

consensus on the weighting of those causes, and a consensus on scoring of suffering. Problems can arise with terminology, so that terms used in the licensing procedure such as 'mild', 'moderate' and 'substantial' can be interpreted in different ways by people who are not familiar with their use in this technical sense. Issues that are currently being addressed include the use of these terms, the requirement for subdivisions of various categories, and the provision of guidance on their use. It was generally agreed by speakers that more consideration needs to be given to forms of suffering other than pain and to research aimed at developing our understanding both of the signs of suffering and of the actual experience of the animal in terms of intensity and duration.

The meeting concluded with a description of the APC/LASA pilot study to examine some of the issues involved in the UK system of regulation of suffering. The APC's terms of reference for the LASA pilot study were: "To devise the most effective system of retrospective assessment of suffering and severity that will achieve the following goals:

- Provide information about suffering and severity actually experienced by the animals used in a particular project that can be published in an annual publication of information and statistics.
- Provide information that will enable individual establishments and others to refine future prospective assessments.
- Have neutral, or the least additional regulatory impact."

It is hoped that a report on the outcomes of this study will be published in May 2005.

Report of a session, entitled 'Suffering and Severity', of the Laboratory Animal Science Association (LASA) winter meeting held on 24–26 November 2004.

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### The Seventh Amendment of the Cosmetics Directive

The European Union (EU) has adopted a radical piece of legislation intended to put an end to the use of animals to test cosmetics. The measure in question is Directive 2003/15, the Seventh Amendment of the Cosmetics Directive, generally known as the 'Seventh Amendment'. The Directive employs a range of provisions designed to promote its aims, whilst paying regard to global trading rules and to pressures on the cosmetics industry to innovate in order to maintain its competitiveness in the world marketplace.

The Seventh Amendment imposes a series of bans on animal testing in the EU and on the marketing of animal-tested products within the EU. A testing ban applies to finished cosmetic products from 11 September 2004. This is not such a radical measure as it might seem, given that four years earlier the European Commission had advised that the safety of the final product can be derived from knowledge

of the toxicity of the ingredients. Nevertheless, the Seventh Amendment strengthens animal protection by crystallising guidance into a legal norm. Also from 11 September 2004, the Directive prohibits the testing of ingredients or combinations of ingredients with respect to particular tests as soon as *in vitro* methods are validated and adopted in EU legislation. The marketing ban, applicable to final formulations, ingredients and combinations of ingredients, will be introduced *in tandem* with the development of alternatives with due regard to the progress of validation within the Organisation for Economic Co-operation and Development (OECD). With regard to the testing ban, there is a maximum cut-off date of 11 March 2009 applicable to all animal tests. With regard to the marketing ban, this same date applies, although there is an exception with respect to three categories of systemic tests where the development of alternatives is proving to be particularly problematical, namely, repeated dose toxicity, reproductive toxicity and toxicokinetics. For these categories, the deadline is 11 March 2013 with the possibility of extension.

The Seventh Amendment requires the Commission to produce guidelines for a non-animal-tested label which may be used by manufacturers and to publish timetables for the phasing out of the various animal tests and progress reports on the development of alternative methods.

Laboratory animals stand to benefit from the approach adopted by this legislation. The use of flexible timetables within fixed time frames should stimulate efforts to develop alternatives at an early stage and to reduce the risk of endeavours being postponed until the final deadlines draw near. Furthermore, each time a specific category of *in vitro* test gains regulatory acceptance, laboratory animals will be spared that particular ordeal and the practice of animal testing will be progressively driven downwards. The prohibitions on both marketing and testing make a powerful combination. A test ban alone would leave companies free to conduct animal testing outside the EU on products destined for import and sale within the Union. That could be positively detrimental to animal welfare as no fewer animals would be used and the testing might be done under less regulated conditions than would apply in the EU. Conversely, of course, a marketing ban alone is not satisfactory either, because it would leave organisations free to test products on behalf of non-EU countries. The non-animal-tested label will allow consumers to make informed purchasing choices and, given the level of opposition in the EU to the use of animals to test cosmetics, consumer preferences will help to drive the market away from the practice.

The Directive's provision for transparency through publication of timetables and progress in alternatives, plus its due regard to developments in the OECD, will help to secure its acceptance by the global trading community. Undeniably, the legislation does pose a daunting challenge to the cosmetics industry. Nevertheless, there has been progress in the development of alternatives and the Directive provides a considerable interval before the first deadline as well as a

means of extending the second deadline. Furthermore, the European Centre for the Validation of Alternative Methods (ECVAM) has received extra resources for the purpose of meeting the expectations of the Seventh Amendment.

In the light of the foregoing features, it is considered that the Seventh Amendment of the Cosmetics Directive is likely to promote laboratory animal protection, both within and beyond the territory of the EU.

**Directive 2003/15/EC.** *Official Journal of the European Union, L Series 66 11.03.2003: 26*

**Notes of Guidance for testing of cosmetic ingredients for their safety evaluation** (2000) *European Commission, Cosmetex Vol 3*

**Hartung T et al** (2003) ECVAM's Response to the Changing Political Environment for Alternatives. *ATLA 31: 473*

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### **New Zealand's Codes of Welfare for pigs and laying hens**

The fundamental obligations relating to the care of animals in New Zealand were established under the Animal Welfare Act 1999. However, the details of these obligations are found in codes of welfare, which set out minimum standards and recommendations for best practice relating to the physical, health and behavioural need of the species in question. On 1 January 2005, the Ministry of Agriculture and Forestry, New Zealand, issued the latest of these codes, the Animal Welfare (Pigs) Code of Welfare 2005 and the Animal Welfare (Layer Hens) Code of Welfare 2005.

The code of welfare on pigs contains ten chapters: introduction; purpose and interpretation of the code; legal obligations of owners and people in charge of animals; feed and water; shelter and other facilities; husbandry practices and disease and injury control; pre-transport selection; emergency humane destruction; quality management; and stockmanship. Within the code there are 20 'minimum standards' including standards relating to feed, new-born piglets, watering systems, indoor conditions (buildings and maintenance), indoor space, indoor temperature, indoor air quality, the outdoor environment, farrowing, dry sow stalls, tethering, boars, elective husbandry procedures, restraint and handling, movement, weaning, health, inspections, pre-transport selection, and stockmanship.

The code on laying hens contains chapters including introduction; purpose and interpretation of the code; legal obligations of owners and people in charge of animals; management of layer hens; catching, loading, transport, unloading and sale; management practices; and quality management. Within the code there are 18 'minimum standards' relating to hatchery management, food and water, housing, equipment, cage systems, non-cage systems, stocking densities for birds in cages, free-range and barn systems, lighting, beak trimming, moult inducement, identification, ventilation, temperature for incubator-hatched chicks, temperature for growing and adult layer hens, litter

management, disease and injury control, humane destruction, and stockmanship.

Only minimum standards have legal effect; recommendations for best practice, which can be found throughout each document, set out standards of care and conduct over and above the minimum required to meet the obligations in the act, and are included in the codes for educational and information purposes.

**Animal Welfare (Pigs) Code of Welfare 2005** (2005). 63 pp A4 ringbound (ISBN 0 478 07854 4). Also available at <http://www.biosecurity.govt.nz/animal-welfare/codes/pigs/index.htm>

**Animal Welfare (Layer Hens) Code of Welfare 2005** (2005). 50 pp A4 paperback (ISBN 0 478 07809 9). Also available at <http://www.biosecurity.govt.nz/animal-welfare/codes/layer-hens/index.htm>. Both published by the National Animal Welfare Advisory Committee, Ministry of Agriculture and Forestry, ASB Bank House, 101–103 The Terrace, PO Box 2526, Wellington, New Zealand.

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### **Major areas of concern for animal welfare in Europe**

Eurogroup, an organisation representing many animal welfare organisations in the European Union (EU), has produced a new edition of its publication *Analysis of Major Areas of Concern for Animal Welfare in Europe*, which aims to provide a better understanding of European animal welfare issues, particularly those relating to laboratory, farm and wild animals. The document sets out the main animal welfare issues which could be affected by European Community legislation and suggests ways in which these areas of concern might be addressed.

Much of the text focuses on farm animals, wild animals, and animals used in scientific procedures. The section on farm animals is by far the largest, addressing specific welfare concerns for all of the major species of animal kept for farming purposes as well as those that are less common such as farmed deer, game birds, rabbits, goats, ratites (ostriches, rheas and emus), and animals farmed for fur. Specific sections are included on the common agricultural policy, organic farming (particularly the need to further develop welfare standards and marketing rules), the transport of farm animals, biotechnology (including yield and growth promoters, selective breeding, assisted breeding technologies, cloning and genetic modification), and humane slaughter (including implementation and enforcement of existing legislation, religious slaughter, the use of electric goads, and home killing of farm animals for domestic use).

The section on wild animals discusses a number of areas of concern including the wildlife trade, the protection of wildlife and habitats in Europe (eg the catching of wild animals, illegal use of poisons, poisoning of wildfowl, length of the hunting season), and commercial whaling (the