NEWSLETTER

May 2014

HIGHLIGHTS

Interview with Jan Bilton

Winner of the first EPAA 3Rs Laboratory animal technician Award

At the EPAA annual conference, the jury congratulated the University of Leeds' laboratory technician for her award-winning work. On behalf of the EPAA, European Commissioner Janez Potočnik bestowed the 3000€ prize upon Jan Bilton.

European Commissioner Janez Potocnik & Award winner Jan Bilton

You just won the first EPAA 3Rs laboratory technician award and all the members of the jury were impressed by your experience. What led you to become a laboratory animal technician?

As an animal lover I knew I wanted to work with animals, but it actually wasn't always my intention to become a laboratory animal technician. My degree is in Equine Studies and I worked with horses initially, but the equine industry didn't have the career opportunities I needed long term.

I saw an advertisement for animal technicians in a local newspaper and began to work for a large drug development company in the North of England. I worked there for 3 years progressing from a husbandry technician up to obtaining my personal licence and performing a wide range of procedures on a variety of species. I was impressed with the industry and enjoyed my work, but at 26 decided I needed a change and travelled around Asia for a year.

On my return I found employment at the University of Leeds and I have been here for 5 years now.

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What does your current role involve?

I work at a 4500 cage transgenic mouse facility where we create and maintain mouse colonies for the research scientists here at the University of Leeds. We are a small team of 10 so the work is quite varied but my main responsibility is to take care of a variety of immune-compromised and transgenic mouse colonies and to ensure all their needs are met, everything from feeding and watering, to performing procedures when required. More recently I have learnt some transgenic procedures including Embryonic Stem Cells microinjection and have successfully created chimeric mice.

I like to continue to train and develop and I am also a qualified Named Animal Care and Welfare Officer at Leeds, being a port of call for any technician seeking advice regarding the welfare of an animal and always looking for new ways to improve the care and welfare of the mice in our facility.

As well as refining the care, the treatment also reduces the number of mice

How did you learn about the launch of the EPAA award?

The award details were forwarded to me by my area supervisor back in August 2013. She had seen it on the EPAA website and thought that the work I had been doing on mice with Ulcerative Dermatitis might be something I could submit.

You won the 3Rs laboratory technician award for your outstanding work on the treatment of ulcerative dermatitis on mice. Could you please describe how this Refinement method works and what are its benefits?

We had some cases of mice with ulcerative dermatitis in our unit and through repeated scratching of the area the lesions were often very sore, in severe cases the mice would be euthanized for welfare reasons. After failing to see improvement with various treatments I decided to try and break the itch/scratch cycle by trimming the toenails of affected mice.

The results were almost immediate, although the mice would still scratch, they were not damaging the skin and the area would look dryer and begin to heal by the next day. By refining the care we gave these mice their health and welfare really improved and for all the technicians involved it was a great result. As well as refining the care, the treatment also reduces the number of mice as we no longer need to replace those withdrawn. Further benefits are that the treatment is free, simple to teach, non-invasive and quick.

Do you think that working as a laboratory technician entails particular care for animal welfare? Do you have the feeling that animal welfare is an important cause in your country?

Absolutely. If you don't care about animal welfare then you shouldn't be an animal technician.

The UK has been known as a nation of animal lovers for many years and I'm lucky enough to work with a group of people who are definitely that. We all have pets at home and some have worked with animals for many years, which I believe brings a natural empathy and compassion. It's also important that we can all spot the signs of an animal in pain or distress quickly, and know what to do.

Being based in a country with such strong feelings for animal welfare can inevitably result in difficult situations with those who disagree with the use of animals in research. However when work with animals cannot be avoided, then I'm pleased to be one of the technicians involved in their care, because I know I am doing the best that I can for the animals that I am responsible for.

Your work focuses mostly on refinement of animal testing; how do the 3Rs relate to each other

Refinement is the «R» that I can have most effect on being the primary care giver. This is what was so great about the EPAA award – it was targeting technicians, who by the nature of their work have the most impact on welfare. Reduction and Replacement are occasionally applicable to us but really are more likely to be implemented by scientists, managers and industry heads.

I think all the 3R's work together to provide a framework that all those employed in animal research can strive towards and keep in their thoughts when developing protocols and experiments.

When submitting new project licence applications for approval, our scientists need to show how they are implementing each of the 3R's in their proposed research, which shows how the initiative has the ability to change our way of operating.

Being always aware of the 3R's motivates us all to think of new methods, avoid complacency and always look for ways to improve our practices.

