Effectiveness of toxicology-based webinars to promote nonstandard methods for REACH

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Introduction

The REACH regulation is designed to protect human health and the environment whilst promoting the use of alternatives to animal testing.

The regulation explicitly states that tests using vertebrates must be undertaken only as a last resort and includes mechanisms that allow use of non-animal approaches in lieu of the standard animal testing regime.

Here we report on the impact of a free webinar series designed to increase uptake of non-animal testing strategies for REACH, alongside a case study illustrating how non-animal methods can be used to predict skin sensitisation in a WoE assessment.

Webinar content and assessment

Led by experts in relevant fields, and made available to an international audience through a collaboration between the PETA International Science Consortium Ltd. and online news service Chemical Watch, each webinar explored use of validated non-animal approaches to meet REACH Annex VI and VIII endpoints. Following the live sessions, recordings were permanently archived online and made freely available at PIScLtd.org.uk, chemicalwatch.com, and eu-rctcm.jrc.ec.europa.eu.

At the end of each webinar, participants were emailed an optional 12 question web-based survey. Responses to key survey questions for the first four sessions are presented at right.

Figure 1: Summary of webinars to date.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Date</th>
<th>Webinar Registrants</th>
</tr>
</thead>
<tbody>
<tr>
<td>OECD QSAR Toolbox and Read-Across (QSAR/Ra)</td>
<td>October 22, 2014</td>
<td>835</td>
</tr>
<tr>
<td>Skin Irritation and Skin Corrosion (SIS/Cc)</td>
<td>November 11, 2014</td>
<td>736</td>
</tr>
<tr>
<td>Serious Eye Damage and Eye Irritation (SEED/Ei)</td>
<td>December 4, 2014</td>
<td>493</td>
</tr>
<tr>
<td>Skin Sensitisation (SIS)</td>
<td>January 28, 2015</td>
<td>950</td>
</tr>
<tr>
<td>Alternative Approaches to Mammalian Acute Systemic Toxicity Testing</td>
<td>March 5, 2015</td>
<td>547</td>
</tr>
</tbody>
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Webinar impact

Figure 2: In which country are you mainly based?

Figure 3: As a result of attending this webinar, are you more or less likely to use non-testing/non-animal methods for REACH 2018?

Figure 4: I gained some useful guidance on how to incorporate non-testing/non-animal methods into a testing strategy

Figure 5: Regarding the complexity of information, was it:

Figure 6: What do you think are the main barriers to the uptake of non-testing/non-animal methods (e.g. QSARs, read-across) for REACH?

Figure 7: What do you think are the main barriers to the uptake of non-testing/non-animal methods for REACH?

Using a weight of evidence approach to replace animal testing

Webinar participants routinely request demonstrations of potential WoE approaches applied to registered substances. Here we exemplify the use of non-testing/non-animal methods for two substances, from the sensitisation endpoint retrieved from the REACH registration database, using the ADP construct as a framework for organising the available data on the target substance and its related analogues.

Discussion

Evidence suggests that registrants may not be fully implementing non-animal methods12,13 to meet REACH data requirements as required by law. Furthermore, there is a view that ECHA is not fully applying its authority to encourage registrants minimise animal experiments.14 Separate and apart from regulatory oversight, measures must be taken to ensure that registrants understand how to use non-animal methods that can be used to meet REACH requirements. Feedback from participants of these sessions suggests that:

Webinars can provide comprehensive information on strategies incorporating non-standard approaches (Fig. 4, 5)

This information increases participant intention to use non-testing/non-animal methods (Fig. 3)

Lack of clear regulatory acceptance of non-standard approaches is perceived as the most likely barrier to their successful use in place of animal methods for REACH registration (Fig. 6, 7)

Additional webinars are scheduled that will cover the (Zebra)Fish Embryo Acute Toxicity Test to Predict Short Term Toxicity to Fish (April 2015) and ECHA perspectives on the use of non-animal methods (date TBA), but survey results indicate that perceived regulatory barriers may not be overcome by registrant education alone. Regulatory authorities must address these concerns.

References and acronyms

2. AOP - Alternative Organic Product
3. CRO - Contract Research Organisation
4. ECHA - European Chemical Agency
5. EPNO - European Page No.
6. OECD - Organisation for Economic Co-operation and Development
7. REACH - Registration, Evaluation, Authorisation and Restriction of chemicals
8. QSAR - Quantitative structure activity relationship
9. SI/SC - Sensitivity Indices/Sensitivity Coefficients
10. TBA - To be announced