilty of an offence.”*
88. At the time of the submission of the product information to the VMD, of the request, regulation 3 of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994²³ provided:
- “No person shall place on the market, or have in his possession for the purposes of placing on the market, any veterinary medicinal product unless a marketing authorisation (or, in the circumstances described in article 4.1, third paragraph of Council Directive 81/ 851/EEC, an allowance within the terms of that paragraph) has been granted—*
- (a) by the Ministers, or*

²⁰ Under Schedule 1, para 2, Veterinary Medicines Regulations 2008

²¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0082:EN:HTML>

²² http://www.opsi.gov.uk/si/si2008/uksi_20082297_en_1

²³ http://www.opsi.gov.uk/si/si1994/uksi_19943142_en_1.htm

(b) in accordance with Council Regulation 2309/93/EEC,

and it is placed on the market in accordance with such authorisation or allowance.”

89. In order to establish the status of the withheld information with respect to intellectual property rights the Commissioners, on 7 August 2009, asked the VMD for its comments, in relation to each element of the information, on:

*“- The nature of, and legal basis for, the intellectual property right asserted.
- The adverse affect of disclosure upon that right.
- The adverse affect of disclosure upon intellectual property rights in general.”*

90. On 17 August 2009 the VMD advised that it would return to the Commissioner with its response to the queries raised.

91. The Commissioner restated his request for clarification of this issue on 1 September 2009.

92. On 2 September 2009 the VMD advised the Commissioner that its response of 8 April 2009 set out its understanding of the legal basis for the application of the exception under regulation 12(5)(c) and the adverse effects of disclosure. The VMD advised that it was unclear what further comments it could provide to assist the Commissioner.

93. On 3 September 2009 the Commissioner restated the information he required to consider the potential application of the exception under regulation 12(5)(c).

94. The VMD responded to this request advising it required an opportunity to seek legal advice on the issue.

95. On 9 September 2009 the VMD advised the Commissioner that its position in relation to the application of the exception under 12(5)(c) was as set out in its email of 8 April 2009.

96. The Commissioner is of the view that his request for information as set out at paragraph 89 above was clear.

97. The Commissioner notes that he has not received a clear response to this repeated request for clarification. The Commissioner has not received clear argument or evidence in support of the application of the exception under regulation 12(5)(c).

98. The Commissioner notes that the focus of the argument he has received which purports to support the application of this exception is argument in relation to the efficacy and protection of the regulatory system and on the importance of commercial confidence to that system.

99. The Commissioner notes that no specific intellectual property right has been asserted or established, nor has the Commissioner received any argument or

evidence on the application in the present circumstances of the principles and practice of intellectual property law. The Commissioner notes that he has not received appropriate argument or evidence to support the contention that disclosure of the information would result in adverse affect to intellectual property rights. The Commissioner highlights the Ofcom Information Tribunal decision (EA/2006/0078), paragraph 47:

“The Information Commissioner's case was that he had been right in his Decision Notice to say that infringement of an intellectual property right was not sufficient to trigger the exception. He considered that the expression "adverse effect" required something more in terms of actual harm to commercial or other interests. Ofcom and T-Mobile, on the other hand, argue that the question of loss or harm should be taken into account when carrying out the public interest balance required by EIR regulation 2(1)(b), but not at the stage of determining whether the exception has been engaged...

...However we believe that, interpreting the exception restrictively requires us to conclude that it was intended that the exception would only apply if the infringement was more than just a purely technical infringement, (which in other circumstances might have led to a court awarding nominal damages, or even exercising its discretion to refuse to grant the injunction that would normally follow a finding of infringement). It must be one that would result in some degree of loss or harm to the right holder. We do not therefore accept that such harm should only be taken into consideration when carrying out the public interest balance.”

100. The Commissioner is satisfied that is not appropriate to apply regulation 12(5)(c) to information on the basis that the information was provided to the VMD in confidence. The Commissioner is satisfied that the provision of information in confidence, without more, does not automatically create an intellectual property right for the purposes of regulation 12(5)(c). This is because regulation 12(5)(e) provides a separate exception within the EIR for circumstances where disclosure would adversely affect the confidentiality of commercial or industrial information where such confidentiality is provided in law to protect a legitimate economic interest.
101. As set out in paragraphs 70 and 71 above, regulation 12(5)(e) may not be applied to except from disclosure information which relates to information on emissions. Accordingly, regulation 12(5)(e) may not be applied in this instance.
102. The Commissioner is satisfied that the VMD has not made sufficient case for the application of the exception under regulation 12(5)(c). Accordingly, and mindful of the explicit presumption in favour of disclosure contained with regulation 12(2) of the EIR, the Commissioner has no alternative but to order disclosure of the information referred to in paragraph 94 above.

