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Advice Note 01/2015
Animals (Scientific Procedures) Act 1986

Policy on Testing Household Products

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Advisory notes on recording and reporting testing of household product ingredients

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1. Introduction

This advice note describes the implementation of a policy ban on the testing of finished Household Products and the requirements in relation to the testing of ingredients for Household Products on live animals under the terms of the Animals (Scientific Procedures) Act 1986 (ASPAs). The policy concerns tests on animals for the assessment of the safety of Household Products for humans, animals and the environment.

The policy is effective from 1 November 2015.

This advice note is for licence holders under ASPA, particularly project licence holders and prospective project licence applicants wishing to undertake animal testing of finished Household Products or ingredients primarily intended or expected to be used in Household Products. In addition, it will have relevance to sponsors of any such studies.

The UK is a strong advocate for the life sciences and considers the properly regulated use of animals plays an important role in improving the lives of humans and animals and to the safety and sustainability of the environment. A Home Office licence for the use of animals in science can only be granted where no practicable alternative exists, and under controls which keep suffering to the minimum.

This policy forms part of the UK commitment to the principles of the 3Rs (to replace, reduce and refine the use of animals) and supports the drive for the development of non-animal alternatives. Implementing the 3Rs requires that, in every project animals are replaced with non-animal alternatives wherever possible; that the number of animals used is reduced to the minimum needed to achieve the results sought; and that, for those animals which must be used, procedures are refined as much as possible to minimise their suffering.

2. Scope

Finished Household Products

From 1 November 2015, the testing of finished Household Products under the Animals (Scientific Procedures) Act 1986 will be subject to a policy ban. The use of animals to test finished Household Products is therefore prohibited from this date.

Ingredients primarily intended to be used in Household Products

In addition to the ban on *finished* Household Products, the testing on animals of *ingredients* primarily intended or expected to be used in Household Products will be prohibited unless:

- The proposed testing has a regulatory requirement¹, for example under REACH (Registration, Evaluation, Authorisation and restriction of Chemicals)²; and
- No other method or testing strategy for obtaining the results sought, not entailing the use of a live animal, is recognised under the legislation of the European Union³.

Where testing is permitted under these terms, retrospective notification to the Home Office will be required (see section 5 below)⁴.

The policy permits preliminary or range-finding tests in advance of a regulatory test being performed. Such testing is not part of the formal regulatory test requirement, but does enhance the application of the 3Rs to the formal regulatory test e.g. reducing the number of animals used in the formal regulatory test or avoiding the need to repeat studies with revised dose levels. Therefore, preliminary testing of a substance that is directly and wholly associated with the regulatory test to be conducted on that same substance will be permitted with retrospective notification.

For any ingredient where there is no regulatory requirement for testing, exemptions will be made on a case by case basis only and will therefore require a prospective application (see section 7 below) specific to the ingredient under consideration with an associated justification.

¹ For testing to be undertaken under national or international law

² Regulation (EC) No. 1907/2006

³ Further information can be found

at: http://ec.europa.eu/environment/chemicals/labanimals/3r/use_en.htm

⁴ Any work using animals that comes under the Animals (Scientific Procedures) Act 1986 requires a project licence that is subject to a harm benefit analysis. For information see Guidance on the Operation of the Act at: <https://www.gov.uk/government/publications/operation-of-aspa>

3. Definitions

For the purpose of the policy ban 'finished Household Products' are defined as follows:

'Household Products are those bought by the general public for use in the domestic home and garden. They include, but are not limited to, detergents, polishes and cleaning products, laundry products, household cleaners, air fresheners, toilet cleaners, descalants, deodorisers, adhesives, paints and varnishes, sealants, caulks and other decorating materials.'

