INTERGROUP ON THE WELFARE & CONSERVATION OF ANIMALS

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Report of the 268th Session

Wednesday 16 February 2011, 16.00 17.00 hrs
Room LOW N 3.2 – European Parliament, Strasbourg

1. Introductory remarks

Written declaration 87: on the marketing of eggs from hens housed in outlawed cages

Authors : Nicole Sinclaire, Mike Nattrass
Date opened : 10/11/2010
The wd lapsed on 17/02/2011 without having been adopted
Number of signatories : **51** - 25/11/2010

New Hungarian Presidency compromise on novel foods dossier

A compromise has been discussed in trialogue on removing the reference of cloning from the Novel Foods Regulation. The Presidency would like to see no food from cloned animals being placed on the EU market before the adoption and entry into force of specific legislation. However the issue of offspring and the products from offspring is still unsolved.

Antibiotic resistance in animals

Following an oral question to the Commission adopted on 7 February the European Parliament recognised the serious threat posed to animal health due to antibiotic resistance and urged the Commission to draw up data on the use of animal health products across the EU and to develop plans to tackle this threat with a coordinated approach. A resolution will be drafted on the topic and will be discussed in the Agriculture Committee in March.

2. Cosmetics and Animal Testing

Advancing the science on alternatives to animal testing

Bertil Heerink, Director-General of Colipa gave an introduction about the efforts made by the cosmetics industry to replace animal testing as soon as possible.
Following the requirements of the Cosmetics Directive, the European Commission has to provide a report on the scientific progress made towards meeting the deadline of a full marketing ban of animal tested cosmetics in 2013. Preparatory actions were initiated in May 2010 with an EU public consultation for stakeholders. The Commission report will be published in April 2011 and will be submitted to the Council and the European Parliament.
The efforts of the cosmetics industry to replace animal testing with alternatives date back to 1992 when *the Scientific Steering Committee for Alternatives to Animal Testing* -SCAAT was founded. In 2005, realising that the overall agenda on replacement, refinement and reduction of animal tests needed a far more significant initiative, Colipa co-founded together with the Commission and other involved sectors *the European Partnership on Alternatives to Animal testing EPAA*. This year, Colipa has started together with the European Commission a 50 million research programme on systemic toxicology which focuses on the general exposure of the human body to various effects.

Dr Horst Wenck, Chair of the Colipa programme on alternatives to animal testing and Corportate Vice-President of Research for Beiersdorf pointed out that the cosmetics industry is the only industry sector which is solely focused on one of the '*Three Rs'* the replacement R. During the last years the cosmetics industry has put together a considerable track record of alternative testing methods:

- Validation of 11 methods for 4 toxicological effects, applicable across industries,
- An in vitro method for diffusion through the skin (approved by the OECD)
- Ongoing validations for in vitro eye irritation tests (will end this year)
- Pre-validation for 3 skin allergy methods

Toxicology comprises all together 15 different aspects which are called '*endpoints'*. These are grouped in seven sectors (see table below).

Completed endpoints for which alternatives are in use

1	Genotoxicity, eye irritation, acute toxicity	Deadline 2009
2	Skin irritation, phototoxicity, percutaneous absorption, skin corrosion	

Not yet completed endpoints on repeated dose toxicity tests

3	Subacute subchronic toxicity	Deadline 2013
4	Carcinogenicity	
5	Skin sensitisation and photosensitisation	

Not yet completed endpoints

6	Toxicokinetics	Deadline 2013
7	Reprotoxicity including terato-toxicity	Deadline 2013

The process of establishing alternatives to animal testing

First of all, the biological mechanisms that lead to a toxic effect have to be understood. Research has to be carried out for this purpose. On the basis of this knowledge test systems can be developed *in vitro* on cell cultures or non-organism types. Once several testing methods are available they are put in a non-animal toolbox capable of replacing the need for animal test data to allow risk assessment decisions.

There has to be comprehensive evidence that the toolbox is valid and useful in terms of predicting hazard and risk. Only then, it can be officially accepted and used. This last step in the process may take many years. For instance, the alternative for evaluating eye irritation is now in the final stages of validation. Some alternative methods are already available but not yet officially accepted. This takes a long time because regulators have to be absolutely sure about the reliability of a test method.

A classical toxicological test involves just an endpoint meaning a certain symptom on an animal. This symptom comprises of many different mechanisms working in cooperation in the organism that ultimately lead to a certain effect. Each of the mechanisms implies a single essay that becomes part of the toolbox necessary to study a new chemical and any of its potential effects. The toolbox allows simulating toxicological effects without the use of animals.

Acceptance by the regulators

It is necessary to know and understand how to use a non-animal toolbox for hazard characterisation and risk assessment. Each test method of the box has to be pre-validated to proof that it is mechanistically relevant, robust and reproducible and that it can be employed by various laboratories. This very complex and lengthy process is the precondition for acceptance by the regulators.

The Future Colipa Research Programme

- Eye irritation is at an advanced validation stage which should end this year.
- In vitro essays to evaluate genotoxicity have been in use for years. However, they yield a large number of false positives. This is the reason why Colipa carries out research to refine the essays.
- Research on skin sensitisation is the most prominent part as most of the cosmetics are put on the skin.
- Systemic toxicity research is jointly carried out with the European Commission and focuses on effects regarding the whole body and not just the skin.

A research example: Skin Sensitisation

The complexity of approach towards developing an alternative toolbox is explained by the example of skin sensitisation, which can be considered an allergy. Skin allergy involves the potential harmful ingredient to penetrate through the skin. To be metabolised it needs to bind to a protein. The protein bound chemical is then detected by an immune cell with which it travels to the local lymph node system. There the chemical is exposed to so- called lymphatic T cells that will generate a systemic response to skin sensitisation.

To understand and study such complex systems is not an easy task and that is why Colipa has engaged in a complex research programme.

All of the projects are run, instituted and paid for by the cosmetics industry both done internally as well as with universities and in cooperation projects. The cosmetics industry has made substantial progress in this area that will allow creating the next step - a pipeline of potential methods.

Skin sensitisation: method pipeline

The pipeline consists of some methods still being in development and others that are already more advanced in terms of science and progress. They are currently being evaluated. Some of them have been generated totally by the cosmetics industry, some by single companies and some from the outside. A few of these methods have already made it to a stage at which they could become part of the toolbox to be developed for skin sensitisation. They are currently officially pre-validated by ECVAM- the European Centre for the Validation of Alternative Methods.

Summary and conclusions

The development of alternative methods to animal testing is not an easy task. However, the European cosmetics industry can be proud of its success. It is a key contributor to the currently accepted alternative methods to animal toxicity testing that are now used across different industry sectors. The cosmetics industry runs a comprehensive science and development programme and has done so many years before any ban was put in place or written into the law. To close the still remaining gaps is in the interest of the industry as alternative methods are quicker, more effective and cheaper. That it is why it is in their best interest to pursue the research programmes to stop animal testing as soon as possible.

Questions and debate

Anna Rosbach (EFD, DK) asked a question about the systemic toxicity of deodorants. Horst Wenck assured her that all ingredients of deodorants have to undergo a very careful set of testing comprising all aspects from local toxicity to systemic toxicity. Deodorants on the European market can be considered as harmless.

Chris Davies (ALDE, UK) inquired about the potential of developing new cosmetics by using ingredients that are already available. This is a key argument about whether the 2013 deadline must be kept or not. Horst Wenck replied that the cosmetics industry benefits tremendously from the very rapid advances in live science which duplicates its knowledge every three years. This opens many new chances. Due to the aging of Western society skin diseases are likely to increase in future. The pharmaceutical industry has essentially left the field of dermatology because it is too small for them and does not generate enough profits. Thus cosmetics for skin treatment, will have a tremendous chance to benefit the society. That is why the industry needs to have access to novel chemicals to advance science in cosmetics. Chris Davies was not convinced about the argument that the cosmetics industry is moving into an area which has been deserted by the pharmaceutical industry. If there is a health problem the pharmaceutical industry will still be in charge to find a solution and not the cosmetics industry. Horst Wenck replied that the cosmetics industry is legally allowed to provide protective products against the assail of diseases. Thus it has a concrete chance to expand in the sector of skin ailments. Ingredients that have been developed in the past do not correspond to the most sophisticated modern science. Depriving society from advancement and science is not a great service to the general public.