Regulation 12(4)(e) - Internal communications

103. The VMD has refused to disclose certain parts of the withheld information on the basis of its application of the exception under regulation 12(4)(e) of the EIR. The Commissioner has considered whether the Department correctly applied the exception under regulation 12(4)(e).

104. Regulation 12(4)(e) states:

“ For the purposes of paragraph (1)(a), a public authority may refuse to disclose information to the extent that ...

(e) the request involves the disclosure of internal communications.”

105. The Commissioner has considered the withheld information and notes that it is comprised of assessment reports prepared by VMD assessors, employees of the VMD, for internal consideration by the VMD as part of the process of ERA.

106. Accordingly, the Commissioner is satisfied that certain of the withheld information is comprised of internal communications and that the exception under regulation 12(4)(e) of the EIR is engaged.

107. Regulation 12(1) of the EIR provides that a public authority may refuse to disclose information if an exception under paragraph 12(4) or 12(5) applies and, in all the circumstances of the case, the public interest in maintaining the exception outweighs the public interest in disclosing the information.

108. Further, regulation 12(2) provides that a public authority shall apply a presumption in favour of disclosure.

109. Mindful of the presumption in favour of disclosure, the Commissioner has considered that balance of the public interest in relation to that information falling within the exception for internal communications.

Public interest factors favouring withholding the information

110. The internal communications are assessment reports relating to the process of ERA and were made as part of a process by which the environmental risks of the cypermethrin products were ascertained by the VMD.

111. The Commissioner recognises that rigorous consideration of the submissions made by those within the pharmaceutical and agrochemical industry is central to an effective system of ERA. Such rigour is supported by an open internal forum for frank discussion and comment and a free space in which opinion may be expressed.

112. The Commissioner recognises the strong public interest in maintaining such a private thinking space for VMD staff in which ideas may be tested, explored and recorded without inhibition.

113. Further, the Commissioner recognises that public authorities often require a safe space in which to debate 'live' issues without the hindrance of external comment or media attention.
114. Disclosure of such internal communications may inhibit the candid expression of views and diminish the VMD's ability to develop its thinking, make assessments and scrutinise the research before it. Such inhibition could lead to an erosion of candour in the risk assessment process and a distortion of its outcomes. This would not be in the public interest nor in the interest of the environment which the process has been developed to protect.
115. The Commissioner notes that the information which comprises the internal communications is now over ten years old and that the decision making process which these assessment reports influenced is concluded and indeed had concluded at the time of the complainant's request. The Commissioner has considered whether the harm to the process may be diminished by the age of the information and the completion of the process for which it was first produced.
116. The Commissioner notes Mr Justice Burnton's consideration of the question of the timing of disclosures and the public interest test in the 2007 High Court case of *The Office of Government Commerce v ICO and the AG*²⁴. In relation to the application of the exemption under section 35 of the Act, commenting on the position taken by the Information Tribunal at first instance, he stated that:

"the Tribunal did not find that there was no public interest in maintaining the exemptions from disclosure once the Government had decided to introduce the Bill, but only that the importance of maintaining the exemption was diminished.

I accept that the Bill was an enabling measure, which left questions of Government policy yet to be decided. Nonetheless, an important policy had been decided, namely to introduce the enabling measure, and as a result I see no error of law in finding that the importance of preserving the safe space had diminished."

117. The Commissioner recognises that in the instant case the importance of preserving the safe space has been diminished, not merely by the passage of such considerable time, but also by the fact that the decision making process, which the assessment reports were designed and produced to influence and inform, had come to a conclusion. He also finds that the likelihood of a "chilling effect" was remote.

Public interest factors favouring the release of the information

118. The Commissioner considers that there is a public interest in transparency in decision making by a public authority. Public confidence is necessarily dependent on such transparency and on the demonstration by a public authority that it has satisfied all applicable laws and acted with clear probity.

²⁴ Case Nos: CO/5491/2007, CO/4438/2007

119. Further, the Commissioner recognises the presumption in favour of disclosure under regulation 12(2) and notes the importance of access to environmental information as a prerequisite to participation in environmental decision making and access to environmental justice.
120. The Commissioner believes that there is a strong public interest in improving the public's understanding of decisions made by public authorities, particularly, as in this instance, decisions that may have a significant impact on the environment.
121. The Commissioner also believes that disclosure of these internal communications may serve to increase public confidence in the robustness and efficacy of the VMD's system of ERA.