2013 Call for submissions attracted

17 applications from all over Europe one 3000€ prize granted every other year

«Stakeholders must act jointly to find alternatives to animal testing»

EPAA industry co-chair Dr Tzutzuy Ramirez and EPAA adviser Renate Weissenhorn published a call for a joint initiative with AAT stakeholders in an article in The Parliament Magazine on 19th February 2014. The full text is available below*.

Collaboration between the EU, industry and researchers is needed to keep up the momentum in finding alternatives to animal testing, write Tzutzuy Ramirez-Hernandez and Renate Weissenhorn.

The safety of the products must be ensured. To date, most of the safety testing relies on animal testing, an approach required by regulations and considered to be predictive of the adverse effects in humans. However, with the advance in technology and societal driven needs to move towards animal-free alternatives, scientists worldwide are looking for reliable alternatives to reduce, refine and replace (3R's) the use of animals for toxicological testing.

The EU has developed animal welfare regulations since 1986, an example of which is the implementation of the seventh amendment of the cosmetic directive and the creation of the European centre for validation of alternative methods. In November 2005, the European commission began the European partnership for alternatives approaches to animal testing as a unique public-private partnership, with the overall aim to promote alternatives to animal testing based on scientific progress. Since its creation, EPAA has facilitated dialogue between industry partners that need to comply with regulatory safety requirements and services of the Commission.

A fundamental understanding has evolved within the partnership, that an effective reduction of animal testing can only be achieved if all aspects of the 3R concept are taken into account. This means that although the ultimate goal is to replace animal testing with in-vitro methods, we also need to focus on refinement and reduction of animal testing.

EPAA operates through its platforms of science (PoS) and regulation (PoR). Both coordinate projects addressing gaps in advancing the 3R's principle. An example of a PoS activity is the stem cells research project which is performed to identify the potential use of non-embryonic stem cells in safety testing.

At the same time the project establishes an international network of experts in stem cells research in order to increase awareness for the development of safety assessment tools with high relevance to the human situation but also of high reliability. Other PoR projects are dedicated to the optimization of non-animal alternatives applications in the field of skin allergies.

This project tries to move forward non-animal testing strategies for the identification of skin allergens for regulatory purposes in the EU. To achieve this, the EPAA has led meetings with experts from regulatory agencies, the Commission, industry and academia. EPAA has also played a role in advancing the concept of the extended 1-generation study, as a replacement for the 2-generation study. This alternative is an example of reduction through refinement, reducing the number of animals tested by approximately 1000, for each study.

A number of toxicological end points are now addressed by non-animal alternatives, particularly those related to topical application for skin and eye irritation. The next level of replacement would relate to systemic toxicity and reproduction toxicity, which are much more complex. To achieve an in-vitro replacement through such studies, a change of our current approach to the development of alternative methods is necessary.

First we need to better understand the processes which cause toxicity. This will require a significant amount of dedicated and focused research.

We then need to develop in-vitro methods that address key points in the adverse outcome pathway. Combining a number of in-vitro assays, addressing these key events in the pathway may then result in a model that could replace the animal test.

At the same time we will need to develop mathematical models which help to translate in-vitro concentrations into in vivo dose levels.

Therefore, it is important that collaboration among stakeholders is continued and that researchers, industry and regulators jointly discuss the best path forward. The European research and innovation horizon 2020 programme contains the potential for EU funding.

Downloaded the article via https://www.theparliamentmagazine.eu/articles/news/commission-must-act-jointly-stakeholders-find-alternatives-animal-testing

Givaudan

ENGAGING THE SENSES

epaa

The European Partnership for Alternative Approaches to Animal Testing

Introducing Givaudan, the 36th industry partner to join EPAA

We welcomed Givaudan earlier in 2013 as our 36th EPAA member company. Along with Symrise last year, your company reflects the commitment of the fragrance sector towards alternative approaches to animal testing. What triggered this decision?

Givaudan have for many years now been at the forefront of development of alternative methods in the area of skin sensitization and have also been active in the area of in silico modelling. We are very supportive of all approaches that may lead to the reduction of animal use for toxicology and this has become a critical question within the fragrance industry. The application of the REACH regulation in the EU as well as other chemical regulations globally is actually driving an increase in the need for animal testing. Therefore it was appropriate for Givaudan to join the EPAA to forward our 3R goals which are aligned with those of the EPAA. The fragrance sector has a specific interest due to the large numbers of substances used, which are generally characterized by a dermal exposure at low levels, which provides a realistic opportunity for the use of alternative approaches as well as methods in toxicological risk assessments to reduce animal use.

Givaudan is one of the leading blue-chip companies in the Fragrances industry. What are your Vision and Mission ?

