EU member state government contribution to alternative methods

Summary

Article 47 of the new EU Directive 2010/63/EU on the protection of animals used for scientific purposes requires national governments to contribute to the development and promotion of alternative methods. A recent survey of EU member states found that reported funding of alternative (3Rs) methods totalled € 18.7 million in 2013, provided by only seven countries (Austria, Belgium, Denmark, Finland, Germany, Sweden, and the UK). There were indications that the contributions of some of these countries have increased since the implementation of the new Directive. However, funding of alternatives is between 0 and 0.036% of national science R&D expenditure and nearly half of the countries that responded reported that they do not specifically contribute. Data (and, by assumption, financial contribution) remains unavailable from half of the member states across the EU, regardless of the method of collection.

1 Introduction

Directive 2010/63/EU on the protection of animals used for scientific purposes entered into force across the EU on January 1, 2013 (EC, 2010). The Directive places duties on member states (MS) related not only to the authorisation of experiments on live animals. According to Article 47 of the Directive (Box 1), national governments should also assist in the advancement of alternative methods to animal testing. They should do this by *contributing* to the development of alternative methods (Article 47(1)), *nominating laboratories* to assist in the validation of alternative methods (Article 47(2)), and *promoting* the use of alternative methods (Article 47(4)).

Article 47(1) does not specify that the contribution to the development of alternative methods must be financial. However, significant contribution usually has some financial element attributable to it. For example, providing expertise to support validation studies can be measured in terms of the cost of the expert's time and travel. Historically, there is a lack of good data on the expenditure on the development of alternatives by European countries. A survey coordinated by Eurogroup for Animals and ECOPA for the years 2006/7 reported an estimated annual funding of € 17 million (Devolder et al. 2008); however data was only available from 14 of the current MS and was estimated in some of these cases. In 2010, the current 27 MS had to report to the European Commission (EC) under the REACH legislation on how much they had invested on alternative methods. Half of all MS could not identify any specific funding and the total estimated funding in 2010 by the remaining 14 MS was just over € 8 million (see EC, 2012). However, this contribution could have been perceived to be in relation to alternatives for chemicals' safety assessment only and not all areas of animal testing.

We were therefore interested in the extent to which MS had considered their role in the contribution to the development, validation, and promotion of alternative methods outlined in Article 47, and whether, as a result of the new Directive, investment in this area was likely to be increased. In June 2013 our members wrote to their national governments to ask four questions:

- How much did the Government fund alternatives (replacements, reduction and refinement methods) in 2010, 2011, and 2012? How much of this funding was directed towards replacement, reduction, and refinement, respectively?
- How much funding has the Government committed to continuing the development and validation of alternative approaches in 2013 and beyond in line with Article 47(1)?
- Has the Government nominated any national laboratories to assist the European Centre for the Validation of Alternative Methods (ECVAM) in the validation of alternative methods (so called NETVAL) (Article 47(2))? If not, why not?
- How does the Government propose promoting alternative methods and disseminating information thereon, within Article 47(4)?

Thirteen of our members wrote to their government department, minister, or asked a parliamentary question. For the remaining MS a letter addressed to the National Contact Point (NCP) (designated in Article 59(2) of the Directive) was sent in English. In

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November 2013 replies from 18 MS had not yet been received and therefore a reminder email was sent to the NCP. Funding of alternative methods was compared to the national science and technology research and development (R&D) expenditure for each country for 2011, reported by Eurostat (EU, 2013), as data for 2013 are not yet available.

Article 47 of Directive 2010/63/EU

1. The Commission and the Member States shall contribute to the development and validation of alternative approaches which could provide the same or higher levels of information as those obtained in procedures using animals, but which do not involve the use of animals or use fewer animals or which entail less painful procedures, and they shall take such other steps as they consider appropriate to encourage research in this field.
2. Member States shall assist the Commission in identifying and nominating suitable specialised and qualified laboratories to carry out such validation studies.
3. After consulting the Member States, the Commission shall set the priorities for those validation studies and allocate the tasks between the laboratories for carrying out those studies.
4. Member States shall, at national level, ensure the promotion of alternative approaches and the dissemination of information thereon.
5. Member States shall nominate a single point of contact to provide advice on the regulatory relevance and suitability of alternative approaches proposed for validation.
6. The Commission shall take appropriate action with a view to obtaining international acceptance of alternative approaches validated in the Union.