The balance of the public interest

122. The Commissioner notes that the safety of cypermethrin sheep dips has been and remains a matter of considerable public and governmental concern. The Commissioner recognises that the VMD has presently suspended the use of these products and is engaged in an examination of their environmental impact.
123. The Commissioner notes the large amount of information on this issue which has been placed into the public domain by the VMD, but the Commissioner finds that the information requested would significantly add to public knowledge of the issues, despite the range of information already available.
124. The Commissioner is satisfied of the key role of free and frank internal discussion of the submissions of the pharmaceutical and agrochemical industry in the VMD's assessment of the environmental risks posed by the cypermethrin sheep dip products.
125. However, the Commissioner notes that the internal communications at issue in this matter are over ten years old and relate to a decision making process which is complete and was complete at the time of the complainant's request. Further, the Commissioner does not consider that the disclosure of these internal communications in these present and very particular circumstances should, or will have, a 'chilling effect' on VMD staff in any future assessment of environmental risk with regard to Market Authorisation applications. The Commissioner's decision in respect of the internal communications contained within these assessment reports relates only to that withheld information now before him and is not to be interpreted as of general applicability to all assessment reports prepared by the VMD, the disclosure of which will, in accordance with the EIR, be required to be considered on an individual basis.
126. In light of the above analysis, the Commissioner is satisfied that in relation to those internal communications of the VMD, identified within the withheld information and set out in Annex 2, the balance of the public interest in maintaining the exception does not outweigh the public interest in disclosing the information.

Regulation 13 - Personal data

127. The Commissioner has considered whether the requested information is excepted from disclosure under regulation 13(1) of the EIR.
128. Regulation 13(1) of the EIR provides that, to the extent that the information requested includes personal data of which the applicant is not the data subject, a public authority shall not disclose the personal data where disclosure would contravene any of the data protection principles or section 10 of the Data Protection Act 1998 (the DPA). (For the full text of regulation 13 see Annex 1 hereto).
129. "Personal data" is defined in regulation 2(4) of the EIR as having the same meaning as in the DPA.
130. Section 1(1) of the DPA defines personal data as follows:
- "personal data" means data which relate to a living individual who can be identified –*
- (a) from those data, or*
- (b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller,*
- and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual."*
131. The VMD has submitted that the withheld information contains personal data comprised of:
- (a) the names of employees of the VMD
 - (b) the names of employees of the producers of the cypermethrin products
 - (c) the names of consultants to the producers of Robust and Ecofleece
 - (d) the details of authors, of reports provided by those producers to the VMD or cited by them.
 - (e) the curriculum vitae of the expert author of a report prepared on behalf of one of the producers
 - (f) the details of a limited company whose employee provided a report to the VMD on behalf of one of the producers of the cypermethrin products.
132. This information is further set out in Annex 2.
133. The VMD has submitted that the information described in paragraph 131 above is personal data and should be excepted from disclosure under regulation 13 of the EIR.
134. The Commissioner is satisfied that that information at paragraph 131 (f) above, detailing the name and address and telephone number of the consultancy which provided one of the reports contained within the withheld information, does not fall

within the exception under regulation 13 of the EIR. This is because this information is not personal data but relates to a limited company and does not relate to a living individual.

135. The Commissioner is satisfied that the information described at paragraph 131 a) – e) above is personal data in that it “relates to” living individuals who can be identified from that data or from those data and other information which is in, or is likely to come into the possession of, the data controller.
136. The Commissioner has considered whether disclosure of the personal data above would contravene any of the data protection principles (the data protection principles are set out in Annex 1 hereto). The VMD has argued that release of this information would breach the first data protection principle.
137. The Commissioner has considered whether disclosure of any of the personal data described at paragraph 131 above would breach the first data protection principle.

The first data protection principle

138. The first data protection principle provides that:

“Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless-

- (a) at least one of the conditions in Schedule 2 is met, and*
- (b) in the case of sensitive personal data, at least one of the conditions in schedule 3 is also met.*

139. The VMD has not provided the Commissioner with specific argument on why it considers that processing the personal information of the individuals in question, through disclosure of their identities to the complainant, would be unfair. However, the Commissioner has himself considered the question.
140. In his *Awareness Guidance* ¹²⁵ the Commissioner suggested factors which may be relevant when considering the concept of fairness. In this case the Commissioner has given consideration to the following:
 - Does the personal data relate to an individual's public or private life?
 - Do the individuals have an expectation that their personal data would not be released?
 - Would processing cause any unnecessary or unjustified distress?
141. The Commissioner is of the opinion that disclosing personal data is generally less likely to be considered unfair in cases where the personal data relates to an

