

Policy Statement

The use of Organophosphate sheep dips and implications for operator safety

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The voice of British farming

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NFU Policy Statement on the use of organophosphate sheep dips

The NFU has considered the recent scientific literature review carried out by the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) on the long-term neurological, neuropsychological and psychiatric effects of low-level exposure to organophosphates in adults. Upon reviewing the literature, COT have stated that, *‘Collectively, the evidence is reassuring. It suggests that exposures to cholinesterase-inhibiting organophosphates that are insufficient to cause overt acute poisoning do not cause important long-term neurological toxicity in adults, and that if toxic effects on the nervous system do occur then they are minor and subtle’*.

The NFU has put a huge amount of time and effort into this issue over the years but despite this, neither the NFU nor anybody else has been able to establish a causal link between health problems and use of organophosphate (OP) sheep dips. Without that causal link we do not have evidence to pursue legal damages, or a ban on OP sheep dips.

This document provides the NFU’s policy position, as informed by the COT’s conclusions, on the health implications surrounding the use of OP sheep dips.

NFU policy position

“The NFU is a membership organisation and the health and safety of our members and consumers is of paramount importance.

“Improving and protecting the health and welfare of the national sheep flock is a priority and as members of SCOPS (Sustainable Control of Parasites in Sheep) and RUMA (Responsible Use of Medicines in Agriculture Alliance), the NFU views the appropriate and responsible use of veterinary medicines by our farmer members as a major commitment to this objective.

“Ectoparasitic diseases of sheep such as blowfly strike, ticks and scab infestation, can be truly horrific and organophosphate dips are currently the most effective veterinary medicinal product available in the fight to control and prevent infestation.

“Organophosphate dips can be dangerous chemicals if not used correctly or safely.

“Under the Veterinary Medicines Regulations 2013, it is an offence to use sheep dip unless this is done by, or under the supervision and in the presence of, a person who holds either a Certificate of Competence in the Safe Use of Sheep Dips showing that Parts 1 and 2 or units 1 and 2 of the assessment referred to in the Certificate have been satisfactorily completed, or NPTC Level 2 Award in the Safe Use of Sheep Dip (QCF). This ensures that the dip user understands the safety precautions and licence conditions of the OP product.

“The NFU is guided by the scientific and regulatory advice given in relation to OP products and acknowledges the conclusions of the scientific review undertaken by the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) in relation to the toxicological risk to humans of low-level exposure.

“The NFU would welcome any research into alternatives to OP products.”

The background and context

Organophosphates are a class of chemicals, some of which can bind to and inactivate an enzyme, acetylcholinesterase, which is important to the function of the nervous system. This property has

been exploited in their use as insecticides in agriculture and horticulture, as veterinary medicines to prevent or treat infestations (e.g. sheep dips), as human medicines (malathion only – as a treatment for head lice), and as public hygiene products (e.g. for control of cockroaches). However, to people who are exposed to them inadvertently during their manufacture or as a consequence of their use, this can represent a health risk. In addition, intentional human poisoning has occurred as a result of deliberate self-harm, and through the use of different formulations of organophosphates as chemical warfare agents.

The farming sector has a long history of association with organophosphate chemicals and some commentators, especially those actively involved in sheep production in the 1970s and 1980s, have speculated that previous use of these chemicals has resulted in demonstrable human health impacts.

A major effort to eradicate sheep scab was undertaken between 1976 and 1992. This included compulsory supervised national dipping using sheep dips during specified periods, movement controls, and segregating dipped and non-dipped sheep in markets. Fleece samples were checked for evidence of dipping. Where outbreaks occurred, there was full tracing of contact sheep by the State Veterinary Service. (The majority of the dips used during the 1970s were Organochlorine based (such as Lindane) rather than Organophosphate based).

Scab eradication was not achieved despite this intensive effort. The reasons were linked to an increase in the size of the national flock (from 27 million in 1976 to 45 million in 1992), greater movement of sheep around the country and a lack of treatment by some sheep farmers.

In 1992 dipping ceased to be compulsory and sheep scab was removed from the notifiable list of diseases. Farmers were still obliged to deal promptly and satisfactorily with any outbreak of scab in their flocks. The Sheep Scab Order, which gave powers to Local Authorities to investigate cases of scab and to require control measures under the supervision of a private veterinary surgeon, was introduced in 1997. This introduction was at the industry's request so that it could deal with those less responsible individuals who did not treat their sheep against scab. The Order made it an offence for sheep farmers to have sheep with scab and not treat the whole flock.

In December 1999, following advice from the Veterinary Products Committee (VPC) about possible human health risks posed by the design of existing containers, OP sheep dips were removed from the market. However, alternatives were limited, being mainly synthetic pyrethroids which can have very damaging environmental impacts, especially for the wildlife of watercourses. (Synthetic pyrethroid dips (Novartis's Robust, Virbac's Auriplak and Bimeda's Ecofleece) had their marketing authorisations suspended in 2006 due to ecotoxicity concerns surrounding the products).