Our Vision is to be our customers' essential partner in developing sustainable fragrance and flavour creations by engaging with our customers in collaborative dialogues during the development, creation and refinement of their products.

Our success continues to be built on innovation which is the common denominator in building capabilities. Our focus is on building partnerships with our clients and continuing to grow our position and presence in all major mature and developing markets. We maintain significant investments in cutting-edge research and consumer understanding programmes to remain the leading innovator in the industry.

The 3Rs declaration is one of the EPAA founding acts. Being an EPAA member, Givaudan is committed to facilitating development of alternative methods. What are your top priorities in terms of endpoints?

Obviously all toxicological endpoints are important and need to be considered. However, as leaders in the area of dermal sensitization this is clearly one area where we can make a contribution. In addition the promotion of risk assessment and testing strategies to approach safety assessment from a risk perspective rather than one of hazard, as is often the case with regulation, is of particular interest to us and is a rich area for exploration of 3R goals.

Givaudan experts are collaborating with EPAA on our Skin Sensitization project . What do you expect from this project team?

Several things. Firstly to be able to bring together key actors and researchers in the field to find a common approach to finally end the use of animals for this endpoint. The cross fertility of ideas and discussion is a useful role the EPAA can play here. Also, promotion of regulatory acceptance of approaches is important. Finally, the EPAA probably has an important role to play in coordinating efforts towards use of the alternative methods beyond just hazard assessment and into the vital need for potency and risk assessment.

EPAA is a Public-Private Partnership across 7 sectors of activity, including Fragrances. Besides EPAA, do you also interact with other sectors through associations or other platforms on alternative approaches and/or safety testing?

The EPAA is rather unique here in the involvement across several sectors focused on alternative approaches. This is another benefit of membership. Within Europe we are also members of ECETOC which similarly covers several industrial sectors which through its science programmes looks to advance safety testing approaches.

While it has ongoing operations on international cooperation on 3Rs, EPAA is committed to improving development, validation and acceptance of alternative methods in Europe. As a global company, is Givaudan particularly focused on Europe?

No. We are a global company with a significant (44%) part of our turnover in developing markets. We have to meet chemical and other relevant regulations on a global scale and therefore it is important that, whilst Europe is leading the efforts, that these are also accepted in other regions of the world. For example we are involved in a programme with the US EPA in the area of environmental testing and are looking to develop the acceptance of alternatives in Asia-Pacific.

Introducing Zoetis, the 37th industry partner to join EPAA

We are proud to welcome Zoetis, formerly Pfizer Animal health as our 37th EPAA member company. Your company is one of the leading stakeholders in the Animal health industry. What are the Vision and Mission of Zoetis?

Our vision is that our products, services and people will be the most valued by animal health customers around the world. Our mission is that we build on a six-decade history and singular focus on animal health to bring customers quality products, services and a commitment to their businesses.

Zoetis is fully committed to the development and use of scientifically validated alternative testing methods that are acceptable to regulatory authorities and do not compromise patient safety or the effectiveness of our medicines. Zoetis continues to engage and participate in cross-industry efforts aimed at developing and refining new in-vitro testing and predictive informatics-based systems that hold promise for future reduction of animal usage.

Zoetis representatives are involved in the EPAA Vaccines consistency approach project, whose potential is quite significant in terms of reduction and replacement of animal testing. How does Zoetis contribute to this project and what do you expect from this project?

Dr Catrina Stirling from Zoetis is an active member of the vaccines project committee working closely with other animal health members on several aspects of the project. The main areas of focus have been the Rabies potency test and first steps in alternative toxicity tests for Clostridial vaccines. Dr Stirling co-organised a veterinary Rabies potency test workshop and has been actively involved in internal validation work on both the serology and ELISA tests for Rabies. Zoetis hopes that by the end of 2014 it will be possible for us to move all our Rabies vaccines to the serology test from the challenge method with the long term aim to gain regulatory acceptance for the ELISA test only. Zoetis considers acceptance of the glycoprotein ELISA only method for Rabies vaccine potency would be a major achievement in the 3Rs field.

We are also actively involved in the project to validate the new cell line assay for Clostridium septicum toxicity testing and will work with the vaccines project committee to try to carry on this work and identify and validate the same type of approach for other Clostridial species. This again would be a big step forward as currently these tests use a large number of animals for release testing. Zoetis hopes that through these collaborative efforts 3Rs methods for the veterinary vaccine industry can move forward as there are significant technical, financial and regulatory challenges in developing and gaining regulatory approval of alternative methods that cannot be overcome by individual companies.