²⁵http://www.ico.gov.uk/upload/documents/library/freedom_of_information/detailed_specialist_guides/awareness_guidance%201%20personal_information_v2.pdf

- individual's public or professional life rather than their private life. The threshold for releasing professional information will generally be lower than that in releasing information relating to an individual's private or home life.
142. The Commissioner recognises that individuals employed in a role where they are performing a public function should expect more information about them to be disclosed. However, in this case the Commissioner is satisfied that those individuals identified within the withheld information would not reasonably expect their identities to be revealed. These individuals, while carrying out an important technical role, would not have considered themselves of sufficient seniority within their organisation to have anticipated public disclosure of their identity.
143. It may be argued that disclosure of the identities of people performing a public role improves accountability and that such individuals should expect information about their work to be made available.
144. The Commissioner has considered the decision of the Information Tribunal in *Ministry of Defence v Information Commissioner and Mr R Evans*²⁶. In this case the Tribunal decided that the Ministry of Defence should release the details of its staff. The Commissioner is satisfied that in that case the Tribunal's decision was influenced by the fact that staff details were already widely available and may be distinguished from the instant case.
145. Further, the Commissioner has considered the decision of the Information Tribunal in the case of *House of Commons v ICO & Norman Baker MP*²⁷. In that case the Information Tribunal found that the release of additional personal information did not constitute processing for a new purpose, because the data subjects were aware that one of the purposes for which their personal data were processed was the release of information to the public as they had been told that some information would be released under the publication scheme.
146. In the instant case the Commissioner is satisfied that none of those individuals identified within the withheld information, set out in paragraph 148 (a) - (e) above, had any expectation or received any indication that any of their personal data might be released into the public domain or considered their respective roles to be a 'public role' with the attendant expectations of public scrutiny of the individual performer of that role. Further the Commissioner is satisfied that the identity of these individuals had not previously been made widely available within the public domain.
147. The Commissioner is satisfied that the withheld information set out in paragraph 148 (a) - (e) above constitutes personal data and that disclosure of that personal data would constitute unfair processing in breach of the first data protection principle.
148. Accordingly, the Commissioner is satisfied that regulation 13(1) of the EIR applies and that the condition under regulation 13(2)(a)(i) is satisfied. The Commissioner

²⁶ EA/2006/0027

²⁷ EA/2006/0015, EA/2006/0016

is satisfied that the VMD is entitled to withhold from disclosure that personal data set out in paragraph 148 (a) – (e) above.

Procedural matters

The duty to make environmental information available - Regulation 5 Extension of time - Regulation 7

149. Regulation 5 of the EIR requires that a public authority, which holds environmental information, make it available upon request as soon as possible and no later than 20 working days after the date of receipt of the request.
150. Under regulation 7(1) of the EIR a public authority may extend this time limit to 40 working days if it reasonably believes that the complexity and volume of the information requested means that it is impracticable either to comply with the request within the earlier period or to make a decision to refuse to do so. Regulation 7(3) states that the public authority must notify the applicant within 20 days of receipt of the request if it wishes to extend the time for response under this provision.
151. In this case, the complainant made its request for information on 14 October 2005. This request was received by the VMD on 17 October 2005. On 4 November 2005 the VMD replied to the complainant advising that, due to the complexity of the matter, it wished to extend the time limit for response by 20 working days until 12 December 2006.
152. The VMD did not provide a substantive response to request of 14 October 2005, until 17 February 2006. The Commissioner notes that the VMD did not explicitly claim reliance on regulation 7 to the complainant, but in any event this response clearly exceeded the forty days allowed by regulation 7.
153. In the response of 17 February 2006 the VMD provided the complainant with some of the requested information. This information was provided outside of the statutory time limit, therefore the Commissioner finds that the VMD failed to comply with regulation 5(2) in relation to this information.
154. As explained above, the Commissioner finds that the VMD ought to have provided the complainant with some of the information it withheld in response to his request. Therefore the Commissioner finds that the VMD failed to comply with regulation 5(2) of the EIR, as it has failed to provide the complainant with the requested information within the appropriate time period, that is, subject to the application of regulation 7, no later than forty working days from the date of its receipt of the complainant's request.

Refusal notice - Regulation

155. Regulation 14 (2) provides that, if a request for information is refused to any extent, the public authority must issue a refusal notice within twenty working days. As with regulation 5, this time limit can be extended to forty working days if regulation 7 is cited.

