THE USE OF ANIMALS IN TESTING HOUSEHOLD PRODUCTS

A Discussion Paper and Statement of Principle

THE BOYD GROUP

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THE BOYD GROUP is a forum for open exchange of views on issues of concern related to the use of animals in science. Participants in the Group span a range of expertise and perspective. They include veterinarians, scientists using animals (from industry and academia), members of animal welfare organisations, anti-vivisectionists, members of government and charitable bodies funding or directly engaged in research, philosophers and others.

The Group's objectives are:

(i) to promote dialogue between these diverse people and organisations;

(ii) to clarify key issues of concern identified by participants, and to reveal the basis of the different opinions and beliefs; and

(iii) where possible, to identify points of consensus and make practical recommendations.

The discussion paper was prepared by Maggy Jennings and Jane A. Smith on behalf of the Boyd Group, drawing on points made in debate within the Group as well as contributions from participants with particular expertise, and has been agreed by all participants in the Group. The statement of principle was drawn up by the Group following exhaustive discussion of the issues.

ACKNOWLEDGEMENTS

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1. INTRODUCTION – WHAT NEXT AFTER COSMETICS?

In 1997, the UK Government announced an end to the use of animals in testing finished cosmetic products. In 1998 this was extended to include cosmetic ingredients as well. Both steps were achieved through voluntary agreements with the contract testing organisations that carried out this type of work (Home Office 1999). Project licences will no longer be issued for testing cosmetics ingredients or finished products.

The use of animals for testing cosmetics and toiletries has been a controversial issue for many years, largely because these products are widely seen as inessential luxuries, and hence the animals used in testing them suffer for human vanity. A Boyd Group discussion paper explores the particular reasons for concern, and is available via the Group's web-site (www.boyd-group.demon.co.uk). The paper covers issues relating to the nature of the products, the reasons why animal tests were carried out in the UK, and still are carried out abroad, the regulatory process, alternatives, and the impacts of the tests on animals.

Cosmetics, however, are only one of the many classes of non-medical products that are tested on animals. Animal tests are an integral part of pre-marketing safety assessment for the vast majority of new chemical substances, whatever type of product they are destined for. Home Office data show that animals are used in toxicology or other safety/efficacy evaluation not only of "substances used in the household", but also of substances used in agriculture, industry, food additives and other foodstuffs, as well as of substances that may be pollutants (see Home Office 2002).

Many of the issues and concerns addressed in the Boyd Group's paper on cosmetics testing are also relevant to other categories of product, and several animal protection groups have singled out household product testing as the next area in which to campaign to achieve a ban on the use of animals. The Government has also said that it is exploring "*the feasibility of a ban on testing finished household products on animals*". However, no-one has yet defined the sort of products which would be included in such a ban, nor explained why these should be selected rather than any other category of product. The Boyd Group therefore decided to consider the issues raised by the use of animals in household product testing and whether it would be feasible to advise that use of animals in testing these substances should, like cosmetics, be banned in the UK.

2. THE BOYD GROUP'S CONCLUSIONS – A STATEMENT OF PRINCIPLE

After exhaustive discussion of the issues, the Boyd Group drew up the consensus statement of principle shown overleaf. Note that the statement is about finished product, not ingredients, testing. This paper provides background information to support the Group's statement and explores some of the issues addressed in discussion of the desirability and feasibility of a ban on the use of animals in testing household products in the UK. Several difficulties were identified in discussions leading to the preparation of this statement and these are explored in the paper. One organisation, although supporting the aims of the statement, felt that these difficulties had not been resolved satisfactorily, for the reasons given in Note 1 on page 3.

USE OF ANIMALS IN HOUSEHOLD PRODUCT TESTING

A statement of principle from the Boyd Group, December 2002

1. Members of the Boyd Group are agreed that when the cost-benefit analysis required under the Animals (Scientific Procedures) Act 1986 is applied to the use of animals in testing finished products, there are strong ethical reasons to take into account not only the need to ensure the safety of the products when they are marketed, but also the potential need for the products themselves.

2. Members believe that it is unacceptable to use animals in developing and testing new products that are widely perceived to be convenience products for which there is little potential need because similar non-medical products with adequate efficacy are already available. The consensus within the Group is that animals should not be used in tests on another variety of infant nappy, another washing powder, or any other kind of finished "household product" and that such tests ought not to be allowed in the UK (but see also note 1 opposite).

3. In practice, it is possible to avoid using animals in assessing the safety in use of most household products, since
   (i) there are no regulatory requirements to test finished household products except under the new EU Biocidal Products Directive, and
   (ii) risk assessments are usually made using knowledge of the toxicity of the products' ingredients and their synergistic effects, enabling proper classification and labelling of the products under regulations administered by the DTI.

   In the relatively rare cases where such predictions are not possible, members of the Group believe that the new household products should be foregone (see note 1).

4. Whilst it is difficult to come up with a clear-cut, categorical definition of a household product, it is evident that any such ban on animal testing would apply to all products that are intended for use in the home and widely available in supermarkets, general and DIY stores. This would cover:
   - detergents and other products for use in laundry (including stain removers) and dishwashing (including rinse-aids, dishwasher cleaners)
   - household cleaners for ovens, baths, toilets, surfaces, windows, cars and similar
   - air-fresheners, toilet blocks and similar
   - polishes for furniture, cars, shoes and similar
   - paper products such as infant nappies, sanitary towels, tissues and hand-towels
   - paints, glues (and removers), and other furnishing and DIY products intended for use in the home
   - household pesticides (which are mostly milder re-formulations of agrochemicals that have already been tested according to regulatory requirements, and so should not require further testing).

5. Although relatively few animals are used in testing finished household products in the UK (see note 2 opposite), a ban on such testing would spare these animals, and would serve as a statement of principle by the UK, that could help to open up debate on the morality of using animals to test finished non-medical products more generally, and might spare animals abroad in the longer-term.

6. The Group recognises that a unilateral ban on animal testing of household products may not be the most effective practical means of safeguarding animals and enhancing their welfare, since other countries continue to allow such animal tests, and testing may simply be exported from the UK. For these reasons, the UK Government should accompany such principled action with vigorous efforts to encourage its partners and other states to implement similar bans on animal testing of new household products - as well as other products that are widely regarded as luxuries or convenience products (such as cosmetics).

7. On the last point, the UK and other influential countries should make strenuous efforts to ensure that global regulatory requirements for animal testing move away from a prescriptive tick-box approach, to one that promotes "sensible toxicology" and so allows the use of animals to be reduced, refined, or avoided altogether. In particular, they should demand that
   (i) regulatory acceptance of validated non-animal alternative tests be expedited, and
   (ii) studies that toxicologists widely regard as unnecessary, and that are therefore carried out solely to meet regulatory requirements rather than assess safety, be eliminated from the regulations.

NOTES ON THE STATEMENT OF PRINCIPLE:

1. One organisation, although supporting the aims of the statement, feels that the difficulties alluded to in it, and explored in the following discussion paper, have not been satisfactorily resolved. In particular, that (i) a ban on animal tests of finished household products in the UK could encourage companies to test products under less regulated circumstances overseas (see point 6 in the statement), if it was felt that toxicity could not be reliably predicted from that of the ingredients and that there might be hazards for consumers and (ii) that a unilateral ban could reduce the UK's ability to influence policy in other countries (see point 5 in the statement). For these reasons, the organisation argues instead that all proposed animal tests of finished household products in Britain should be referred to the Animal Procedures Committee on a product-by-product basis, for rigorous cost-benefit analysis. The APC advises the government on implementation of the Animals (Scientific Procedures) Act 1986 and would bring a range of perspectives to bear, including the views of anti-vivisectionists, animal welfare, science and industry, and informed public opinion.

2. In Britain in 1999, 341 animals (all rats) were used to test "substances intended for use in the household". In 2000 the number of animals used for this purpose rose to 1242, including 179 rats, 534 guinea pigs, 169 rabbits and 360 fish; and in 2001, 590 animals were used: 376 rats, 176 guinea pigs, and 38 rabbits. (*Source*: Home Office 2000, 2001a and 2002).

As is the case for all non-medical substances, it is impossible to tell from the Home Office statistics how many animals are used in tests of finished products and how many in tests on ingredients. For all non-medical substances, it would be more meaningful if the Home Office statistics listed the number of animals involved in tests on finished products and ingredients separately, sub-dividing each category into the various regulatory or other reasons for the tests, and noting how many different substances are actually tested.

3. DEFINITION OF A HOUSEHOLD PRODUCT

Although individuals and companies all have their own fairly clear notions of what they mean by a "household product", no standard, easily applicable, comprehensive definition is available.

Practical definitions: A glance at any supermarket shelf shows that a wide range of products could be considered to be for use in the household - not just detergents and cleaning products. Such products include:

- detergents and other products for use in laundry (including stain removers) and dishwashing (including rinse-aids, dishwasher cleaners, impregnated scouring pads)
- household cleaners for ovens, baths, toilets, surfaces, windows, cars and similar
- disinfectants - bleach, fungicides - toilet blocks and similar
- air-fresheners
- polishes for furniture, cars, shoes and similar
- paper products such as infant nappies, sanitary towels, tissues and hand-towels
- paints, glues (and removers), and other furnishing and DIY products intended for use in the home
- household pesticides, e.g. fly/wasp/ant killers, houseplant sprays (which are mostly milder re-formulations of agrochemicals - see section 4.1.3).

To explore the question of definition, the Boyd Group contacted six contract-testing organisations (CROs) and three major manufacturers of household products (two making own-label products, the other manufacturing for other retailers) in the UK. All of the companies seemed to have working, but not all-embracing, categorical, definitions of what they mean by a household product. For example, one contract testing organisation, which has decided that it will not test household products or ingredients, referred to "cleaning products, polishes, air fresheners and other similar supermarket goods", but noted that, "We see potential difficulties in agreeing watertight definitions and will therefore deal with such situations case-by-case. Where there is any doubt as to the definition of a particular material, such cases will be reviewed by the ethical review process".

The two own-label manufacturers of household products define these according to the business area they fall into, which leads to several definitions, for example:

"Fabric and home care"	Dishwashing detergents
	Household cleaners
	Laundry detergents
"Tissue and towel products"	i.e. paper products

The other manufacturer defines household products as those "not covered by specific regulations", i.e. products not covered by cosmetics, pesticides or biocides, medicines, pharmaceuticals or medical devices regulations. These exclusions leave products that have broadly similar uses but that might be employed in different settings - i.e. home, institutional (schools, hospitals etc) and industrial settings (e.g. de-greasers). Therefore, an element of judgement is still required. Note that this definition would exclude pesticides, such as fly sprays, used in the home.

Legislative definitions: There is no definition of a household product in any legislation. This is different from cosmetics and toiletries, which are defined by the EU Cosmetics Directive.

Home Office definition: In the UK Home Office Statistics, data on the use of animals for toxicological or other safety/efficacy related purposes are classified according to the nature of the substance tested. "Substances used in the household" is a separate category and the figures include tests on both finished products and their constituent ingredients although these are not recorded separately (see section 4.3 for further discussion). However, there is no definition of the kinds of substance that fall into this category and it is left to holders of safety testing project licences to decide how to classify their use of animals when they make their annual statistical returns to the Home Office. It is recognised that any one substance may be used in more than one different type of product, e.g. in industry, agriculture or the home, but the project licence holder classifies the use of animals according to the particular context and the expected primary use of the product. Some other European countries have a similar categorisation system.