2 Summary of responses

Responses to the questions were received from only 13 MS, out of 26 contacted. Questions directed at the National Contact Point were the least successful method of contact. This is unfortunate since the role of NCPs is to act as a point of contact on the Directive and their details are publicly available on the European Commission website (http://ec.europa.eu/environment/chemicals/lab_animals/ms_en.htm). The failure of national governments to respond to queries related to the implementation of the Directive made by legitimate stakeholders is of immediate concern. Language barriers could explain the lack of some responses, but not in all cases, since formal requests in the national language even via parliamentarians, were not dealt with by countries such as Italy, Portugal, and France.

Based on our survey, we can identify that only a total of € 18.7 million has been allocated by only seven MS (Austria, Belgium, Denmark, Finland, Germany, Sweden, and the UK), see Table 1. Five MS (Czech Republic, Ireland, Latvia, Luxembourg, and Spain) have not allocated any funds for 2013 and did not in previous years; the competent authority for Slovakia did not know if funding had been allocated. None of the replies broke down the amounts by replacement, reduction, and refinement methods, as requested.

Out of those responding with allocation, the funding of alternatives was between 0 to 0.036% of national R&D science expenditure in 2011, with the UK providing the most funds, both in real terms and as a proportion of their science R&D expenditure (over € 11 million, see Tab. 1). Funding appears to have increased significantly on previous years for four of the seven countries: Austria, Denmark, Finland, and the UK. However, funding from the remaining three contributing countries and the five non-contributing countries appears to be very similar to 2010.

Our data is not directly comparable to the Devolder et al. (2008) survey, since this asked an open-ended question about funding, included non-EU countries, did not provide absolute figures by country, and included estimates from other sources, including industry contributions, even where the government said it did not provide specific funds. Since the specific government funding pledged for 2013 from the seven MS reported in our survey is in excess of the Devolder et al. estimate, we can however assume that funding overall has increased, although not significantly.

At least 15 laboratories have been nominated by seven MS according to the replies we received. However, we believe the figure is higher, as in July 2013 ECVAM accepted 13 laboratories from those nominated to join the NETVAL (see http://ihcp.jrc.ec.europa.eu/our_labs/eurl-ecvam/eu-netval/eurl-ecvam-appoints-members-of-eu-netval). Some governments that were not specifically funding alternatives, such as Spain, Latvia, and the Czech Republic, nominated laboratories, whereas some pledging funds reportedly did not (Austria, Denmark and the UK).

Only six MS provided a reasonable response to how they were going to 'promote the use of alternative methods' (Article 47 (4)) above standard requirements within the Directive, such as ethical committees, animal welfare bodies, and national contact points. Finland, Germany, and UK already have national centres for the 3Rs and were planning to delegate this responsibility to them. Denmark and Spain indicated that new centres or networks would be created for this purpose. Austria reported their support for the EUSAAT annual conference and other educational seminars. Neither Malta nor Luxembourg currently have animal testing facilities registered under the new Directive. Their negative responses to the funding and promotion of alternatives appeared to reflect this fact; nonetheless there is no reason why such countries could not also promote alternative methods.

There are positive signs that there has been an increase in promotion and funding of alternative methods in some EU countries. Nonetheless, funding appears to be at very low levels and is less than 0.05% of national science research and development budgets. In addition, in keeping with previous surveys, it appears that engagement in alternatives (and in the requirements of Article 47 specifically) remains restricted to a familiar group of MS, less than a third of the total in the EU. Even then, there is inconsistency in the extent of their investment. For example, the UK is the largest financial contributor but it did not nominate

Tab. 1: Summary of the responses from 27 Member States in 2013 on their efforts to fund and promote alternatives to animal testing according to Article 47 of Directive 2010/63/EU

Member State	Method of contact	Previous funding, €	Funding for 2013 (Article 47(1)), €	Nomination of laboratories (Article 47(2))	Promotion of alternatives (Article 47(4))	Science R&D expenditure 2011, million € (EU, 2013)	% investment in alternatives out of science R&D expenditure
AT	Letter to minister	74,700 (2010) 1,506 (2011) 85,988 (2012)	290,000	None as yet	Support for EUSAAT Linz conference, seminars for regulators of animal experiments	8,263	0.0035
BE	Letter to minister	395,497 (2010) 0 (2011) 0 (2012)	155,600	4	Some oversight of the animal welfare body in each establishment	7,556	0.0021
BG	Letter to NCP	No reply				220	?
CY	Letter to NCP	No reply				86	?
CZ	Letter to government department	0	0	Yes, unknown	Created a NCP	2,875	0
DK	Various parliamentary questions	0	402,176 (3 million DKK)	None as yet	Creation of a new 3Rs center	7,437	0.0054
ET	Letter to NCP	No reply				379	?
FI	Letter to minister	40,000 (2010)	100,000 40,000 (2011) 40,000 (2012)	1	Plan to promote using the Finnish Centre for Alternative Methods	7,164	0.0014
FR	Letter to minister	No reply				44,922	?
DE	Letter to NCP	5,015,000 (annually from various ministries)	5,015,000	3	Via ZEBET (German centre for 3Rs), also AnimALT-ZEBET database on alternatives	73,692	0.0068
EL	Letter to NCP	No reply				1,342	?
HU	Letter to NCP	No reply				1,205	?
IE	Parliamentary question	0	0	Being considered	Being considered	2,741	0
IT	Parliamentary question	No reply				19,756	?
LV	Letter to NCP	0	0	3	Still being considered	141	0
LT	Letter to NCP	No reply				282	?
LU	Letter to NCP	0	0	None	No animal testing facilities	608	0
MT	Letter to NCP	No reply				47	?
NL	Not contacted, not transposed	n/a				12,292	?
PL	Letter to NCP	No reply				2,836	?
PT	Parliamentary question	No reply				2,557	?
RO	Letter to NCP	No reply				657	?
SK	Letter to NCP	No reply				468	?
SL	Letter to government department	Do not know	Do not know	Do not know	Do not know	894	?

Member State	Method of contact	Previous funding, €	Funding for 2013 (Article 47(1)), €	Nomination of laboratories (Article 47(2))	Promotion of alternatives (Article 47(4))	Science R&D expenditure 2011, million € (EU, 2013)	% investment in alternatives out of science R&D expenditure
SP	Letter to minister	Not possible to determine	No specific budget	7	Cooperation agreement with the Spanish network for the development of alternative methods (REMA), coordination with autonomous regions, educational course planned	14,184	0
SE	Letter to government department	13 million SEK per year	1,689,762 (15 million SEK)	Several	A June 2012 report on how the government can do this is still being considered	13,078	0.013
UK	Parliamentary question	8,635,000 GBP (2010) 8,100,00 GBP (2011) 8,104,000 GBP (2012) (across various ministries)	11,071,467 (9,215,000 GBP)	None as yet	via the National Centre for the 3Rs, inspectors promote 3Rs within institutions and elsewhere, government commitment to reduce numbers (strategy not released yet)	30,993	0.036
TOTAL		**13 replies**	**18,724,005**	**15+**			

any potential NETVAL laboratories; Spain nominated seven laboratories but does not specifically contribute any government funds to alternatives. Within those countries contributing funds there is a 25-fold difference in the proportion of science R&D funding that goes to alternative method development. Large, older EU states such as Italy and France failed to even respond to the survey and concerns remain that historically their investment is not proportionately as high as that of other, smaller MS. There continue to be problems with acquiring information from the newer or more Eastern MS.

Those working in the field of alternatives to animal testing should remain concerned about this apparent lack of commitment across the EU to the development and promotion of alternative methods. It is important that all EU MS are aware that they have a responsibility under Article 47 to contribute. We encourage the European Commission and key individuals within MS to ensure that by the end of 2014 all MS have indicated publicly how they intend to satisfy Article 47. Only when we have a clear answer can we then assess whether this contribution is appropriate, proportionate and, importantly, adequate.

Replies from MS are available on request.

References

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