This definition does not apply to:

- *Biocides, pesticides and plant protection products;*
- *Food contact materials, food and feeding stuffs, medical products and medical devices;*
- *Cosmetics (as they are subject to other restrictions on the use of animal testing);*
- *Products intended to be used in an industrial or institutional setting or by professionals; and,*
- *Packaging or delivery systems e.g. pump sprays etc., unless these are inherent parts of the household product.'*

For the purpose of the policy ban an 'ingredient' is defined in accordance with the definition of "substance" in Article 3 of REACH and Article 2 of Classification Labelling and Packaging Regulations⁵, as follows:

'a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition'.

For the purpose of the policy ban an 'ingredient primarily intended to be used in Household Products' is defined as:

'An ingredient (as defined above) for which, at the time that testing in animals is carried out, it is intended or expected, by the entity commissioning the testing, that at least 50% of the manufactured ingredient will be or is intended to be used in Household Products.'

⁵ Regulation (EC) No. 1272/2008

4. Responsibilities

Project Licence holder:

It is the responsibility of the project licence holder to check whether, for any ingredients tested on animals, the primary intention or expectation is to use it in Household Products as defined in Section 3, and that appropriate project licence authority exists for such testing. The project licence holder should be able to demonstrate that they have exercised due diligence in seeking appropriate evidence from entities commissioning testing.

Where there is a regulatory requirement for the testing of a substance, the project licence holder is required to retrospectively notify the Home Office of the test. This is in addition to all other requirements set out in the Operational Guidance for licences under ASPA (see Section 5 below).

The Home Office will require a *prospective* project licence application (or prospective application for an amendment to an existing project licence) for any substance primarily intended or expected to be used in Household Products for which the proposed testing does *not* have a regulatory requirement (see Section 7 below). The Home Office Inspectorate will consider the application and it may be referred to others, including the Animals in Science Committee (ASC), for advice before the decision is taken on whether the testing may be authorised. No testing may commence until specific licence authorisation is received.

Establishment Licence holder:

The Establishment Licence Holder is ultimately responsible for compliance of all aspects of work at their establishment, including work under this policy ⁶.

⁶ See Standard Condition 20 of the Establishment licence – i.e. robust systems in place to prevent unauthorised procedures.

5. Substances (ingredients) for which there is a regulatory requirement for animal testing

The Project Licence holder must notify the Home Office of animal testing that has commenced for a substance, under this policy, for which there is a regulatory requirement. Notification **must** be made within 30 days of the first use of an animal for that particular regulatory purpose using the form at **Annex 1**.

The notification must include:

- a. Project Licence number and holder's name
- b. The title and number of the protocol(s) being used (as on the Project Licence)
- c. Standard test number e.g. OECD (Organisation for Economic Cooperation and Development) test guideline number
- d. Intended purpose or purposes of the substance to be tested (if known)
- e. The species, stage of development and number of animals being used in each protocol; and,
- f. The details of the regulatory requirement under which the testing of animals is being performed

A regulatory requirement may include, for example, the provision of information for registration purposes either directly or in response to a trigger specified by REACH for a data endpoint, or studies included in a regulatory decision of the European Chemicals Agency as part of a substance evaluation.

Wherever possible, the testing should be carried out in accordance with the OECD guidance on the mutual acceptance of data to avoid any duplication of tests.

At the end of each year an additional report, in the format requested by us, must be sent to the Home Office regarding testing of Household Products⁷. This information will be required **in addition** to the annual "Return of Procedures" required each year from all project licence holders. This information must be retained by the Establishment for at least five years.

This data will be published as explained in **Section 9**.

⁷ This form will be made available to project licence holders.

6. Preliminary testing

Preliminary testing of a substance, for example range-finding testing, is sometimes carried out in advance of formal regulatory testing, in order to derive overall 3Rs benefits.

This testing is not part of the formal regulatory test requirement, but the Home Office recognises it as good practice – for example, if it is likely to reduce the number of animals used in the formal regulatory test or minimise the need to repeat a test with revised doses.

Preliminary testing will be permitted if:

- a. The testing is directly and wholly associated with the formal regulatory test to be conducted on that same substance; *and*,
- b. There is an overall 3Rs benefit.

