ASSURING THE SAFETY, QUALITY & EFFICACY
OF VETERINARY MEDICINES

ATI 299

Request

From: [Redacted under section 40 of the FOIA]
Sent: 21 May 2014
Subject: FOIA REQUEST

Under the Freedom Of Information Act 2000 please provide me with copies of all documents held by the VMD that refer to impurities in sheep dip products that contained organophosphorus compounds.

I am especially interested in references to "epichlorhydrin".

I am also especially interested in the documents referred to in the third paragraph of the article below that was published in "The Farmers Weekly".

Evan Jones

Iraqi Nerve Gas Found in Sheep Dip

By Donald MacPhail
Farmers Weekly
8-25-1

A deadly nerve gas ingredient used by Saddam Hussein was found in sheep dip, reveal government documents obtained by FARMERS WEEKLY.

Campaigners say the revelation strengthens the case of hundreds of farmers who claim to have been

poisoned by the chemicals.

The documents show that the Veterinary Medicines Directorate expressed concern about high levels of tetraethylpyrophosphate (TEPP) in 1991.

The directorate, which authorises animal medicines, raised concerns about the impure active ingredients in a letter to sheep-dip manufacturers.

It was written during a review to examine the safety of human and animal medicines. Some active ingredients in dip contained up to 10% impurities.

The letter says: "Unless much purer active ingredients are used, toxological profiles of the impurities and related substances will be required."

It adds: "Levels of neurotoxic impurities such as TEPP should be tightened."

TEPP was the first organophosphate insecticide to be developed. It was withdrawn from sale as a dip in the UK because it was toxic and unstable.

Iraqi leader Saddam Hussein is known to have used TEPP as an ingredient to manufacture nerve gas for use in chemical warfare.

Campaigners claim the letter proves that government agencies had doubts about sheep dip impurities but continued to license the products to farmers.

Elisabeth Charles, a partner in solicitors Gabb & Co, said manufacturers and the directorate knew toxicity levels in sheep dip had been inadequately controlled.

"If farmers have been injured by impurities then the government seems as culpable as the manufacturers," she said.

"Clearly the [directorate] had doubts about highly toxic impurities but were happy to license products for farmers. We all need an explanation for this."

Andrew Watterson, of the Occupational and Environmental Health Research Group at Stirling University, said farmers who used impure dip were at risk.

This could shed light on the question of why some people seemed so much more badly affected by organophosphates than others, he added.

A spokesman for the Department for Environment, Food and Rural Affairs admitted that the products had been used before the review.

But there was no evidence that they had damaged human health, he added.

The spokesman said: "We were gathering evidence to make sure they were safe before they could be given marketing authorisation."

As well as being found in impurities, TEPP can also be created when organophosphate dips degrade, said Prof Watterson.

He called for more transparency from DEFRA on quality control monitoring and details of levels of contamination when dip breaks down.

VMD Reply

Sent: 17 June 2014
To: [Redacted under section 40 of the FOIA]
Subject: FOIA REQUEST

Your Request

Thank you for your email dated 21 May 2014. We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

You asked for copies of all documents held by the Veterinary Medicines Directorate (VMD) that refer to impurities in sheep dip products that contained organophosphorus compounds. You said you were especially interested in references to "epichlorhydrin" and in the documents referred to in the third paragraph of the article that was published in "The Farmers Weekly" (‘documents that show that the VMD expressed concern about high levels of tetraethylpyrophosphate (TEPP) in 1991’).

Our Reply

Information rather than documents

As a general point you should note that the FOIA gives you an entitlement to information rather than documents and it is in this context that we have answered your request taking account of the information we hold.

Background information

In their assessment of the information we hold my colleagues that deal with these matters recommended that I provide you with the following information by way of background to these issues and your reference to documents that show that the VMD expressed concern about high levels of tetraethylpyrophosphate (TEPP) in 1991. The information comes from a letter sent by the VMD's then CEO, Dr Rutter in September 2001 to a concerned member of the public who had sent us newspaper cuttings about OP sheep dips.

We have not included the name of the member of the public as the disclosure of the name would breach the first data protection principle and fail to meet any of the relevant conditions set out in Schedule 2 of the Data Protection Act 1998 (DPA) . The First Principle in the DPA requires that disclosure must be fair and lawful, and, in particular, personal data shall not be processed unless at least one of the conditions in Schedule 2 is satisfied. The person concerned would not have expected their name to be disclosed to the public and so disclosure would not be "fair" in the manner contemplated by the DPA. Furthermore, disclosure would not satisfy any of the conditions for data processing set out in Schedule 2 of the DPA. In particular, we do not consider that there is a legitimate interest in disclosure in this case. There is no public interest in making information about such an individual available in this way contrary to what would have been their legitimate expectation at the time.