156. Under regulation 14(3) the refusal notice must specify the public authority's reason for refusing to disclose the requested information, including any exception relied on and the matters considered by the public authority in reaching its decision on the balance of the public interest.
157. The Commissioner considers that the VMD's letter of 17 February 2006 can be considered its refusal notice. However, this notice was issued outside the statutory time limit, therefore the Commissioner finds that the VMD failed to comply with regulation 14(2).

Internal review – regulation 11

158. Regulation 11(1) of the EIR provides that an applicant may make representations to a public authority in relation to the applicant's request for information, that the authority has failed to comply with the requirements of the EIR in relation to that request. The complainant in this case made such representations and request for review on 7 March 2006.
159. Thereafter, the VMD and the complainant continued in correspondence regarding the disclosure of information regarding the authorisation of cypermethrin products and on 28 June 2006 the VMD provided the complainant with further detailed information concerning its application of the exceptions to the complainant.
160. The Commissioner is satisfied that this letter of 28 June 2006 represents the VMD's reconsideration of its decision as set out in its letter of 17 February 2006.
161. Regulation 11(4) of the EIR requires that the authority notify the applicant of its decision in relation to the applicant's representations no later than forty working days after receipt of those representations.
162. In failing to provide the complainant with notice of its decision, in response to the representations of the complainant under regulation 11(1) of the EIR, within the appropriate time period the VMD has failed to comply with regulation 11(4) of the EIR.

The Decision

163. The Commissioner's decision is that the public authority, the Veterinary Medicines Directorate, did not deal with the request for information in accordance with the Act. The Commissioner is satisfied that the information which was withheld from disclosure by the Veterinary Medicines Directorate relates to information on emissions.
 - The Commissioner's decision is that VMD was not entitled to refuse to provide the withheld information on the basis that it was excepted under regulation 12(5)(e) of the EIR.

- The Commissioner is satisfied that the VMD was not entitled to refuse to provide some of the withheld information on the basis that it was excepted under regulation 12(5)(c) of the EIR.
- Further, the Commissioner is satisfied that the VMD was not entitled to refuse to provide some of the withheld information on the basis that it was excepted under regulation 12(4)(e) of the EIR.
- The Commissioner is satisfied that some of the withheld information was excepted under regulation 13 of the EIR but that the VMD was not entitled to refuse to provide some of the withheld information under this exception.
- The Commissioner is satisfied that in failing to provide the complainant with a response to its request for information within the appropriate time period, the VMD has failed to comply with regulation 14(2) of the EIR.
- Further, the Commissioner is satisfied that the VMD has failed to comply with regulation 11(4) of the EIR in that it failed to provide the complainant, within the appropriate time period, with notice of its decision, in response to the representations of the complainant under regulation 11(1) of the EIR.

Steps required

164. In light of his findings the Commissioner requires that the Veterinary Medicines Directorate disclose to the complainant that withheld information as set out in Annex 2.

Failure to comply

165. Failure to comply with the steps described above may result in the Commissioner making written certification of this fact to the High Court pursuant to section 54 of the Act and may be dealt with as a contempt of court.

Right of Appeal

166. Either party has the right to appeal against this Decision Notice to the Information Tribunal. Information about the appeals process may be obtained from:

Information Tribunal
Arnhem House Support Centre
PO Box 6987
Leicester
LE1 6ZX

Tel: 0845 600 0877
Fax: 0116 249 4253
Email: informationtribunal@tribunals.gsi.gov.uk.
Website: www.informationtribunal.gov.uk

If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

Any Notice of Appeal should be served on the Tribunal within 28 calendar days of the date on which this Decision Notice is served.

Dated the 10th day of December 2009

Signed

**Steve Wood
Assistant Commissioner**

**Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF**

Annex 1

Legal Annex: Relevant statutory obligations

Regulation 2 - Interpretation

Regulation 2(1) In these Regulations –

“environmental information” has the same meaning as in Article 2(1) of the Directive, namely any information in written, visual, aural, electronic or any other material form on

–

- (g) the state of the elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites including wetlands, coastal and marine areas, biological diversity and its components, including genetically modified organisms, and the interaction among these elements;
- (h) factors, such as substances, energy, noise, radiation or waste, including radioactive waste, emissions, discharges and other releases into the environment, affecting or likely to affect the elements of the environment referred to in (a);
- (i) measures (including administrative measures), such as policies, legislation, plans, programmes, environmental agreements, and activities affecting or likely to affect the elements and factors referred to in (a) and (b) as well as measures or activities designed to protect those elements;
- (j) reports on the implementation of environmental legislation;
- (k) cost-benefit and other economic analyses and assumptions used within the framework of the measures and activities referred to in (c) ; and
- (l) the state of human health and safety, including the contamination of the food chain, where relevant, conditions of human life, cultural sites and built structures inasmuch as they are or may be affected by the state of elements of the environment referred to in (b) and (c);