Carl Schlyter (Greens/EFA, SE) wanted to know about the relationship and the cooperation between the cosmetics industry and the pharmaceutical industry. Horst Wenck replied that the European Partnership for Alternatives to Animal testing was formed in collaboration with the chemicals industry and the pharmaceutical industry. There is an intensive cooperation in the EPAA. Several non-animal test methods in use have been stimulated by research from pharmaceutical industry as for instance the OECD conform bioavailability essay which was originally founded by Roche. Carl Schlyter asked also for information concerning nanotoxicity. Horst Wenck replied that nanotoxicity is nowadays a nice term to generate grants. However, as along as a system is analysed carefully it is not of importance if it is nano-, macro- or dissolved. Most of the products a human body is exposed to are solutions which are of sub-nano-size.

Ending animal testing for cosmetics

Emily McIvor, Senior Advisor, Research and Toxicology HSI-Europe stressed that the campaign to end the testing of cosmetics on animals has a long and proud history. It has resulted in an EU wide test ban and a three phased introduction of a marketing ban.

There are currently two large coalitions of animal protection groups in the European Union and one of those was formed directly in response to end cosmetics testing. The subject is of enormous interest to citizens.

She welcomed the fine work which has been done by the cosmetics industry in developing alternatives and was aware about the relevance of the scientific debate. She stressed however that in relation to the 2013 ban the public has waited a very long time.

The EU-legislative developments can be traced back to 1993 when the sixth amendment to the Cosmetics Directive banned the marketing of animal tested cosmetics from 1998. Two further Commission Directives delayed the ban again, first to 2000 and then to 2002. In the more recent history, the seventh amendment to the Cosmetics Directive (2003) introduced the phased introduction of the test and marketing bans. The public campaigning continued throughout.

It is important for legislators to remember that large parts of the general public want cosmetics testing to be stopped right away, regardless of any other information. This can be seen in the success of cosmetics companies that market animal test free products.

MEPs who where involved in negotiating will remember that the 2009 ban was meant to be in place regardless the availability of alternatives. There was no opportunity to shift from 2009. However, the 2013 ban has always been subject to delay if alternative methods are not available.

The 2013 ban included three endpoints that could be delayed, - that is toxicokinetics, repeated dose toxicity and reproductive toxicity. The 2004 Commission report to the European Parliament and Council clearly stated that those three endpoints would be the only ones for which a derogation was possible.

However, due to changes in language and interpretation additional endpoints are now included in the 2013 ban. This means that legislators' intention in making the 2009 ban an absolute ban with no cut-off have been undermined by language shifting, changing the interpretation. The Commission will now respond to written questions to say that additional endpoints carcinogenicity and skin sensitisation belong in the 2013 deadline because they actually fall under the general heading for repeated dose toxicity.
Neither toxicologists nor regulators have ever separated the endpoints in that way. Those endpoints are always as separate stand alone tests. This is partly why it is so important to keep the 2013 deadline.

The public never supported a compromise allowing a delay to the 2013 ban as it believes that a ban creates the necessary momentum for the replacement of animal methods. Keeping the ban would only affect 'new to the world' cosmetics ingredients and just until animal tests are replaced. Existing cosmetics and their ingredients can still be used and these ingredients can be reformulated to allow innovation. There is no longer a requirement to test finished products. This is sufficient evidence that existing ingredients can be reformulated safely. Citizens know that there are thousands of products available and the success of brands like the '*Body Shop'* is testimony to the fact that innovation can continue. Cosmetics companies can be successful with no new animal testing.

The relevant argument relating to science is the general scientific need to replace animal methods. This is not only due to animal welfare concerns. Alternative methods are quicker, more effective and cheaper. Animal tests introduce inherent uncertainty to risk assessment which is due to physiological differences between animal species and humans. Regulators have difficulties to extrapolate results from the effects of high test doses on small animals to low dose human exposure. The commonly used animals in toxicity testing have a life span of one or two years but human exposure to certain substances can last for decades. Animals in tests are exposed to single substances but real life exposure by human beings is to a cocktail of chemicals.

The cosmetics sector has led the way to replacing animal test methods other sectors lag behind. The EPAA has produced results but other sectors and the regulators are often resistant to change.

Conclusion

From 1993 to 2002 research for the development of alternative methods was quite slow. There was a marked speeding-up of the progress after the 7Th amendment to the Cosmetics Directive was agreed. This was due to the fact that the 2009 ban was shaped as a cut-off with no opportunity for delay. The 2009 ban has been shifted in part to 2013 because of changes in the interpretation of language.
The 2013 deadline needs to stand and should not be postponed. Citizens recognise that thousands and thousands of products are already on the market. Animal welfare organisations are only talking about a break in producing 'new to the world' ingredients and not about a permanent state in blocking the cosmetics industry from innovation. They refer to a period of time between 2013 and when alternative methods are available but with no opportunity to sell those products in the mean time.
She ended by stating that even the Draize rabbit-eye test for which international campaigns to end it began in 1982 is still in use despite the ban of 2009.

Questions and debate

Chris Davies (ALDE, UK) wanted to know why the Draize rabbit-eye test is still in use. Horst Wenck replied that it is against the law to use the Draize eye irritation test. Since 2009, any ingredient in a cosmetic that is tested with

the Draize eye test would make the cosmetic unsellable in the European Union. Allegations that this test is still in use are incorrect. Emily McIvor countered that in questioning Member States authorities on the enforcement of the bans no satisfactory evidence has ever been produced that the Member States are enforcing the 2009 ban or the 2004 phase of the marketing ban. Eye irritation was listed in the Colipa slides as completed despite it is not because the alternative method for identifying mild or non-irritation is not yet in place. She was very pleased to hear about Colipa's confidence that no cosmetics are coming into the EU which have been tested using the Draize eye test.

Roger Helmer (EPP, UK) stated that bans are introduced in a sort of cheerful insouciance without fully considering aspects practical enforcement. A similar case is the cloning of animals for food supply. There is no scientific test that can proof if a piece of meat comes from the offspring of an animal that has been cloned and there is no scientific test to find out whether a cosmetic contains an ingredient that has been tested on animals. He feared that imposing unilaterally a particular ban on cosmetics from a worldwide source would lead to problems with the WTO.
Emily McIvor replied that the cosmetics marketing ban has been evaluated as WTO compliant. Part of the reasoning is that the ban simply stops someone outside the EU to do what is banned inside the EU .
In relation to enforcement regulators can ask for safety data sheets and they can see when a test was carried out. The two cut offs, 2009 and 2013 have contributed in making that assessment quite confusing. That is another reason why the 2013 ban is important because at that point any testing done after 2013 would signal that the product should not be on sale in the EU and it would make the job of enforcement very much easier.
Bertil Heerink confirmed that the requirements of the 7th amendment to the Cosmetics Directive have led to a track record of scientific progress. The research on the replacement of animal tests has also created a spin off effect on the refinement of methods. The European cosmetics industry is leading on the global level and is not worried by WTO challenges. The ethical considerations, the economic aspects and the health and safety dimensions related to the development of alternatives to animal testing constitute a package which is robust and credible. The cosmetics industry will therefore continue to invest in research on alternatives to animal testing.
Horst Wenck added that the cut off date of 2009 is absolute and the testing ban already applies throughout the European Union. No testing is allowed as of March 2009. The bans of 2013 are scientifically more complex and this is recognised by the European decision making process. This is precisely why the cosmetics industry sees scientific progress as a fundamental aspect.

Catherine Soullie (EPP, FR) criticised that the products of the '*Body Shop'* had been praised in Emily McIvor's presentation. She pointed out that the ingredients of their products have also been tested on animals, even if this was done in the past. She wanted to know how to keep cosmetic products outside the European Union which have been tested on animals without restrictions.
Emily McIvor replied that the importance of setting a fixed cut off date is to make a distinction. It is fair to differentiate between testing that has been carried out in the past and cannot be changed anymore and testing that will be carried out in future and which should be stopped. There is an acknowledgement that history cannot be changed but from 2013 we have the opportunity to ensure that all cosmetics companies selling products in the EU have not carried out new animal tests. Replying to Mrs Soullie's question of animal testing in third counties she stressed that to avoid this, the EU marketing ban of cosmetic products tested on animals is essential. This will force companies to apply the same policies in and outside the EU.
Horst Wenck stressed that the cosmetics industry does not export animal testing to third countries as the European testing facilities are very competitive in terms of pricing. During the last decade it would have been legally possible to carry out animal testing in third countries but it would not have made a difference. He emphasised that the good results in the development of alternative tests are not so much due to the EU ban on animal testing as to the dramatic progress in life science which has allowed speeding up the research.

4 Closing remarks

The Chairman asked all MEPs present to support an Intergroup letter to Commissioner Dalli calling on the Commission to stick to the 2013 deadline of the marketing ban.
The next Intergroup meeting will take place on Thursday 10 March 2011 from 10.00-11.00 o'clock in the room LOW N 3.2. It will focus on Pig welfare with speakers from Eurogroup for Animals and Alsatian pig farmer.

Intergroup on the Welfare & Conservation of Animals February 2011

ATTENDANCE

Members of the European Parliament (14)

Arsenis, Kriton (Vice-President)	S&D	GR
Davies, Chris	ALDE	UK
Foster, Jacqueline (Vice-President)	ECR	UK
Gerbrandy, Gerben-Jan	ALDE	NL
Helmer, Roger	ECR	UK
Koch, Dieter-Lebrecht	EPP	DE
Leichtfried, Jörg (Vice-President)	S&D	AT
Paulsen, Marit (Honorary Secretary)	ALDE	SE
Pietikäinen, Sirpa (Vice-President)	EPP	FI
Rosbach, Anna	EFD	DK
Schlyter, Carl (President)	Greens/EFA	SE
Soullie, Catherine (Vice-President)	EPP	FR
Vattimo, Gianni	ALDE	IT
Wojciechowski, Janusz (Vice-President)	ECR	PL

Assistants and Trainees to Members of the European Parliament (20)

Böcker, Julian	Assistant to Ms Jeggle (EPP, DE)
Bono, Joseph	Assistant to Mr Helmer(ECR, UK)
Deblock, Sarah	Assistant to Mr Davies (ALDE, UK)
Ershad, Sakib	Assistant
Felten, Noël	Assistant to Mr Franco (EPP, FR)
Fiala, Judith	Assistant to Mr Leichtfried (S&D, AT)
Janowicke, Sonia	Trainee
Jenkins, Cassi	Assistant to Mr Howitt (S&D, UK)
Koskenvoima, Pekka	Trainee to Mr Schlyter (Greens/EFA, SE)
Langguth, Katrin	Assistant to Ms Roth-Behrendt
Letters, Chris	Trainee to Ms Lambert (Greens/EFA, UK)
Morsch, Edelmayer, Dorothea	Trainee to Ms Köstinger (EPP, AT)
Murray, Kate	Assistant to Mr Martin (S&D, UK)
Ott, Ljubow	Assistant to Mr Koch (EPP, DE)
Pena, Judith	Assistant to Ms Soullie (EPP, FR)
Perman, Jeanette	Assistant to Mr Schlyter (Greens/EFA, SE)
Sergo, Leida	Assistant to Ms Paulsen (ALDE, SE)
Steinhoff, Ruth	Assistant to Ms Hirsch (ALDE, DE)
Tuippo, Miriam	Assistant to Ms Pietikäinen(EPP, FI)
Vauchelle François-Xavier	Assistant to Ms Grossetête (EPP, FR)

Guest Speakers and Observers (21)

Bargum, Willem	Political Advisor, ALDE Group
Blanchard, Marie	Manager Public Affairs
Borczak, Karolina	L'Oreal
Gautrais, Bruno	DG SANCO, European Commission
Gazzane, Samira	European Policy advisor ECEAE
Grahek, Urska	JRC, European Commission, stakeholder relations
Heerink, Bertil	Director General Colipa
Jenmiar Kozni	IFRA
Lalloum, José	Managing Partner, Logos
Laroche, Charles	Laroche Conseil
Majerczyk, Magdalena	ECR Political Advisor
Marie, Christope	Fondation Brigitte Bardot
Matkowska, Milenia	Dods EU Monitoring
McIvor, Emily	HIS
Miczki, Tamara	DG PRES, European Parliament
Moser, Eleonora	Behaviourist, Pets
Schoch, Liliane	Comurnat
Singhofen, Axel	Political Advisor, Greens/EFA
Taalman, Rob	Director Colipa
Vermooten, Colipa	Director Colipa
Wenck Horst	VP Beiersdorf

Intergroup Secretariat (1)

Erler, Andreas