In July 2000 the VPC advised that in the short term OP sheep dips should be permitted to return to the market in their existing containers with the addition of a vented tap, whilst long-term improvements were developed that would minimise the risks of operator exposure to OP concentrate. This advice was based on a balanced risk assessment that took into account animal welfare concerns about the increasing incidence of sheep scab.

In June 2001 the VPC considered proposals from three manufacturers for closed transfer systems, i.e. improved container design. VPC advised Ministers that, subject to resolution of a number of issues, all of these were capable of meeting the objective of minimising operator exposure to OP concentrate.

In September 2001, the Government suspended the marketing authorisations for OP sheep dips, pending satisfactory completion of plans being developed by marketing authorisation holders for closed systems for transferring OP dip concentrate from the container to the dip bath. This action was taken in line with advice from the VPC.

Defra announced in November 2001 that 2 OP sheep dip products had received approval to return to the market based on the incorporation of a closed transfer system.

The two products incorporating the approved closed transfer systems were Osmonds Gold Fleece Sheep Dip, marketed by Bimeda and Coopers Ectoforce Sheep Dip, marketed by Schering Plough. These products were available to farmers in November 2001 and later joined in the market place by Paracide Plus, marketed by Animax Ltd.

Current OP dip products

The Veterinary Medicines Directorate's list of veterinary medicinal products authorised for use in the UK against ectoparasites in sheep (revised 15th May 2012) includes 2 OP sheep dips:

- Paracide 62, marketed by Animax Ltd (70 day withdrawal); and
- Osmonds Gold Fleece™ Sheep Dip, marketed by Bimeda (49 days withdrawal)

The active ingredient of Paracide 62 and Osmonds Gold Fleece is Diazinon, a broad-spectrum organophosphorus (OP) insecticide used for external parasite control on sheep, cattle and companion animals.

The science base underpinning the NFU's policy statement

The UK Government asked the COT to consider whether prolonged or repeated low level exposure to organophosphates, or acute exposures to organophosphates at levels insufficient to cause overt toxicity, could cause long-term adverse health effects.

In 1999 COT published an initial report and identified the need to address research gaps in five different areas. After consideration, Government was of the opinion that research projects to address two of the questions had already been commissioned prior to publication of the COT report. The remaining three recommendations were advertised in the Ministry of Agriculture, Fisheries and Food (MAFF) Research Requirements 2000-2001. As a result, a total of six research projects were commissioned which addressed COT recommendations, with a seventh on the effects on children and in utero exposure.

Subsequently, ten further research projects were commissioned by Government, with COT asked to advise on the significance of these research findings.

COT's first review was presented in 2007. As some of the research projects were still in progress, COT advised that it would need to revisit all of the work once the final reports were available. Furthermore, as other work had been published in the scientific literature, including uses of OP insecticides other than in sheep dips, COT stated that its advice could only be finalised in the context of consideration of all the available relevant research.

At that stage COT concluded that:

- Research to address "How common is dipper's flu and what causes it?" had not provided evidence for a flu-like condition related to sheep dipping.
- Two other projects indicated that those who metabolise OPs faster than the 'norm' were more likely to report ill-health. This was the reverse of the hypothesis tested.

COT 2014 conclusions

The working group within COT (comprising the COT Chairman and one other member of COT, along with four external scientists who were judged to bring special expertise) carried out a systematic review of relevant research that had published in peer-reviewed scientific journals up to September 2013. Preliminary consideration indicated that the most pertinent evidence would come from epidemiological investigations in human populations, and that toxicological studies in animals and in vitro would be less telling. The search was therefore limited to studies in humans; reports of other types of research were not reviewed systematically.

Since 1999, thirteen new papers have been published on the relation of low-level exposure to organophosphates to peripheral neuropathy (i.e. impaired function of the nerves outside the brain and spinal cord). These added to thirteen studies that were already available at the time of the last COT report. COT's literature review conclusions are listed below:

- COT state that the evidence suggests that there is no long term risk, through low level exposure, of obvious damage to the peripheral nerves in hands and feet – this conclusion has been strengthened with time.
- There is uncertainty as to whether long-term low level exposure to OP causes detectable impairment of the process which triggers nervous impulse going from the periphery of the body inwards to the brain or spinal cord. COT suggests that, 'If there is an effect, it is likely to be small'.
- Few studies have looked for effects of low-level exposure to organophosphates on background patterns of electrical activity in the brain (electroencephalography or EEG), patterns of brain activity in response to standardised sensory stimuli (event-related evoked potentials), or the electrical activity in muscles (electromyography or EMG). In general, COT commented that these studies, 'do not suggest a hazard, but the evidence base is slim'. One study suggested impairment in the brain's processing of auditory information, but without independent replication, COT stated that, 'little can be drawn from this isolated finding'.
- Overall, COT have found there is no consistent evidence of low-level exposure to OP having adverse effects on any specific aspect of cognitive function. If low-level exposure to OPs does cause long term brain function impairment, then the effects, at least in the majority of cases, must, COT concluded, be 'minor and subtle'.
- COT comment there is insufficient evidence to conclude that, in the absence of acute poisoning, low-level exposure to OP can cause long-term structural changes in the brain.
- The evidence from eleven studies suggests no increased risk of Parkinson's disease from exposure to OP that is insufficient to cause overt acute poisoning, although a small elevation of risk cannot be ruled out.
- Findings from the only two studies on the relation of OP to later dementia are not strongly suggestive of a hazard, but point to the need for further research. This, COT state, should be conducted only through studies with adequate rigour and statistical power.
- Fourteen studies have investigated the association of low level exposure to OP with common mental disorders such as depression and anxiety. Overall, there is no consistent evidence of a link. The balance of evidence led COT to suggest that low-level exposure to OP does not lead to an increased risk of suicide.