“historical record” has the same meaning as in section 62(1) of the Act;

“public authority” has the meaning given in paragraph (2);

“public record” has the same meaning as in section 84 of the Act;

“responsible authority”, in relation to a transferred public record, has the same meaning as in section 15(5) of the Act;

“Scottish public authority” means –

- (a) a body referred to in section 80(2) of the Act; and

(b) insofar as not such a body, a Scottish public authority as defined in section 3 of the Freedom of Information (Scotland) Act 2002(a);

“transferred public record” has the same meaning as in section 15(4) of the Act; and
“working day” has the same meaning as in section 10(6) of the Act.

Regulation 5 - Duty to make available environmental information on request

Regulation 5(1) Subject to paragraph (3) and in accordance with paragraphs (2), (4), (5) and (6) and the remaining provisions of this Part and Part 3 of these Regulations, a public authority that holds environmental information shall make it available on request.

Regulation 5(2) Information shall be made available under paragraph (1) as soon as possible and no later than 20 working days after the date of receipt of the request.

Regulation 5(3) To the extent that the information requested includes personal data of which the applicant is the data subject, paragraph (1) shall not apply to those personal data.

Regulation 5(4) For the purposes of paragraph (1), where the information made available is compiled by or on behalf of the public authority it shall be up to date, accurate and comparable, so far as the public authority reasonably believes.

Regulation 5(5) Where a public authority makes available information in paragraph (b) of the definition of environmental information, and the applicant so requests, the public authority shall, insofar as it is able to do so, either inform the applicant of the place where information, if available, can be found on the measurement procedures, including methods of analysis, sampling and pre-treatment of samples, used in compiling the information, or refer the applicant to the standardised procedure used.

Regulation 5(6) Any enactment or rule of law that would prevent the disclosure of information in accordance with these Regulations shall not apply.

Regulation 12 - Exceptions to the duty to disclose environmental information

Regulation 12(1) Subject to paragraphs (2), (3) and (9), a public authority may refuse to disclose environmental information requested if –

- (a) an exception to disclosure applies under paragraphs (4) or (5); and
- (b) in all circumstances of the case, the public interest in maintaining the exception outweighs the public interest in disclosing the information.

Regulation 12(2) A public authority shall apply a presumption in favour of disclosure.

Regulation 12(3) To the extent that the information requested includes personal data of which the applicant is not the data subject, the personal data shall not be disclosed otherwise than in accordance with regulation 13.

Regulation 12(4) For the purposes of paragraph (1)(a), a public authority may refuse to disclose information to the extent that –

- (a) it does not hold that information when an applicant's request is received;

- (b) the request for information is manifestly unreasonable;
- (c) the request for information is formulated in too general a manner and the public authority has complied with regulation 9;
- (d) the request relates to material which is still in course of completion, to unfinished documents or to incomplete data; or
- (e) the request involves the disclosure of internal communications.

Regulation 12(5) For the purposes of paragraph (1)(a), a public authority may refuse to disclose information to the extent that its disclosure would adversely affect –

- (a) international relations, defence, national security or public safety;
- (b) the course of justice, the ability of a person to receive a fair trial or the ability of a public authority to conduct an inquiry of a criminal or disciplinary nature;
- (c) intellectual property rights;
- (d) the confidentiality of the proceedings of that or any other public authority where such confidentiality is provided by law;
- (e) the confidentiality of commercial or industrial information where such confidentiality is provided by law to protect a legitimate economic interest;
- (f) the interests of the person who provided the information where that person –
 - (i) was not under, and could not have been put under, any legal obligation to supply it to that or any other public authority;
 - (ii) did not supply it in circumstances such that that or any other public authority is entitled apart from the Regulations to disclose it; and
 - (iii) has not consented to its disclosure; or
- (g) the protection of the environment to which the information relates.

Regulation 12 (6) For the purpose of paragraph (1), a public authority may respond to a request by neither confirming or denying whether such information exists and is held by the public authority, whether or not it holds such information, if that confirmation or denial would involve the disclosure of information which would adversely affect any of the interests referred to in paragraph (5)(a) and would not be in the public interest under paragraph (1)(b).

Regulation 12(7) For the purposes of a response under paragraph (6), whether information exists and is held by the public authority is itself the disclosure of information.

Regulation 12(8) For the purposes of paragraph (4)(e), internal communications includes communications between government departments.

Regulation 12(9) To the extent that the environmental information to be disclosed relates to information on emissions, a public authority shall not be entitled to refuse to disclose that information under an exception referred to in paragraphs (5)(d) to (g).

Regulation 12(10) For the purpose of paragraphs (5)(b), (d) and (f), references to a public authority shall include references to a Scottish public authority.

Regulation 12(11) Nothing in these Regulations shall authorise a refusal to make available any environmental information contained in or otherwise held with other information which is withheld by virtue of these Regulations unless it is not reasonably capable of being separated from the other information for the purpose of making available that information.

Regulation 13 - Personal data

Regulation 13(1) To the extent that the information requested includes personal data of which the applicant is not the data subject and as respects which either the first or second condition below is satisfied, a public authority shall not disclose the personal data.

Regulation 13(2) The first condition is –

- (a) in a case where the information falls within any paragraphs (a) to (d) of the definition of “data” in section 1(1) of the Data Protection Act 1998, that the disclosure of the information to a member of the public otherwise than under these Regulations would contravene –
 - (i) any of the data protection principles; or
 - (ii) section 10 of the Act (right to prevent processing likely to cause damage or distress) and in all the circumstances of the case, the public interest in not disclosing the information outweighs the public interest in disclosing it; and
- (b) in any other case, that the disclosure of the information to a member of the public otherwise than under these Regulations would contravene any of the data protection principles if the exemptions in section 33A(1) of the Data Protection Act 1998(a) (which relates to manual data held by public authorities) were disregarded.

Regulation 13(3) The second condition is that by virtue of any provision of Part IV of the Data Protection Act 1998 the information is exempt from section 7(1) of the Act and, in all circumstances of the case, the public interest in not disclosing the information outweighs the public interest in disclosing it.

Regulation 13(4) In determining whether anything done before 24th October 2007 would contravene any of the data protection principles, the exemptions in Part III of Schedule 8 to the Data Protection Act 1998 shall be disregarded.

Regulation 13(5) For the purposes of this regulation a public authority may respond to a request by neither confirming nor denying whether such information exists and is held by the public authority, whether or not it holds such information, to the extent that –

- (a) the giving to a member of the public of the confirmation or denial would contravene any of the data protection principles or section 10 of the Data Protection Act 1998 or would do so if the exemptions in section 33A(1) of the Act were disregarded; or
- (b) by virtue of any provision of Part IV of the Data Protection Act 1998, the information is exempt from section 7(1)(a) of the Act.

Annex 2**Schedule of Documents****Analysis of redactions to the Renewal Application Assessment Report for Robust - VMP12208A AN414/98**

Page	Line	Nature of information	Exceptions claimed	Commissioner's decision
1	1	Name of author of dossier for Robust being assessed	13	Withhold
1	6 – 9	Formulation details	12(5)(e) 12(5)(c)	Release
2	6 – 7	Concentrations in wool post dipping	12(5)(e)	Release
2	12 - 16	Method to degrade cypermethrin dip	12(5)(e) 12(5)(c)	Release
2	22,23,25	Comment from VMD assessor on information required for Phase II assessment	12(4)(e)	Release
2	26 – 31	Manufacturer's study of metabolism of product by sheep	12(5)(e)	Release
2	32 – 34	VMD assessor's comments on metabolism study	12(4)(e)	Release
2	35 – 36	Manufacturer's study of metabolism of product by sheep	12(5)(e)	Release
2	37	VMD assessor's comments on metabolism study	12(4)(e)	Release
3	1 - 6	VMD assessor's comments on metabolism study	12(4)(e)	Release
3	7 – 10	Manufacturer's study of metabolism of	12(5)(e)	Release

Page	Line	Nature of information	Exceptions claimed	Commissioner's decision
3	11 - 17	VMD assessor's comments on metabolism study	12(4)(e)	Release
3	18 - 21	Manufacturer's study of metabolism of product by sheep	12(5)(e)	Release
3	22 - 24	VMD assessor's comments on metabolism study	12(4)(e)	Release
3	31 - 35	Manufacturer's data supporting use of parent compound rather than metabolites for predicted Environmental Concentration (PEC)	12(5)(e)	Release
3	36 - 37	VMD assessor's comments on PEC	12(4)(e)	Release
4	Row 4	Bioaccumulation in mussel	12(5)(e)	Release
4	Row 10	Degradation in sea water	12(5)(e)	Release
4	Row 11	Degradation in marine sediment	12(5)(e)	Release
5	Row 1	Accumulation in sediment	12(5)(e)	Release
8	10 -16	Discussion on partitioning of cypermethrin into water from sediment	12(5)(e)	Release
8	25 - 27	VMD assessor's comments on the discussion of absorption on to	12(4)(e)	Release

Page	Line	Nature of information	Exceptions claimed	Commissioner's decision
		sediment		
9	2 - 5	Data on alternative to terrestrial arthropods as indicators of cypermethrin toxicity in dung	12(5)(e)	Release
10	4,15	PNEC for soil invertebrate (same value for both lines)	12(5)(e)	Release
12	Final	VMD assessor's name	13	Withhold

**Analysis of redactions to Application for a Marketing Authorisation for Ecofleece
- 31/07/95 VMP 14202 APPN. No. 799/95**

Page	Line	Nature of information	Exceptions claimed by VMD	Commissioner's decision
1		Name of company contact	13	Withhold
5	8 - 42	Study of residues in fleece, including bath replenishment rates, analysis method and data for residues in wool	12(5)(e)	Release
6	1 - 6	Study of residues in fleece, including bath replenishment rates, analysis method and data for residues in wool	12(5)(e)	Release
7	7 - 9	Average cypermethrin residues in fleece post dipping	12(5)(e)	Release

Analysis of redactions to Renewal / transfer application Robust (SP04590.38)

Page	Line	Nature of information	Exceptions claimed by VMD	Commissioner's decision
1	Whole page	List of variations submitted within the previous five years	12(5)(e)	Release
2 – 7	All pages	Manufacturer's response to Suspected Adverse Reactions Surveillance Scheme	12(5)(e)	Release
23	8 – 16	Name and address of report supplier	13	Release – save for personal data to be withheld (name only)
24	Whole page	Report supplier's release form for the report	13 12(5)(e)	Release
25 – 26	Final line	Name of report supplier	12(5)(e)	Release
27	Whole page	Report supplier's authentication form	13 12(5)(e)	Release – save for personal data to be withheld (name only)
28	Final line	Name of report supplier	12(5)(e)	Release
29	1 – 3	Formulation details	12(5)(e)	Release
29	20 – 26	Formulation details	12(5)(e) 12(5)(c)	Release
30	2, 24	Employee's name	13	Withhold
31	12 – 21	Neutralisation process for used dip bath	12(5)(e) 12(5)(c)	Release

31	26	Reference to unpublished reports	12(5)(e)	Release
32 – 39	All redactions	Reference to unpublished reports	12(5)(e)	Release
Page	Line	Nature of Information	Exceptions claimed by VMD	Commissioner's decision
40	31 – 33	Information on dip neutralisation process developed by manufacturer	12(5)(e) 12(5)(c)	Release
41 – 46	All redactions	Reference to unpublished reports	12(5)(e)	Release
47	10	Reference to unpublished reports	12(5)(e)	Release
47	21 – 24	Information on the reduced toxic nature of degraded cypermethrin	12(5)(e)	Release
49 – 50	All redactions	Reference to unpublished reports	12(5)(e)	Release
51	11	Reference to unpublished reports	12(5)(e)	Release
51	27 - 31	A note on the disposal of dip after applying the manufacturer's degradation process	12(5)(e)	Release

55 - 58	All redactions	Reference to unpublished reports	12(5)(e)	Release
61	Whole page	Reference to unpublished reports showing author's names	13 12(5)(e)	Release save for personal data to be withheld (names only)
62 - 67		Reference to unpublished reports showing author's names	13 12(5)(e)	Release save for personal data to be withheld (names only)
Page	Line	Nature of information	Exceptions claimed by VMD	Commissioner's decision
68	Whole page	Tabulated study summaries	12(5)(e)	Release
70 – 71	Whole pages	Expert's CV	13	Withhold
72 – 84	Whole pages	Finished product specification	12(5)(e)	Release
85 – 86	Whole pages	Packaging details	12(5)(e)	Release
87 – 121	Whole pages	Sheep tissue residue study report. Provided to give information on cypermethrin remaining in sheep liver, muscle, fat and kidney for intervals up to 21 days post-dipping	12(5)(e)	Release

Analysis of redactions applied to Dossier for Ecofleece

Page	Line	Nature of information	Exceptions claimed by VMD	Commissioner's decision
1	2, 10, 11	Name of VMD employee	13	Withhold
2	17 - 22	Calculation to arrive at line 23	12(5)(e)	Release
4	3 – 16	Consideration of the toxicity of used dip for disposal purposes	12(5)(e)	Release
6	5 – 8	Sign off by Cross Vetpharm employee	13	Withhold