In addition Dr Stirling is now working with the vaccines project committee on organising a workshop style meeting on the consistency approach in 2015. This is another key approach in gaining acceptance of in vitro methods for product testing and development. Gaining better global understanding and acceptance of this approach should facilitate its use going forward.

EPAA is a Public-Private Partnership across 7 sectors of activity, including Animal Health. Besides EPAA, do you also interact with other sectors through associations or other platforms ?

We work through trade organizations such as IFAH-Europe -which is also an EPAA partner. We also work directly with regulators to increase the recognition and acceptance of alternative models where such alternatives can be used appropriately.

While it has ongoing operations on international cooperation on 3Rs, EPAA is committed to improving development, validation and acceptance of alternative methods in Europe. As a global company, is Zoetis particularly focused on Europe?

We operate in more than 120 countries on 5 continents. Europe, together with the Middle-East, Africa and Russia is our second largest market behind the US, therefore Europe is most definitely important for us.

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Upcoming events

Eurogroup for animals special event: Putting Animal Welfare at the Heart of the EU: A Plan to deliver a better future for all Animals in the EU
18-19 June 2014 - Brussels
Further information on http://eurogroupforanimals.org/get-involved/putting-animal-welfare-at-the-heart-of-the-european-elections/

CARACAL group meeting - EPAA presentation
10-11 July 2014 - Brussels
On invitation only

9th World Congress on Alternatives and Animal Use in Life Sciences
24-28 August 2014 - Prague
Information and registration on http://www.wc9prague.org/

EPAA-CDSS Joint Stem Cells Forum
3-4 September 2014 - Liverpool
On invitation only

EPAA Workshop on Regulatory Acceptance of Alternative Methods
22 September 2014 - Brussels -
On invitation only

EPAA Workshop on Human & Veterinary Rabies Vaccines
The EPAA Vaccinces Consistency Approach Project
Q4 2014 - Brussels on invitation only

10th EPAA Annual Conference
19 November 2014 - Brussels
Further information will be available on the EPAA website

SEURAT-1 4th annual meeting showcases new results & challenges in alternative methods to animal testing

Report from the event held in Barcelona, 5-6th February 2014

The SEURAT-1 cluster assembled for its fourth annual meeting in Barcelona on 5-6th February 2014. EPAA was kindly invited to attend this event gathering 150 high-level scientists from academia, regulators and industry. The meeting attracted participants coming from as far as the US over two days and is expected to be the last but one annual meeting of the five-year programme.

With the collective aim of ultimately replacing in vivo repeated dose systemic toxicity testing with animal-free solutions, the SEURAT-1 cluster is the largest EU initiative ever undertaken on alternative methods to animal testing, comprising 70 European research partners equally co-financed through a unique public-private partnership between the European Commission (FP7 Programme administered by DG Research & Innovation) and Cosmetics Europe. SEURAT-1 combines five research projects (COSMOS, Scr&Tox, DETECTIVE, HeMiBio and NOTOX), a central data and knowledge management project (ToxBank) and a coordination action (COACH).

EURL ECVAM (the European Union Reference Laboratory for Alternatives to Animal Testing), hosted by the European Commission Joint Research Centre, Institute of Health and Consumer Protection (JRC-IHCP), is heavily involved in three of the five complementary research projects, and manages the coordination efforts of the entire cluster. The cluster's communication efforts were supported by EPAA, with live-tweeting on @EPAA3Rs and some coverage targeting the EPAA members.

SEURAT-1 cluster

This annual meeting was the largest so far, attracting more than 150 participants; case studies were discussed through dedicated presentation, poster and breakout sessions. All the projects are well advanced in their work programmes and a wide variety of new methodologies and tools for mechanistic-based toxicology were unveiled at the meeting. Results on development of complex bioreactors, imaging human tissues, innovative 'omics' techniques, differentiation of human pluripotent stem cells and modelling tools were presented.

Much attention has been devoted to the Proof-of-Concept (PoCs) of the SEURAT-1 strategy, i.e. to develop complementary theoretical, computational and experimental (in vitro) models to predict toxicity in humans and apply the predictions in safety assessment of chemicals. Another scientific achievement was the launch of the public COSMOS database, a one-stop-repository of chronic toxicity data.

Proceedings

A synthesis report is now available, highlighting major scientific achievements of SEURAT-1 presented in Barcelona (download pdf version below).
A full description of the projects' deliverables will be provided in the next SEURAT-1 Annual Report, to be made available on the SEURAT-1 website.

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"Animal Testing – Science or Tradition? What future for alternatives to animal testing?"

Report from the expert meeting held in the European Parliament, Brussels, 19th February 2014

In the morning of February 19th, MEP Sidonia JĘDRZEJEWSKA organized a breakfast meeting on the theme "Animal Testing – Science or Tradition: what futures to alternatives to animal testing?", where EPAA was invited to give a presentation, along with other speakers.

MEP Sidonia JĘDRZEJEWSKA (EPP-Poland) is a member of the parliamentary intergroup on animal welfare and sits in the Budgets committee of the Parliament.

In front of a 50-person attendance (including MEP assistants, animal welfare NGO representatives, industry and Commission representatives as well as European public affairs professionals) EPAA Industry co-chair Tzutzuy Ramirez and EPAA Secretariat adviser Renate Weissenhorn gave a 20-minute presentation introducing EPAA and two of its flagship activities: The Skin Sensitization project as an example of the cross-sector nature of our work, and the Stem Cells projects, as a promising alternative for replacement. Renate Weissenhorn started with an overview on EPAA, its history, its vision and mission and its membership and Tzutzuy Ramirez focused on the part specific to our projects.

Other speakers included Emily McIvor from Humane Society International and Prof. Coenraad Hendriksen, from the Dutch Intravacc (vaccines authority). They both mentioned EPAA in their presentations, echoing their participation in the EPAA Mirror Group. CAAT-EU was also represented by François Busquet who provided a US perspective.

This event was a great opportunity to give a briefing on EPAA to MEP JĘDRZEJEWSKA and several assistants of other MEPs. It showcased the fruitful collaboration between industry and the EC and helped to put EPAA on the map by

giving a flavour of our activities to people outside our usual circle. Live-tweeting of the event was organized via our account @EPAA3Rs, and also followed by several stakeholders from civil society (HSI, Eurogroup for animals, CAAT-EU etc.).

The event's proceedings can be downloaded from http://www.sidonia.pl/files/12iii14.pdf

« Are there any scientific reasons why we cannot change the paradigm? »

MEP Jedrzejewska

From left to right: E. McIvor (Humane Society International & EPAA MG), MEP S. Jedrzejewska (Host), R.Weissenhorn, T. Ramirez, Ch. de Saintes (EC DG RTD & EPAA SC)

EPAA's international collaboration with the Institute for In Vitro Sciences

In the autumn of 2012, EPAA signed a Memorandum of Understanding (MoU) with the US-based Institute for In Vitro Sciences (IIVS) to coordinate efforts in progressing the international use of non-animal testing methods. The two organizations agreed to combine resources and collaborate to promote international awareness and education of these methods, and to provide science-based advocacy to key stakeholders. Since the signing of the MoU, IIVS has engaged in several activities in China which provided direct contact with scientists and key decision makers on the implementation of in vitro methods.

Dr. Quanshun Zhang, Manager of International Outreach at IIVS, attended the International Congress of Toxicology (ICT) in Seoul, Korea to interact with a delegation of scientists from China. These scientists came from major areas of government and academic institutions including the CFDA, CDC, Ministry of Environmental Protection, Chinese Academy of Science and Sun Yat-Sen University. Korea, with the formation of the Korean Center for the Validation of Alternative Methods (KoCVAM), serves as a model for the adoption of OECD Test Guideline methods and participation in international validation efforts. An "Alternatives Methods Section" of the Congress featured speakers from JaCVAM, ICCVAM and ECVAM who further reinforced advantages of international harmonization of alternative methods.

At the Chinese Society of Toxicology (CSOT) in Guangzhou, China, Dr. Zhang presented a poster on behalf of EPAA titled "International Sharing of Scientific Knowledge in Affecting Change in Regulatory Testing Approaches". Over 1,500 toxicologists attended the meeting from industry, government and academic/research institutions. As China considers changes to its regulatory testing requirements it is critical to discuss the advantages of in vitro testing approaches with key decision makers and thought leaders within China.

In addition to annual conferences such as the ICT and SOT, IIVS represented EPAA's commitment to international outreach at less formal venues designed to introduce industry scientists and students to in vitro methods. For example, Dr. Zhang was invited to speak at the Skin Biology Symposium organized by the Beijing Daily Chemical Association; an organization comprised of domestic cosmetic and ingredient manufacturers. The presentation focused on the application of 3D skin models in safety and efficacy assessment of cosmetics and ingredients. Dr. Zhang also delivered a lecture to graduate students at the Beijing Technology and Business University (BTBU). See more about BTBU in the previous story.

To broaden general awareness of alternatives in China, EPAA helped support the translation into Chinese and publication of The Three Rs and the Humanity Criterion by Prof. Michael Balls. This edition is an abridged version of The Principles of Humane Experimental Technique by William Russell and Rex Burch. This newly translated book will be distributed free of charge to many libraries and all major universities within China.

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