- COT found that current evidence suggests that there is an ‘excess’ of multiple neuropsychiatric symptoms in people who have been exposed to OP at levels insufficient to cause overt acute poisoning. However, evidence does not support the existence of a specific syndrome of “chronic organophosphate-induced neuropsychiatric disorder” (COPIND) as has previously been hypothesised. (COT comment that it is unclear whether the observed ‘excess of symptoms’ is a consequence of chemical toxicity or occurs through psychological mechanisms, and suggest it is possible that people who are aware of having been exposed to potentially toxic chemicals are more inclined to notice and report symptoms. Studies on the relationship of symptoms to polymorphisms and activity of the enzyme, paraoxonase (PON1), have not clearly established a causal link with poorer capacity to detoxify organophosphate compounds.)

COT’s final concluding statement is that it seems unlikely that further research on neurophysiological, neuropsychological and psychiatric outcomes would identify any important hazard from low-level exposure to organophosphates.

NFU actions and conclusions

The NFU is science led when forming policies so COT’s conclusions are significant. We have also considered our previous support for members’ claims in terms of legal enquiries and obligations.

Under the Veterinary Medicines Regulations 2013, it is a legal requirement that the purchasing and use of OP sheep dip occurs under the supervision of someone holding an NPTC Certificate of Competence in the Safe Use of Sheep Dips as a very minimum measure of competence. In addition, the innovations in improved container design (closed transfer systems) and the very clear instructions on providing high levels of operator safety (protective clothing, safe storage and dosage and administration), coupled with the medical advice on product datasheets provides reassurance that there is currently sufficient safety margin to allow sheep farmers and their workers to take responsible precautions to protect themselves from what are widely acknowledged as hazardous chemicals.

The NFU has also considered the legal context. A group of farmers took a case to the High Court in 2002 seeking damages for OP poisoning. Considerable effort and resources were allocated on the case, including on a health pilot study to identify if there was a link between OPs and the range of symptoms presented amongst the group. Ultimately however, the High Court struck the claims out. The principal issue was causation – the claimants could not prove that their symptoms were caused directly by exposure to OP dips. The court’s decision to strike out was appealed, but it was later upheld by the Court of Appeal.

This legal history is a really important consideration in providing the NFU’s policy direction. It was mentioned in the court transcript that over £1m had been spent in legal aid funding the claimants and the group litigation.

The NFU recognises, and sympathises with the conviction of some sheep farmers in holding previous exposure to OP dips accountable for various degenerative health problems. However, substance to these conclusions has not been found in science or the legal courts.

As we understand it, the COT findings will inform, but not dictate, the Government’s future policy on OP sheep dips and we will therefore, continue to monitor and consider our policy position in light of any future Government announcements.

Pertinent references and websites

In developing this policy statement, various external websites and resources have been used as information sources and references.

The main ones are:

1. Veterinary Medicines Directorate – Advice on the use of sheep dips and other related information pages http://www.vmd.defra.gov.uk/mswd/sheepdip_advice.aspx
2. The Veterinary Medicines Regulation 2013 <http://www.vmd.defra.gov.uk/public/vmr.aspx>
3. The Committee of Toxicity of Chemicals in Food, Consumer Products and the Environment <http://cot.food.gov.uk/>
4. The COT Statement on Organophosphates <http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2014/cotstatorg>
5. The Health and Safety Executive Sheep dipping - Advice for farmers and others involved in dipping sheep <http://www.hse.gov.uk/pubns/ais41.htm>
6. The National Office of Animal Health – ‘Organophosphates’ <http://www.noah.co.uk/issues/ops.htm>
7. AHVLA – ‘Sheep Scab’ <http://www.defra.gov.uk/ahvla-en/disease-control/notifiable/sheep-scab/>
8. Snell & Ors v Robert Young & Co Ltd. & Ors [2002] EWCA Civ 1644 (21 November 2002) <http://www.bailii.org/cgi-bin/markup.cgi?doc=/ew/cases/EWCA/Civ/2002/1644.html&query=snell+and+others&method=boolean>