Retrospective notification is required (as with formal regulatory testing) and must therefore be submitted to the Home Office within 30 days of the first use of an animal, using the form at **Annex 1**.

If preliminary testing for a substance is carried out under the authority of one project licence, but the formal regulatory testing is carried out under the authority of a different project licence, the regulatory testing will require a separate notification.

7. Substances (ingredients) for which there is no regulatory requirement for animal testing

Specific project licence authority is required to use an animal test for an ingredient which is intended or expected to be used primarily in Household Products and for which there is no regulatory requirement (for example, if the substance is in the earlier stages of discovery).

The application for authorisation, via a project licence application or amendment to an existing licence⁸, must include a strong justification for the proposed testing which is sufficiently detailed to be assessed in a thorough harm benefit analysis. Wherever possible and appropriate, such non-regulatory tests on ingredients should conform to internationally accepted test guidelines such as OECD guidelines.

The application will be considered by the Home Office Inspectorate and normally also by the Animals in Science Committee (ASC). The Home Office will then make a decision on whether the testing should be authorised.

Testing at the establishment must not commence until licence authority has been granted. We expect to be able to grant or refuse an application for a licence or amendment within 40 working days of receiving a complete and correct application.

At the end of each year an additional report, in the format requested by us, must be sent to the Home Office alongside the annual Return of Procedures regarding such non-regulatory testing of Household Products (see Section 9).

Information regarding the authorised testing must be retained by the Establishment for at least five years after the testing has been completed.

⁸Information on how to apply can be found here: <https://www.gov.uk/research-and-testing-using-animals>

8. Implementation

Licence conditions

The policy ban will be implemented through conditions on relevant project licences and will be added as 'Additional Conditions. Future project licences will have these conditions applied.

The Secretary of State will impose the following condition on the project licences which will become effective on 1 November 2015:

The following conditions apply to the testing of finished Household Products or their ingredients:

- a) *The use of animals in testing finished Household Products under this licence is prohibited.*
- b) *The testing of substances under this licence is prohibited where more than fifty per cent of the substance is intended or expected, at the time of testing, to be used as an ingredient in a household product unless there is a regulatory requirement under national or international legislation for testing which is authorised by a project licence or a non-regulatory requirement which is specifically authorised by the Secretary of State.*
- c) *If testing is carried out for a regulatory purpose, the licence holder must notify the Home Office of all such testing within 30 days of the first animal test, using the form of notification required by the Secretary of State.*
- d) *If testing of a substance is proposed under this licence where more than fifty per cent of the substance is intended or expected, at the time of testing, to be used as an ingredient in a household product and the testing is not for a regulatory purpose, the licence holder must apply for prospective authorisation to carry out such testing which, if granted, will be specific to the substance and purpose for which the application is made.*

The conditions above are effective from 1 November 2015. It is the responsibility of project licence holders to implement the conditions above where they apply, such licences will be recalled upon implementation for amendments.

9. Statistics

As previously described, in addition to the prospective applications and the retrospective notification sent within 30 days of the first use of animal, the Secretary of State will also require the project licence holder to provide periodic additional reports regarding the testing of Household Products. The relevant sections of this guidance explain that such additional reports will be required annually (at least initially) and the request will relate to tests completed during the previous calendar year. This will be collected alongside and in addition to the annual Return of Procedures in the January of each year.

These reports will require information about the protocol(s), the numbers of animals used on each protocol and the actual severity experienced by each animal. The format of the report will closely follow the annual Return of Procedures to minimise the burden of additional data recording. We will introduce this as a 'pilot' collection in January 2016 for any testing performed during November and December 2015 following the implementation of this policy.

