KEEP ANIMALS OUT OF REACH:
Supplementary report on Acute Toxicity Testing

EXECUTIVE SUMMARY

In this report, Animal Defenders International, the National Anti-Vivisection Society, and the Lord Dowding Fund for Humane Research, present compelling evidence to show why the acute toxicity tests in the REACH proposal should adopt a non-animal approach.

Our evidence is based on leaked photographs and documents from Inveresk Research International, a contract testing laboratory based near Edinburgh in Scotland. The leaked information sent to ADI includes a horrific report of an acute toxicity test undertaken in rats to obtain safety data for an anti-fouling paint.

On behalf of their client, Hempel's Marine Paints A/S, Denmark, Inveresk subjected 10 rats to a test atmosphere containing aerosolised Hempel's GLOBIC SP-ECO 81900 anti-fouling paint at a high concentration. This was in order to investigate the paint's acute inhalation toxicity following a single 3-hour exposure.

Slow and laboured respiration was seen from approximately 30 minutes into the exposure period in all animals. 3 males and 3 females were found dead between 1 to 3 hours after dosing commenced. The remaining 4 animals were killed post-dose.

The mortality rate as a result of exposure to the paint was therefore 100%. The only conclusion that could be drawn from this experiment was that the paint showed significant toxicity. A value for the lethal concentration which would result in the death of 50% of the animals (LC_{50}) could not be established. No other conclusions could be drawn.

In our report, ADI discusses the conduct of the experiment, and the data which was already available at the time which could have prevented the substantial, prolonged, and unnecessary suffering of these animals.

We analyse the experiment in the context of the Annex V proposals, and explain why it should never have been allowed to take place.

The need for stringent application of the provisions of Annex IX of REACH, which indicate the circumstances under which testing should be waived, is also discussed and highlighted by our evidence.

This evidence shows:

- The extent of the pain and suffering inflicted on the rats as a result of this experiment (see p.9)
- The experiment's unreliability in terms of:
  - species differences (p.9)
  - relevance to the human situation (see p.10)
  - experimental procedure (p.10)
  - discrepancies in the experimental report (see p.12)
- The experiment's unacceptability in terms of:
  - animal suffering (see p.13)
  - UK and European legislation (see p.14)

- Why the experiment was unnecessary and unjustifiable in terms of:
    - Annex IX (p.14)
    - available evidence of existing data from acute inhalation studies undertaken before 1999 on complete products and ingredients which were the same as, or similar to, those found in GLOBIC SP-ECO 81900 (pg. 15-19)
    - the Dangerous Preparations Directive (1999/45/EC) (pg.20)
    - the alternative, non-animal, testing methods available (pg. 21)

Upon consideration of this evidence, Animal Defenders International is able to conclude overall that:

- **on the basis of pre-1998 LC_{50}s on two ingredients making up about 50% by weight of the paint, *and***
- **if it is legitimate to apply EC recommendations found in Annex 1b (section 2) of the REACH proposal regarding DNELs and PNECs to LC50s,**

the particular experiment described in this report could not be justified, and would have been waived under REACH by applying criteria set out in Annex IX clause 1.1 (use of existing data), as cuprous oxide and xylene - making up approximately 50% by weight of the paint - were present in the test atmosphere at a combined concentration twice that of their LC_{50}s, and cuprous oxide was present at approximately 158% of its LC_{50} value.

Thus it could have been **predicted** that the concentration of paint used would cause 100% mortality, based on these two ingredients alone (pg. 16-17); there was no need for the rat test to take place.

There was also **existing human data** for one ingredient – xylene – which showed that even the test atmosphere paint concentration stated to be recommended in the protocol (5 mg/litre) would have had a xylene concentration well above that which has been observed to cause toxicity in humans (pg. 18-19).

The symptoms observed in the Inveresk experiment were also consistent with those **previously reported** for xylene in rodents and humans (pg. 18).

Under the REACH proposals, it is clearly possible for this type of unacceptable situation to occur again – where chemicals whose ingredients have already been tested are re-tested as complete products.

In order to obtain the required safety information on these chemical substances, millions of animals will be used. The aims of REACH are to protect human health and the environment, and to minimise animal suffering. At this late stage in the REACH programme, the only people with the capacity and ability to ensure that these aims are fulfilled are the parliamentarians.

Upon consideration of our evidence highlighting the extent of the problems associated with conducting animal tests, we are therefore calling upon the European Parliament to:

- **vote against** the amendment to include an animal test for acute toxicity in Annex V;
- **vote in favour** of MEP Caroline Lucas' non-animal alternative strategy, which not only proposes and justifies alternatives to animal tests for acute toxicity, but also alternatives to the skin sensitisation, reproductive toxicity, eye irritation, and repeated dose toxicity animal tests, amongst others; and
- **ensure that** the legislation in place actively enforces the implementation of Annex IX to the REACH programme

As it now stands, REACH will bring about the painful deaths of millions of animals, in experiments that are unreliable, unethical, and unnecessary, and the REACH programme will fail to achieve its objectives anyway.

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