Dr Rutter wrote: *"Despite the language used in those Press reports I can openly assure you that the review of OP sheep dips that began in 1988 was a matter of public knowledge.*

It may, however, help if I explain the context of that review and in so doing I will address your specific question about TEPP.

The Medicines Act of 1968 established a legal framework for a staged introduction of much more comprehensive controls than were previously in place. The Act provided for the granting of product licences of right (PLR) to products that were on the market before the coming into force, in 1971, of the 1968 Act. Product licenses of right included some OP sheep dips.

The alternative to a staged introduction would have resulted in the removal of all human and veterinary medicines from the market until they had been reviewed product by product. The enormity of such a task of reviewing all medicines in a short period of time was not possible and it was, of course, totally impractical to put on hold the use of all human and animal medicines in the interim.

New European Community legislation (Council Directive 81/851), which came into force on 28 September 1981, harmonised the authorisation process for veterinary medicinal products across the Community. These rules also required that product licences, including product licences of right, issued before the entry into force of 81/851 should be reviewed and licensing authorities were permitted to request data in support of each product. This was a general review and data were required concerning the quality, safety and efficacy of the formulations.

The order in which veterinary medicines were to be reviewed was publicly announced in June 1987 and they were taken in order of perceived consumer safety issues. The review of OP dips was scheduled to begin in November 1987.

In the first stage of the review all companies were asked for data to support their product licences and were given the time to generate the data. Following that first stage and an initial consideration of the data that were produced, we wrote to the licence holders again in 1991 (i.e. the letter referred to in the Press reports) because of concerns over some data deficiencies. Whilst it was known that TEPP was an impurity of diazinon, it was also known that stabilisers in the formulation helped to delay degradation that may otherwise lead to the production of TEPP and Sulfotepp. And whilst stabilised formulations were available from manufacturers before the review of OP dips, our letter required that unless much purer active ingredients were used toxicological profiles of the impurities and related substances would be required. We also insisted that limits controlling levels of impurities such as TEPP should be tightened.

I hope this answers your question and that you are assured that improvements were made to the safety of OP dips. Indeed that process has not stopped in the sense that we have continued requiring companies to improve the safety of these products in the light of improved scientific knowledge and expertise. For example, not only have we continued with scientific research, practical safety measures such as improved labelling has been introduced and the Government has required companies to introduce closed transfer systems (which minimise operator exposure to concentrate). The first of these new systems is expected to be available on the UK market place shortly."

<u>Potentially very broad request</u>

We want to be as open as possible in answering requests. However, we believe that your request is potentially very broad and gathering the information together could involve a significant cost and diversion of resources from the Agency's other work even taking into account your areas of special interest.

Section 12(1) of the FOIA allows us to refuse a request for information if we estimate that the cost of complying with the request would exceed the appropriate limit, which currently stands at £600. On the basis of our estimates, we consider that the cost would exceed this limit and, as such, we are refusing your request as you currently frame it.

New request

But we do want to help you obtain the information you are looking for if we can. If you were to make a new request for a narrower category of information, it may be that we could comply with that request within the appropriate limit, although I cannot guarantee that this will be the case.

In reframing your request you may want to look at the information already available on the VMD website and consider the background information above. Sheep dip material is on our website at:

https://www.gov.uk/government/organisations/veterinary-medicines-directorate

Considering commercially sensitive data

In reframing your request you may also want to take into account that we may not provide information we regard as commercially sensitive data, for example product related information. In these circumstances, we may consider that Section 43 of the FOIA would apply to such information and that it would not be in the public interest to release it. Section 43 exempts information whose disclosure would be likely to prejudice the commercial interests of any person.

We decide this on a case by case basis but as a guide it is useful to understand that companies are obliged to provide certain information related to their commercial arrangements to the VMD as part of the regulatory system. Such information is vital for the VMD and we must be able to ensure that companies provide the information in the knowledge that we will not release it. Publishing such information could undermine the veterinary pharmaceuticals industry's trust in the regulatory process as well as the companies' commercial position. This could lead to companies becoming unwilling to place product on the UK market, which would have a detrimental impact on animal welfare.

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Our Service

If you are unhappy with the service you have received in relation to your request and wish to make a complaint, you may request an internal review within two calendar months of the date of this e-mail. If you would like to request an internal review please write to [Redacted under section 40 of the FOIA] at the VMD via ati@vmd.defra.gsi.gov.uk. If you are not content with the outcome of the internal review you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office
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