A detailed analysis of the testing on animals of ingredients primarily intended to be used in a household product will be published. It is expected that this will form part of the ASRU Annual Report. We intend to provide a description of the work that has taken place which will include the regulations that require the testing of ingredients for Household Products, the type of testing (e.g. skin sensitisation, eye irritation), the numbers and species of animals used and the actual severity of procedures performed. Each project licence holder's report will therefore be required to include this information as a minimum.

Project licence holders will also be required to provide the usual data on all procedures completed under their project licence through the normal Return of Procedures process.

Section 10 Frequently Asked Questions

What is meant by the word “primarily” in the context of “ingredient primarily intended to be used in Household Products”?

An ingredient is primarily intended to be used in Household Products if, *at the time of the animal testing*:

- a. It is intended or expected (by the entity commissioning the testing) to be used in Household Products; and,
- b. It is estimated or envisaged (by the entity commissioning the testing) that at least 50% of the manufactured ingredient will be used in Household Products.

What happens if testing on a particular project is already being carried out at the time the ban comes into place?

If the testing is required by regulation then it can be continued and you should follow the guidance for retrospective notification. If the testing is not required by regulation, you should consult your local inspector.

What happens if not all the planned testing is carried out?

It is possible that you notify the Home Office of testing but not all of it takes place, for example because the preliminary testing showed the subsequent testing not to be required, or the contract for testing is not proceeded with. In this case there is no need to amend the notification you have already sent to the Home Office. Nevertheless, data for all animals which are used must be included in the specially required report as well as in the annual Return of Procedures.

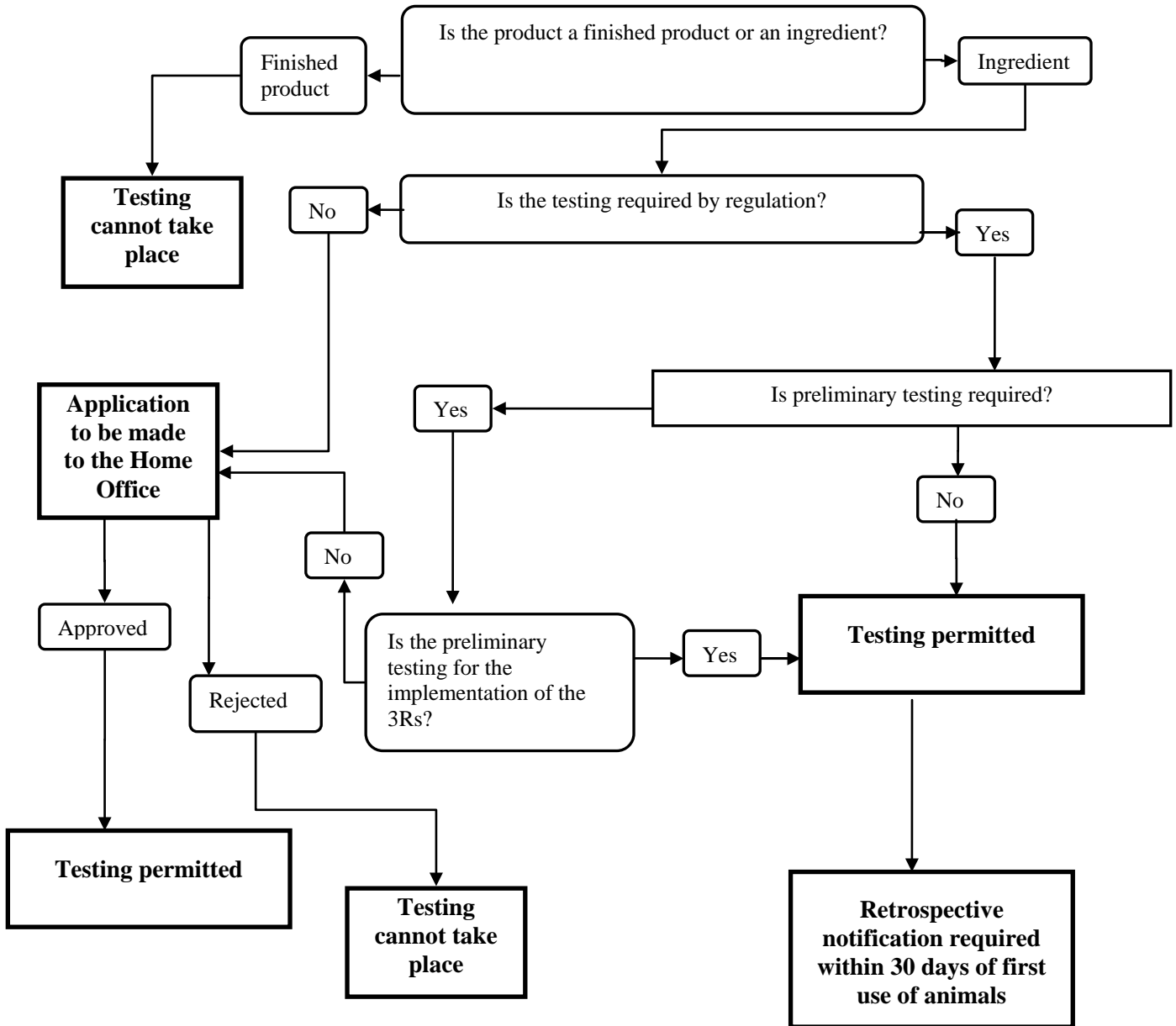
What if an ingredient was not primarily intended for use in a household product at the time of testing but subsequently more than 50% of the ingredient is used in this way?