4. BACKGROUND INFORMATION

4.1 Purpose of animal tests on household products and ingredients

4.1.1 *General comments*

The general purpose of testing household products and their ingredients is the same as that of testing all other non-medical products and ingredients. The tests are carried out as part of the overall safety and risk assessment of the substances, and, in the case of products such as pesticides and rodenticides, to assess efficacy. The majority of tests are done to meet international legislative/regulatory authority requirements, which are intended to protect the consumer, the workforce and the environment.

When looking at the reasons for animal tests it is important to distinguish between tests on finished products and those on their chemical ingredients.

4.1.2 *Testing chemical ingredients*

All new chemical substances, *whatever* products they might eventually be used in, have to be tested according to certain legislative requirements before they can be marketed. These legally required tests are intended to provide data for risk assessments, aimed at protecting:

- the workforce which manufactures and supplies the new chemical;
- workers who use the new chemical in manufacturing other products;
- the environment;
- consumers and others who may be exposed to the chemical when products containing it are marketed and used.

Within the EU, the most significant legislation is Directive 67/548/EEC, on the Classification, Packaging and Labelling of Dangerous Substances, together with its subsequent amendments and annexes. Annex V of the Directive sets out legally binding EU standardised animal (and other) testing methods, intended to determine the hazardous properties of new chemicals. These EU test methods are consistent with international Organisation for Economic Co-operation and Development (OECD) guidelines, which cover tests carried out in all OECD countries.

The Directive 67/548/EEC requires manufacturers and suppliers in each EU country to notify a Competent Authority (CA) of any new chemical substance. They must provide the CA with an information dossier about the properties of the new substance, including the results of animal tests carried out according to Annex V protocols, and draft risk assessments. In the UK, under the Notification of New Substances Regulations 1993 (NONS), the Competent Authority is the Health and Safety Executive and the Environment Agency acting jointly. Once the CA has evaluated the notification dossier, it is forwarded to the European Chemicals Bureau (ECB), which maintains databases of information on both new and existing substances.

In recent years, the ECB has dealt with data from around 300 to 350 new substances per annum. Most such notifications come from the UK (28% - i.e. around 80 to 100 new chemicals per annum), followed by Germany (25%) and France (12%). Figure 1 (opposite) shows the range of purposes for which the new substances are used. Note that many of the chemicals - e.g.

colouring agents, stabilisers, odour agents - could be used in manufacturing a variety of different products, and it is usually difficult to predict all the likely end-uses of new chemicals when they are first manufactured, tested and marketed. Figure 2 (below) illustrates the diversity of industrial areas in which the new chemicals are used.

Figure 1: Uses of new chemical substances notified to the European Chemicals Bureau
Source: European Chemicals Bureau (2002)

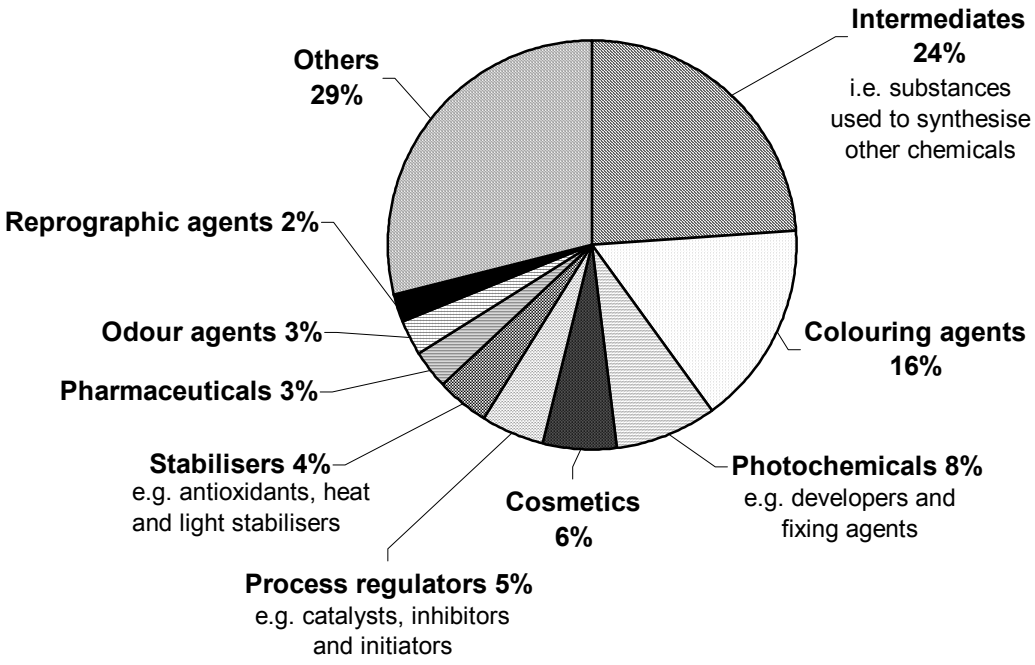
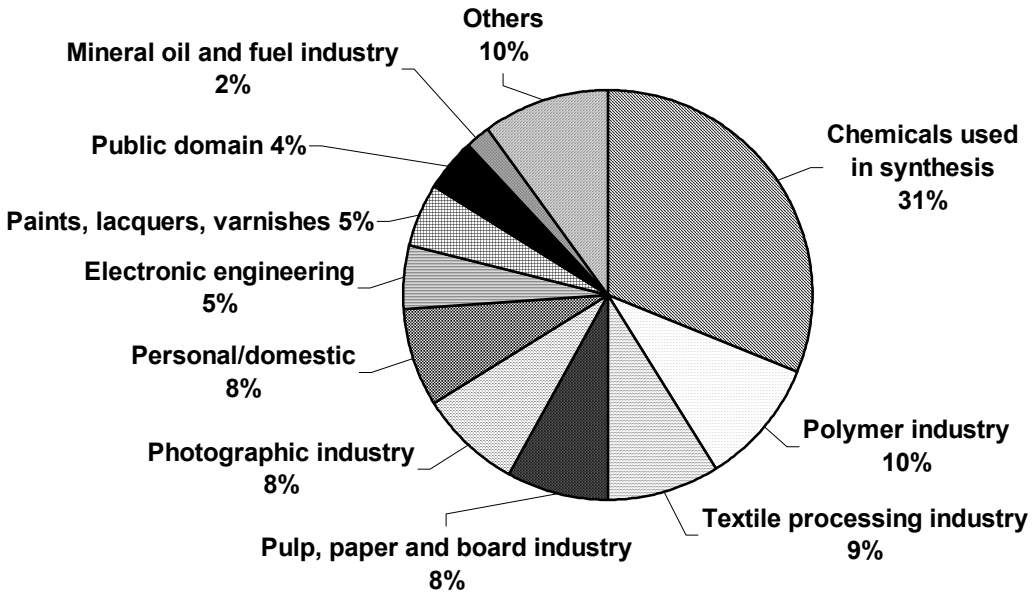


Figure 2: Industrial areas in which new chemical substances notified to the ECB are used
Source: European Chemicals Bureau (2002)



The Dangerous Substances Directive requires testing of *new* substances (i.e. those not on EINECS, the European Inventory of Existing Substances), but imposes no obligation to test existing substances. Several recent developments, however, are likely to require testing of *existing* substances, in the immediate future:

- high production volume (HPV) chemicals screening programmes, which aim to collect data on health and environmental effects of all chemicals produced in high volume (mainly chemicals used in industry), and will require tests to fill gaps where data are missing or unavailable;
- the endocrine disruptor screening programme in the US and possibly similar in the EU, aimed at assessing the effects of chemicals on the hormonal systems of humans and wildlife; and
- an EU White Paper on the Strategy for a Future Chemicals Policy (February 2001), which may lead to legislation requiring the testing of substances already on the market for which safety data are deemed inadequate.

If these programmes are implemented as currently written, many tests will have to be carried out on existing chemical substances - even those that have been in general use for years, and including many chemicals used in household products. This will result in a huge increase in the number of animals used. For example, draft proposals for an EU Chemicals Strategy could require the use of up to 10 000 000 animals within the EU.

4.1.3 *Testing finished products*

Unlike new chemical ingredients, there are no specific legal requirements to carry out particular animal tests on finished non-medical products in order to assess safety and/or efficacy - with the exception of pesticides and other products that have biocidal activity.

In the UK, the Chemicals Hazard Information and Packaging for Supply Regulations 1994 (CHIP) require suppliers of all products throughout the supply chain, regardless of the quantity manufactured and marketed (with a few exceptions such as medicines and cosmetics which are covered by other regulations) to:

- provide information about the hazards that the products pose;
- classify the products according to the nature and degree of hazard;
- package them safely; and
- label them appropriately.

In the case of consumer products, the Department of Trade and Industry's Consumer Safety Unit is responsible for administering CHIP.

Where household products are concerned, manufacturers can usually predict the likely risks posed by the finished products using knowledge of the toxicity of the ingredients and their synergistic effects - and carrying out a "conventional calculation" laid out in CHIP. UK manufacturers say that they carry out animal tests on finished household products only rarely, if ever - when, for example:

- the CHIP conventional calculation and their own toxicological assessments are significantly different; or

- when foreign regulatory authorities require specific tests relating to the safety of the workforce in the country in which such products are being manufactured (e.g. testing carried out by a UK multinational in Japan, under Japanese regulations aimed at protecting the Japanese workforce).

In the case of household pesticides, which are covered by pesticides regulations, these are mostly milder re-formulations of agrochemicals that have already been tested, and so should not require further testing.

Some animal experiments may also be carried out to understand the mechanisms underlying toxicity and to develop treatments in the event of accidental poisoning. In addition, the new EU Biocidal Products Directive may require animal tests of finished household products that have biocidal activity - e.g. surface cleaners.

4.1.4 *Cosmetics compared with other non-medical products*

There is an important difference between cosmetics and other products. With a few exceptions, most cosmetic products are intended to have a benign effect and would not be expected to be seriously harmful if applied wrongly/accidentally. In contrast, many other products are toxic because of the use for which they are intended and thus the amount of acceptable toxicity may be different. For example, some products such as disinfectants, pesticides, bleaches, and agrochemicals are designed to be toxic, and/or are likely to be so due to their required action. Household products, for example, are a significant source of childhood (and domestic animal) poisonings. The tests carried out on these kinds of products or their constituent chemicals are done to identify hazardous properties and to guide the choice of safety precautions that will reduce risk to an acceptable level - not, as in the case of cosmetics, to establish that they have no unacceptable biological effects.

Note also that, by volume, more household, industrial and agrochemical products are produced, used and go down the drain and into the atmosphere, and thus have greater potential impact on human health and the environment, than cosmetics products.

4.2 Impact on laboratory animals of testing non-medical substances

The overall impact on animals of testing any kind of non-medical substance, including cosmetics, depends on the number of animal lives taken and the level of suffering caused to the animals by the test procedures, the effects of the substances that are tested and confinement of the animals in a laboratory environment.

4.2.1 Number and species of animals used

Table 1 overleaf shows the number of animals used in Britain for testing different kinds of non-medical substances over the 5-year period 1997 to 2001. Table 2, also overleaf, shows the animal species used in the tests carried out in 2001.

Table 1: Animals used for safety testing non-medical substances in Britain, 1997-2001
Source: Home Office statistics

Reason for using animals	Number of animals used:				
	1997	**1998**	**1999**	**2000**	**2001**
Testing substances intended for use in **agriculture**	53 277	55 573	48 041	35 278	40 969
Testing substances intended for use in **industry**	73 855	57 942	57 425	53 857	52 620
Testing substances intended for use in the **household**	2 004	1 448	341	1 242	590
Testing **food additives**	1 451	1 960	2 771	4 703	3 463
Testing **other foodstuffs**	6 069	2 013	2 082	1 303	6
Testing **finished cosmetics**	98	0	0	0	0
Testing **cosmetics ingredients**	1 168	559	0	0	0
Testing substances that may be **environmental pollutants**	27 521	34 017	32 301	35 017	38 221
TOTAL	**165 443**	**153 512**	**142 961**	**131 400**	**135 869**

Table 2: Species of animal used for safety testing non-medical substances in Britain, 2001
Source: Home Office statistics

	Number of scientific procedures[a], involving:							
Type of test	**Mice and rats**	**Other rodents[b]**	**Rabbits**	**Dogs**	**Birds**	**Fish**	**Other species[c]**	**Total**
Acute lethal	1777	-	-	-	1040	17557	-	**20374**
Acute & subacute non-lethal	20410	-	66	71	192	10287	-	**31026**
Subchronic & chronic (i.e. longer term) tests	6154	-	-	112	-	1199	2240[d]	**9705**
Carcinogenicity	2990	-	-	-	-	-	-	**2990**
Mutagenicity	3488	-	-	-	-	-	-	**3488**
Reproductive toxicity	25446	-	652	-	320	8471	-	**34889**
Skin sensitisation and irritancy tests	1401	15387	2614	-	-	-	-	**19402**
Eye tests	-	-	1284	-	-	-	-	**1284**
Toxicokinetics	477	-	-	13	24	289	17	**820**
Other tests	4863	326	-	32	301	6459	29	**12010**
Total	**67006**	**15713**	**4616**	**228**	**1877**	**44262**	**2286**	**135 988**

Notes for Table 2:
a A rough guide to the numbers of animals used - sometimes more than one procedure is carried out on the same animal. Data on number of animals used by test type are not available.
b Mainly guinea pigs
c No non-human primates were used for these purposes in 2001
d All amphibians

When compared with cosmetics, the sum total of animal suffering caused in testing other non-medical substances, such as those used in the household, agriculture and industry, is likely to be greater - because more animals are used for these purposes and because the substances themselves may have more substantial effects on the animals. An important difference, also noted in 4.1.4 above, is that substances used in cosmetics (as well as food additives and other foodstuffs), are intended to have a benign effect, whereas other non-medical substances are often more toxic, and thus it is likely that more animal suffering will be caused in testing them.

4.2.2 *Types of animal test carried out on non-medical substances*

The types of animal test carried out on non-medical substances in general are shown in Table 2. The tests carried out on each particular class of substance are not described in the Home Office statistics, but the animal species involved indicate the tests that are done on each type of substance - see Table 3 below.

Table 3: Species of animal used for safety testing non-medical substances in Britain, 2001
Source: Home Office statistics

Species	Number of animals used in testing substances for:						
	Agriculture	Industry	Household	Food additives	Other foodstuffs	Pollution	**Total**
Mouse	4796	3895	-	563	-	78	**9332**
Rat	23754	30163	376	2692	6	659	**57650**
Guinea-pig	2802	12433	176	6	-	-	**15417**
Hamster	-	40	-	-	-	-	**40**
Other rodent	48	-	-	-	-	208	**256**
Rabbit	1054	3317	38	126	-	-	**4535**
Dogs (all beagles)	120	18	-	76	-	-	**214**
Pig	6	-	-	-	-	-	**6**
Goat	6	-	-	-	-	-	**6**
Cattle	12	-	-	-	-	-	**12**
Other mammal *	-	-	-	-	-	22	**22**
Bird	1797	74	-	-	-	6	**1877**
Amphibian	-	-	-	-	-	2240	**2240**
Fish	6574	2680	-	-	-	35008	**44262**
Total	**40969**	**52620**	**590**	**3463**	**6**	**38221**	**135 869**

Note for Table 3: * No non-human primates were used in 2001

As Tables 2 and 3 show, mice and rats are used in testing all the classes of non-medical substances, mainly in acute and subacute systemic toxicity tests and in studies of reproductive toxicity. Guinea pigs are mainly used to test substances for skin sensitisation and irritancy, and the majority of rabbits are used in skin and eye tests. Dogs are mainly used in longer-term systemic toxicity studies. Birds are mainly used for short-term systemic toxicity tests and reproductive studies, and fish in ecotoxicity studies. Non-human primates are rarely used, but in 1998 forty marmosets were used to test "substances used in industry" (Home Office 1999). This was probably for testing chemical ingredients called phthalates, because of concern about their safety when used in toys mouthed by babies.

4.3 Number of substances tested

The Home Office statistics used to construct Tables 1, 2 and 3 record the number of animals used each year for each of the different purposes, but do not provide information on how many substances are actually tested, nor whether the substances involved are ingredients or finished products. For example, it is not known how many "substances used in the household" were tested using the 1242 animals recorded for 2000, or the 590 animals used in 2001, nor whether the animals were used in testing ingredients or finished products. Neither is it possible to tell what kinds of substances/products were involved – were they detergents or oven cleaners, paints or solvents, for example? – nor which legislation they were tested for and for which country. This sort of information would be more useful than the present classification of data in the Home Office statistics. It would be more meaningful if the Home Office statistics listed the number of animals involved in tests on finished products and ingredients separately, sub-dividing each category into the various regulatory or other reasons for the tests, and noting how many different substances were actually tested.

To find out more about household product testing in the UK, the Boyd Group asked six contract-testing organisations (CROs) and three major manufacturers of household products (two making own-label products, the other manufacturing for other retailers) about their current use of animals for this purpose. It was found that:

(i) none of the six CROs has carried out animal tests on finished household products in recent years. In particular, of the six CROs contacted:
- one tests pharmaceuticals only;
- one tests pharmaceuticals and food additives only;
- one has a policy that it will not test finished household products, nor ingredients where it is anticipated that 50% or more of the end-use will be in household products;
- three will consider testing finished household products, but one says that it has not carried out any such tests in the past ten to fifteen years, one that it has not conducted animal tests on finished household products for at least three years, and the other that it rarely if ever tests such products nowadays. All three will test ingredients that may be used in household products;

(ii) none of the three major manufacturers has facilities for carrying out animal tests in Britain, and none asks contract organisations to carry out animal tests on finished household products in Britain - but the two own-label manufacturers occasionally conduct such tests abroad.

Nevertheless, although these findings suggest that most if not all of the animals used in tests on "substances intended for use in the household" were used to test ingredients rather than finished products, enquiries of the Home Office reveal that a small (but unknown) proportion of the tests carried out as recently as 1999 and 2000 did involve finished household products - but it is not known how many, nor what kinds of products were involved.

4.4 Benefits of testing non-medical substances

The Animals (Scientific Procedures) Act 1986, which regulates the use of laboratory animals in the UK, requires that a cost-benefit analysis is applied to proposed uses of animals, before a project licence can be granted. That is, the likely impacts on the animals (the "costs" to the animals) have to be weighed against the potential benefits of the studies, and the Home Office has to be satisfied that the benefits of the work can be considered to justify the costs to the animals.

In the case of product testing, the potential benefits that might be weighed against costs to animals are of two kinds:

(i) the benefits of the safety tests - which aim to ensure that the risks posed by the products are properly understood, so that the products can be labelled appropriately and used safely; and

(ii) the necessity and benefits of the new products themselves.

As with cosmetics and toiletries, the need to assess the safety/risk of other non-medical products is not disputed. In contrast, the need for the new products and the need for/relevance of animal tests are disputed, at least by some people.

Presumably, the perceived needs for household products, i.e. their "benefits", are similar to those for cosmetics and toiletries, and might include the following:

To the consumer:

- wider choice of more labour-saving convenience products
- products that are more effective
- safer products
- products that are more environmentally friendly

To the environment:

- less toxic, more environmentally friendly products, less chemical material down the drain

To industry, Government:

- competitiveness, contributions to the national economy, profits for shareholders, employment.

However, where safety tests are concerned, such factors are not considered in the weighing of costs and benefits that has to be carried out by the Home Office in deciding whether or not the use of animals can be licensed under the UK Animals (Scientific Procedures) Act 1986. In the case of safety testing, the benefits of using animals are viewed solely in relation to the objective of ensuring that products and ingredients can be manufactured and used safely. There is no requirement that the nature and significance of the likely benefits of the substances themselves be considered (Home Office 2001b).

5. CONCERNS ABOUT ANIMAL TESTS ON HOUSEHOLD PRODUCTS AND INGREDIENTS

5.1 General comments

Concerns about the use of animals in product testing all tend to hinge on an assertion that animals are being used, and therefore suffer, in tests that are unnecessary - because the products themselves are unnecessary, and/or because the animal tests are not necessary to assess the risks posed by the products.

Based on these two concerns, the following arguments might be used in support of a ban on the testing of finished household products:

(i) that, where animals are used in non-medical product testing, the cost-benefit assessment required under the Animals (Scientific Procedures) Act should take into account the benefits of the products themselves, as well as the need to ensure their safety;

(ii) that, on these grounds, it is morally unacceptable to use animals to test new finished household products, because such products are widely perceived to be convenience products for which there is little potential need because products with adequate efficacy are already available. In other words, animals should not suffer for the development and testing of new household products, such as another washing powder, a more convenient infant nappy, or a new fly spray;

(iii) that, in any case, it is rarely necessary to use animals to test finished household products because:

- there is no legal requirement to carry out tests on such products in Britain; and
- larger companies, at least, usually have sufficient data on the chemical properties and toxicity of individual ingredients that they can predict the likely synergistic effects when the ingredients are combined in new products, and thus can avoid animal tests of finished household products; and
- where this is not possible, *in vitro* alternative tests, not requiring the use of sentient animals but equally capable of predicting the likely toxic effects of the new products, are usually available; and

(iv) where it is considered that the risks of such new products cannot be adequately assessed without the use of animals the Boyd Group's consensus view is that the new household products should be foregone and the animal tests should not be carried out*.

Questions about the need to use animals apply both to household product testing and to other non-medical product testing. Issues include the need for the products themselves, the need for the particular animal tests and their relevance, the availability of alternatives, the prolonged nature of validation and acceptance of non-animal tests, and the difficulty of challenging and changing the international regulatory system. These aspects are explored further in section 6.

* See also note 1 on page 3

5.2 Comparison with other non-medical products

The aim of a ban on the use of animals in finished household product testing in the UK would be to reduce animal suffering and loss of animal life. However, although it might appear that a ban on household product testing is the next logical step after banning cosmetics testing, and this might have political and popular appeal, such a ban would result in little net gain for animal welfare. This is because, as with cosmetics testing, relatively few animals are used in testing household products, and the tests in any case are likely to be done abroad. Nevertheless, a ban could have other important roles, in addition to sparing the relatively few animals that are currently used in the UK, in that:

(i) a ban would serve as a statement of moral principle, that it is unacceptable to use animals to test new products that are developed largely for human convenience, where products with adequate efficacy are already available; and

(ii) such a statement of principle could help to open up debate on the morality of using animals to test finished non-medical products more generally.

5.3 Concerns of various interest groups

5.3.1 *Animal protection groups*

All animal protection groups that know that animals are used for safety testing are concerned about this use of animals. The arguments put forward about the morality of testing, the necessity of the products, the relevance of animal tests and the need for alternative approaches, are the same as for cosmetics testing.

5.3.2 *Public perceptions*

It is difficult to judge the level of public concern about the use of animals for testing household products or non-medical products in general. Many people probably do not know that animals are used for this purpose and may believe that they have little contact with chemicals outside the home and garden. It is interesting that people buy products for killing – whether this is "germs", insects, rats or pigeons – which say "safe for pets" or warn of adverse effects – but apparently do not think how such information was obtained.

Interestingly, when the RSPCA has tried to cover testing household products in interviews and/or information given to journalists, there has never been much interest in pursuing the subject. Unlike cosmetics, there is not a large "cruelty-free" product market for household products – in fact the emphasis is more on products being "environmentally friendly". Note the conflict here between cruelty-free and environmentally friendly. Developing new more environmentally friendly products will result in more tests on animals.

As far as household or garden products are concerned these seem to be less commonly viewed as "trivial" than cosmetics. Or perhaps few people have thought about it? There is a greater diversity of products used by more people. Household products are for "beautifying" the home and not the person, or they are labour saving, appealing to the desire to increase leisure time. Advertising emphasis is on cleanliness being next to godliness – it is a virtue to kill all known germs dead, get clothes whiter or retain their colour better, whereas it is not necessary to dye your hair more effectively or try vainly to preserve youthfully serene skin.

Nevertheless, a recent MORI opinion poll indicates that more than three out of four people think that household products should not be tested on animals (see Table 4 below). In focus groups organised by MORI, participants put "household cleaners" closer to "cosmetics" than "medical purposes" on a "continuum of the degree of acceptability" of animal use. However, participants found it difficult to decide where to place household products on this continuum. This seemed to be because, whilst participants were concerned about animal welfare, they also could see a use for household cleaners and felt that if such products could pose risks to human health they should be adequately tested - even if this meant using animals (MORI 1999, page 22).

Table 4: Ordinary people's views on the use of animals in product testing
Source: MORI opinion poll conducted in Britain in 1999, on behalf of the Medical Research Council (MORI 1999)

	Animal experimentation is....			
	always justified	sometimes justified	never justified	Don't know
Total respondents: 1014	(%)	(%)	(%)	(%)
For testing potential new medicines	21	45	30	4
Testing the safety of chemicals used in the workplace	8	25	61	6
Testing the safety of household products e.g. disinfectants, DIY products	4	15	77	4
Testing the safety of cosmetics e.g. skin care products, make-up	4	9	85	3

5.3.3 *Toxicologists/regulators*

Those toxicologists and regulators who are concerned with the use of animals for testing cosmetics are likely to apply the same principles, such as consideration of the need for and relevance of animal tests and the availability of acceptable alternatives, in deciding test strategies for any other chemical substance, whatever type of product the chemical is eventually intended for. Many toxicologists would prefer that the regulatory guidelines enabled more flexibility of approach, promoting "sensible toxicology" over a "check list" approach to hazard identification. This would mean that animal tests would no longer be required solely in order to fulfil regulatory authority requirements, and animals would be used only where toxicologists consider it scientifically essential for adequate risk assessment.

5.3.4 *Industry*

It has already been said that the major companies rarely test finished household products – and are already in a position to cope with a ban on the use of animals in finished household product testing in Britain. Whether this also applies to finished industrial products, agrochemicals and food additives and other non-medical products is uncertain.

The major household product manufacturers in the UK are all active in developing and promoting acceptance of alternatives to animal tests. However, there must be a number of companies that manufacture chemicals who are not major (or even minor) players in the alternatives field.

Representatives of the companies contacted by the Boyd Group say that they try to carry out animal tests on non-medical substances only when they consider this toxicologically necessary, but that they are sometimes hamstrung by inflexible, overly prescriptive regulations, particularly with respect to ingredients testing. In general, they feel that bans on testing certain categories of substance would have little effect on animal welfare or numbers used, since the legal requirements to test ingredients and certain products would remain and the tests would most likely be categorised differently in statistical returns to the Home Office, or exported to other countries (e.g. outside the EU) where animal welfare standards may be lower. They suggest that it would be more effective to make animal testing unnecessary, by reforming regulatory requirements and developing alternatives, than to ban it. Some particular suggestions for change are listed in section 6.

6. ALTERNATIVE APPROACHES IN NON-MEDICAL SUBSTANCE TESTING

There are several current problems that limit the development and use of non-animal approaches, and are barriers to reducing and refining the use of animals involved in testing chemical products and ingredients. These include:

- current scientific limitations in developing non-animal tests and replacement alternative approaches;
- prescriptive and restrictive regulatory demands for animal tests, including international requirements;
- the bureaucratic nature of the regulatory process which makes it difficult to challenge the *status quo* and leads to inertia in the development of potential alternatives and acceptance of validated alternative methods; and;
- the relative priority given to solving these problems, including inadequate funding and lack of a coherent strategy.

Scientific limitations: As noted in section 4.2.2, animal tests of non-medical substances are mainly aimed at assessing the chemicals' effects on human skin and eyes, and characterising the acute and systemic toxic effects that are caused when substances enter the body – which may be by a variety of routes of exposure, such as by inhalation, through the skin, or by ingestion.

A step-wise approach is used in the assessment of skin and eye irritancy. This means that animal tests should only be carried out when toxicological understanding and/or the results of *in vitro* screening tests do not allow a substance's potential irritant effects to be predicted with sufficient confidence to enable the substance to be classified and labelled according to international guidelines. However, complete replacement of animal use with non-animal tests, such as *in vitro* systems, has not yet been achieved. A particular problem is that the underlying biological mechanisms of irritant responses in skin and eyes are not yet fully understood, making it difficult to identify the key responses of *in vitro* cellular systems that are predictive of irritancy *in vivo.* Cytotoxicity, for example, is likely to be predictive of moderate and more severe irritancy, but may miss more subtle effects. In addition, immunological responses may be involved and these are difficult to mimic in *in vitro* systems, because it is difficult to get cells to interact as they would *in vivo*.

Some progress, however, has been made in implementing reduction and refinement alternatives in animal tests that are used to assess sensitisation. For example, reduced group sizes are now possible in the guinea pig skin maximisation test. The original method involved 20 test and 10 control animals, but the revised method halves this number, requiring 10 test and 5 controls. Beyond this, a local lymph node assay test has been developed as an alternative to the maximisation test. This refined test, which uses mice, is much less injurious to the animals before they are killed. It has been validated in the USA and Europe and now forms the basis of OECD Test Guideline 429 (Gerberick *et al.* 2000), formally adopted by the OECD in April 2002. In Britain, the Health and Safety Executive and Home Office now consider that the local lymph node assay is the method of first choice for determining the skin sensitisation potential of substances, and case-by-case specific scientific justification is now required for the use of the guinea pig maximisation test for skin sensitisation.

Tests for systemic toxicity are also difficult to carry out in *in vitro* systems. The toxic effects of substances to which humans and other animals are exposed are influenced by the route of exposure (e.g. ingestion, inhalation, through the skin) and by the body's physiological response to the potential toxin. These factors influence whether, and how much of, the substance enters the body; where it goes within the body, whether, how far and how rapidly the substance is cleared from the body; whether and how far its toxicity is neutralised by the body; and whether and how the substance is broken down within the body into other chemical substances that may be more or less toxic than the original. All of these factors are difficult to mimic in isolated cells and tissues. Again, tests examining the effects of substances on cells *in vitro* are able to distinguish chemicals that are likely to be weakly toxic from those likely to be strongly toxic, but are less reliable in distinguishing between chemicals that have weak and mild/moderate effects. In addition, such cytotoxicity studies may not pick up tissue-specific toxic effects. For example, specific nerve toxins may not be identified in *in vitro* tests that do not employ nerve cells. Many types of cell may be needed to detect all types of toxicity.

Although replacement alternatives have not yet been validated, some progress has been made in refining acute systemic tests to avoid lethal end-points (OECD 2000). Ideally animals should be killed as soon as toxic signs develop and it becomes possible to identify the organs affected. However, only one of the more severe tests in which death can be an end-point has been deleted from the OECD guidelines. The OECD has withdrawn Test Guideline 401 (for the classical LD50 test), but at least one of the three alternative tests still involves death as an end-point and use of refined tests is optional (see further discussion below).

Regulatory issues: In spite of the scientific difficulties involved in developing alternatives there is still much that can be done to reduce, refine and avoid the use of animals in regulatory testing. The current regulatory focus is on assessing the primary hazards posed by chemical substances, rather than carrying out risk assessments that relate to the contexts in which the chemicals are or will be used. In particular, the mood of regulators and NGOs is to demand more test data to support the effective control of chemicals which have been in general use for many years (decades in some cases). Current proposals will require primary hazard assessments to plug data gaps on existing substances and, as noted, these could require the use of millions of animals. In all cases, the need for obtaining systematically the whole set of data currently required can be questioned (e.g. the base set notification type of approach). Replacing such a "tick-box" approach by a more reasoned and flexible decision-making process could reduce the required additional testing to the minimum necessary to adequately assess the real risks.

In particular, the following practical steps could be taken to assist and promote the use of alternative testing approaches that help to remove or limit the use of animals, and improve the welfare of those animals that are used:

- encourage influential governments such as the UK to demand that the process of review and legal acceptance of alternative methods is expedited in Europe and globally through the OECD. Current timings lead to delays of years in the acceptance of new alternative methods or in the deletion of obsolete or superseded animal tests (e.g. LD50). If an alternative exists that meets the scientific objective and

is more humane, such as the Fixed Dose Procedure, the less humane method (such as the LD50 test) should be immediately deleted from the regulations in favour of the more humane test (in this case the Fixed Dose Procedure) and should not be accepted by the regulatory authorities. The regulatory requirements should also make provision for more use of validated *in vitro* tests, computer modelling and predictions from known structure-activity relationships of substances ((Q)SAR);

- require that, when available, epidemiological studies and scientifically valid case studies on humans be fully taken into account, as well as marketplace history of safe use and human exposure, all of which could replace some animal testing – particularly where tests on existing substances are proposed;
- avoid prescriptive testing requirements when developing new legislation, so as to allow toxicologists always to take the Three Rs fully into account;
- in general, move away from the tick box prescriptive approach in current legislation, allowing only those studies that are considered toxicologically necessary to be carried out. For example, if a substance is not absorbed across the skin, why is there a need to carry out systemic exposure test for this route?

Such steps would be a major contribution towards reducing animal testing, by eliminating unnecessary animal tests, repeat testing and studies carried out to meet regulatory requirements rather than to assess safety.

7. JUSTIFICATION FOR ANIMAL USE IN PRODUCT TESTING – SOME ETHICAL QUESTIONS

The use of animals in product testing is a complex area for ethical consideration. Difficult issues are posed by the desire, on the one hand, to develop more effective products that pose fewer hazards, but, on the other, to avoid harming laboratory animals. The following three questions to think about were raised in the Boyd Group's discussions:

a) Is developing more environmentally friendly and/or less toxic products a justifiable use of animals or can generalisations not be made?

b) Is developing products that are easier to use, e.g. pour on/rinse off products as an alternative to using scrubbing brushes any less trivial a goal than developing anti-ageing products?

c) Is the use of animals to develop more effective and/or more humane poisons for invertebrate and vertebrate animals justifiable? People buy these products for use in the household - or invite pest control experts in to do it for them. Yet there is a certain irony involved, in that householders can freely use rodenticides to kill *pest* rats found in the home or garden, whereas the use of *laboratory* rats and mice in developing and testing these and other products is subject to strict control, requiring Home Office licences.

Responses to these questions and comments on the other issues raised in this paper and associated statement are welcomed.

They can be made via the Boyd Group's web-site, at **www.boyd-group.demon.co.uk**, where further information about the Group's work can be obtained, or by writing to: The Boyd Group, PO Box 423, Southsea, PO5 1TJ, UK.

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