Freedom of Information Act 2000 (FOIA)
Environmental Information Regulations 2004 (EIR)

Decision notice

Date:	**10 September 2024**
Public Authority:	**Health and Safety Executive (HSE)**
Address:	**Redgrave Court, Merton Road, Bootle, L20 7HS**

Decision (including any steps ordered)

1. The complainant has requested HSE to provide a list of all applications for PT1 Derogation under the UK Biocidal Products Regulation Article (BPR) 55 for the period 1st January 2020 to 31st December 2022. HSE disclosed some information but withheld the remainder, citing section 43 of FOIA.

2. During the Commissioner's investigation HSE accepted that the request should have been considered under the EIR. It issued a revised response to the complainant and disclosed some further information. For the remaining withheld information, HSE cited regulation 12(5)(c) of the EIR.

3. The Commissioner's decision is that HSE is not entitled to rely on regulation 12(5)(c) of the EIR. He has also found HSE in breach of regulations 5(2), 11(4) and 14(2) of the EIR.

4. The Commissioner requires HSE to take the following steps to ensure compliance with the legislation.

    - Disclose the remaining withheld information to the complainant.

5. HSE must take these steps within 30 calendar days of the date of this decision notice. Failure to comply 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.

Request and response

6. On 9 August 2023, the complainant wrote to HSE and requested information in the following terms:

   "Please provide a list of all applications for PT1 Derogation under the UK BPR Article 55 for the period 1st January 2020 to 31st December 2022.

   Please provide the information in .csv file format, to include the following data:
   Name of applicant entity.
   Name of product(s).
   Date of application.
   Date approved, or rejected.
   If approved, period of derogation granted.
   Date of HSE derogation withdrawal.
   Active substance(s).
   HSE Fee charged."

7. HSE responded on 6 October 2023. It disclosed the requested information, except for those applications that were "sensitive, declined and authorisation not issued" under section 43 of FOIA.

8. The complainant requested an internal review on 20 October 2023.

9. HSE carried out an internal review and notified the complainant of its findings on 11 January 2024. It upheld the application of section 43 of FOIA.

Scope of the case

10. The complainant contacted the Commissioner on 2 February 2024 to complain about the way their request for information had been handled. The complainant raised concerns over the accuracy of some of the information disclosed and HSE's decision to withhold information under section 43 of FOIA.

11. The Commissioner informed the complainant from the outset that he is unable to consider any complaints over accuracy, as this is not within his remit.

12. The Commissioner identified that the request should have been considered under the EIR. He also felt that based on HSE's submissions the remaining withheld information could be disclosed. He therefore

wrote to HSE to ask it to reconsider the request under the EIR and reconsider disclosing the outstanding information to the complainant.

13. HSE issued a revised response to the complainant under the EIR on 15 August 2024. It disclosed all remaining withheld information to the complainant except the names of the companies whose application were unsuccessful and the names of the products associated with those unsuccessful applications. It relied on regulation 12(5)(c) of the EIR to withhold this information.

14. There was also an issue over the scope of the request. But this was rectified during the Commissioner's investigation.

15. The Commissioner's decision therefore focuses on the remaining withheld information (the name of the company and the name of the product for all declined or unauthorised applications) and HSE's late reliance on regulation 12(5)(c) of the EIR.

Background

16. HSE confirmed that companies who wish to gain authorisation to place a biocidal product on the market in Great Britain under the UK BPR, cannot do so unless they gain approval for the active substance(s) in the relevant product type(s) from HSE. All active substances approved by HSE are published via the following link:

    BPR active substance lists for GB and NI - Biocides - HSE

17. It advised that the requested information relates to all applications for PT1 Derogation under the UK BPR Article 55. Article 55(1) of BPR enables HSE, in case of danger to public health, animal health or the environment, which cannot be contained by other means, to provide short term derogations from the requirements for product authorisation.

18. It said that to meet the increased demand for hand sanitisers during Covid, HSE worked closely with other Government agencies, manufacturers and their trade associations and made arrangements to issue derogations from product authorisation requirements for hand sanitiser products.

19. HSE stated that the derogation applied mainly to hand sanitisers containing propan-2-ol (also called isopropanol, isopropyl alcohol or IPA). Propan-2-ol has already been approved as an active substance for PT1 meaning that hand sanitisers containing it should be authorised before being placed on the market. However, suppliers who did not have an authorisation could still apply for a derogation from product

authorisation under Article 55 of the BPR. HSE produced the following publication for Trading Standards:

HSE guidance for TS on application of BPR to hand sanitisers - rev. June 2020.pdf (regulatorscompanion.info).

Reasons for decision

Regulation 12(5)(c) – intellectual property (IP) rights

20. Regulation 12(5)(c) states that a public authority may refuse to disclose information to the extent that its disclosure would adversely affect IP rights.

21. It is qualified exception. It is therefore subject to the public interest test. In accordance with regulation 12(2) a public authority is required to apply a presumption in favour of disclosure.

22. As outlined in the Commissioner's guidance[1], there is a four-step test a public authority must follow to demonstrate that the exception is engaged. A public authority must demonstrate that:

    1) The information it holds is protected by IP rights and identify the specific IP right(s) that would be adversely affected and the owner of those rights.

    2) The person(s) holding the IP rights would suffer harm (infringement alone will not necessarily result in harm).

    3) The identified harm is a consequence of the infringement or the loss of control over use of the information. And;

    4) The IP rights holder could not prevent the harm or loss of control by enforcing their IP rights.

23. The Commissioner's guidance also states clearly that:

    "Where a third party holds the IP rights, you should not speculate on harms that **might** occur. We will normally expect you to have consulted the third party concerned. This principle was established by the

[1] Regulation 12(5)(c) – intellectual property rights | ICO

Information Tribunal in Derry City Council v Information Commissioner (EA/2006/0014, 11 December 2006)."

24. HSE confirmed that it receives in the region of 1000+ applications each year from companies seeking approval to use a biocide and or pesticide in the UK. It explained that some of these applications will be approved from the information provided. However, some applications may initially be unsuccessful for a variety of reasons but may be approved at a later date following a new application. It stated that a company can submit an application at any time and may submit a new application, following an unsuccessful application, within a few months of their initial rejection.

25. HSE outlined that this is a highly competitive market and the intellectual property contained within the applications received is expensive to generate and has value as part of any future re-submission. It explained that many of these companies spend years developing a product for market and information within these applications can form part of a company's future registration strategy and reveal strategy of emerging markets or uses. Therefore, it stated, the data package received by HSE to support applications contain highly sensitive and commercially valuable information relating to all aspects of the product a company wishes to bring to market.

26. It advised that in order to perform its regulatory functions e.g. the issuing of licenses HSE must be provided with commercial, scientific, and intellectual property in the form of an application. It argued that if companies believe that their intellectual property might be disclosed, this could act as a disincentive for future submissions of applications. HSE stated that this means HSE could experience a decline in the quality and quantity of submissions and subsequent quality and quantity of biocide products coming to market. It commented that this could also act as a disincentive for future submissions of applications, undermining a flourishing UK biocides industry.

27. HSE confirmed that disclosure would likely have monetary consequence for the companies involved if the name of the new product associated with an unsuccessful application was placed into the public domain. This is because it could be utilised by a competitor before the original applicant could submit a new application. It said that product names approved for use in the UK cannot be duplicated. This would therefore mean any company who had their product name taken by a competitor would experience serious monetary loss associated with any work previously undertaken for that product name. HSE confirmed that they would then have to develop a new product name to accompany any new application submitted.

28. It advised that the names of companies associated with unsuccessful applications could also be used to cause reputational damage that would ultimately cause monetary loss in the form of falling share prices for large global companies. HSE stated that they regarded this to be particularly likely if the reasons for an unsuccessful application are not disclosed or are disclosed but discounted by the complainant.

29. HSE confirmed that it has witnessed on a number of occasions how information disclosed under FOIA and EIR has been manipulated to cause reputational damage without justification "to spin a story by a journalist." HSE said it was therefore concerned how companies might be portrayed if their names are disclosed into the public domain following an unsuccessful application.

30. Although the Commissioner can see that HSE is saying that it would be the IP right(s) of each company that would be affected, he notes HSE had not identified the specific IP right(s) in question (whether copyright, database rights or copyright in databases). This is the first requirement, as outlined in paragraph 22 above.

31. HSE has also failed to demonstrate sufficiently that someone would wish to exploit the withheld information, could successfully do so and that these infringements would go undetected or could not be prevented (the remaining requirements of the test outlined in paragraph 22 above).

32. The Commissioner also notes that circumstances have moved on significantly since these applications were put in. They were made at a time when there was an overwhelming demand for such products and other Covid related supplies during a global pandemic. The demand and therefore potential commercial opportunities for such companies, for hand sanitiser, was not the same at the time of the request. The Commissioner suspects too that the short term derogations from the requirements for product authorisation were also no longer in place when the request was made.

33. HSE has stated itself too that many of the companies do not bring Biocidal products to the market as a matter of routine, therefore suggesting that their applications were a one off. Many applications were also simply unsuccessful for lack of information or because they were withdrawn.

34. It is also worth noting that at the time of the request any provider that had been unsuccessful had at least nine months in which to protect its product name. The Commissioner would expect a company that has carried out extensive preparatory work to have already thought about trademarking their brand name.

35. As detailed in paragraph 23 above, a public authority should also contact the third party(ies) concerned and not speculate on their behalf. It is clear that HSE has made no attempt to contact any of the companies concerned in relation to the disclosure of the remaining withheld information. While the Commissioner may not expect HSE to obtain the views of each and every company (as there are a relatively high number), he would expect some attempt to have been made and for HSE to have obtained the views of a representative sample.

36. The Commissioner believes he has given HSE ample opportunity to provide adequate submissions and ample time to contact a representative sample of the companies concerned. It has failed to do so. He considers HSE is aware from other complaints it has dealt with, what level of detail and justification is required in relation to supporting the application of a cited exception.

37. For the above reasons, the Commissioner has concluded that regulation 12(5)(c) of the EIR is not engaged.

Procedural matters

38. HSE failed to issue its refusal notice within 20 working days of receipt. When it did, it failed to deal with the request under the EIR. It therefore breached regulation 14(2) of the EIR.

39. HSE also failed to disclose information to which the complainant was entitled under regulation 5(2) of the EIR (the disclosed information at refusal notice stage and during the Commissioner's investigation), within 20 working days of receipt. The Commissioner has therefore recorded a breach of regulation 5(2).

40. Additionally, HSE failed to carry out an internal review within 40 working days of receipt. The Commissioner has therefore recorded a breach of regulation 11(4) of the EIR.

Right of appeal

41. Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

    First-tier Tribunal (Information Rights)
    GRC & GRP Tribunals,
    PO Box 9300,
    LEICESTER,
    LE1 8DJ

    Tel: 0203 936 8963
    Fax: 0870 739 5836
    Email: grc@justice.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

42. 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.

43. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

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