We recognise that it is not possible to predict all future eventualities. If at the time of testing a product is not primarily intended to be used in a household product (and due diligence enquiries have been made to establish this fact), but after testing is completed the product use changes, retrospective notification is not required. We expect those who are carrying out testing to gather information regarding a product's intended use before testing begins through proper due diligence, and we may seek evidence that appropriate questions have been asked.

Table 1:
Four box grid for testing of finished Household Products and ingredients in animals

	Testing required for regulatory purposes	Testing NOT required for regulatory purposes
Finished Household Products	<p>Policy ban</p> <ul style="list-style-type: none"> • We do not expect ever to need to reverse this ban • There is a legal framework that would allow it but we do not expect it to ever be used and exceptional Ministerial decision would be required with advice provided to Parliament 	<p>Policy ban</p> <ul style="list-style-type: none"> • We do not expect ever to need to reverse this ban
Ingredients (more than 50% intended for use in Household Products)	<p>Retrospective notification required</p> <ul style="list-style-type: none"> • Notification of the testing must be sent within 30 days of the first use of an animal. • Includes preliminary testing required to carry out the regulatory testing or to support the implementation of the 3Rs. 	<p>Exceptional circumstances only</p> <ul style="list-style-type: none"> • Requires prospective authorisation and will be subject to a robust harm-benefit analysis • Will be referred to others, including the Animals in Science Committee, for advice

**Figure 2:
Flow diagram for testing of Household Products**



Retrospective notification form for testing of household product ingredients required by regulations

(to be submitted within 30 days following the first use of an animal)

Section 1-General Information

1.1 Project Licence Holder	
a. Name and contact details	
b. Establishment Licence number for place of testing	
c. Project licence number and title	

Section 2- Details of Project Licence

(Please copy this section for each protocol on the licence which it is intended to use and continue on additional sheets if necessary)

2.1 Project Licence Details for testing on animals of Household Products ingredients	
a. Title and number of protocol (as on PPL)	
b. Expected species, stage of development and number of animals tested	
c. Expected severity classification of protocol (as on PPL)	
d. Type of testing being undertaken (e.g. repeat-dose toxicity). Please include information on any preliminary tests being performed and why.	
e. Intended use for the substance to be tested (if known)	
f. Regulatory requirement, including Testing Guideline or Protocol, under which the testing of the ingredient will be undertaken in animals	

Signature of PPL holder:

Name (in block capitals):

Date: