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Dear Sir or Madam

## Policy issues around '*in silico*' methods – as alternatives to animal testing

In recent years the EU has funded research into developing computer-based methods for evaluating the toxicity of chemicals, called '*in silico* methods'. These are potentially important in making it possible to test large numbers of chemicals (as required by the EU REACH legislation) while also reducing the numbers of tests on animals.

The ORCHESTRA project is funded by the EU to communicate some of those research findings. Our intention is to increase the understanding of these alternative methods among potential users in industry, among regulators and other decision-makers, and in the wider public and policy debates. This survey will help us to find out what people regard as the priorities, as well as what information is needed and how we should communicate it.

- The short questionnaire on the following pages is our invitation to **policy makers, industry managers, educators, political leaders, NGOs, investors, citizens** and all others who are **not specialists** in toxicology to comment on some of the issues that are raised and/or addressed by *in silico* methods.
- Online we are offering a parallel questionnaire specifically for regulators, industry specialists, toxicologists, QSAR developers, scientists and any others with **specialist** knowledge or experience. If you would like to complete that questionnaire, or both, please do so. ([www.in-silico-methods.eu](http://www.in-silico-methods.eu))

We really hope you can take a few minutes to complete the questionnaire with this letter. Please also copy it to others who may be interested.

You can send the completed form by **fax** to Dr. Emilio Benfenati, 0039-02-39014735

or by **post** to Dr. Emilio Benfenati, Mario Negri Institute, Via Giuseppe La Masa 19, 20156, Milano, Italy

Thank you.

Yours sincerely

Dr Emilio Benfenati  
*Head, Laboratory of Environmental Chemistry and Toxicology*

A questionnaire for policy makers, industry managers, educators, NGOs... and citizens

You may find the introductory leaflet on *in silico* methods useful: [www.in-silico-methods.eu](http://www.in-silico-methods.eu)

### Q1 The 2007 REACH legislation on industrial chemicals has four aims.

In your view, what is their relative importance? 0 = not important; 10 = extremely important

0 1 2 3 4 5 6 7 8 9 10

Example	0	1	2	3	4	5	6	7	8	9	10
							X				
1. 'Improve the protection of human health and the environment from the risks that can be posed by chemicals'											
2. 'Enhance the competitiveness of the EU chemicals industry, a key sector for the economy of the EU'											
3. 'Promote alternative methods for the assessment of hazards of substances' (i.e. alternatives to animal testing)											
4. 'Ensure the free circulation of substances on the internal market of the European Union'											

### Q2 The following are some of the ways in which the REACH aims can be achieved.

In your view, what is their relative importance?

0 1 2 3 4 5 6 7 8 9 10

<b>Testing new chemicals</b> Obtaining scientifically sound information on the potential hazards to human health and the environment of <i>new</i> chemical substances produced in the EU or imported into the EU.											
<b>Testing existing chemicals</b> Obtaining scientifically sound information on the large number of <i>substances already in use</i> where there is inadequate information.											
<b>Placing the responsibility and costs onto industry</b> Placing the responsibility on industry to provide the evidence (to propose, carry out and report tests), and to assess and manage the risks, so that industry bears these costs rather than the taxpayer. (Regulators review test proposals and results, do spot checks and focus on problem areas.)											
<b>Caution by regulators towards alternative methods</b> Being conservative and cautious before accepting each proposal to use non-animal methods, in order to prioritise the protection of human health and the environment.											
<b>Requiring industry to share the results of tests</b> Requiring companies to share the results from past and future tests with other companies, to avoid repeating animal experiments.											
<b>Approving animal tests only as a last resort</b> Approving proposals for animal tests only in cases where other methods are not yet available.											
<b>Public investment in developing alternative methods</b> Investing in the development of alternatives to animal testing, and increasing the understanding of these methods by industry and regulators.											
<b>Ensuring open data access to develop <i>in silico</i> models</b> Requiring companies to make the results from animal tests accessible at no cost or low cost to the developers of <i>in silico</i> models, so that <i>in silico</i> models can be developed to replace further animal tests.											
<b>Ensuring <i>in silico</i> models are accessible</b> either at low cost, or freely available online, to enable their use by small companies, regulators, educators, scientists, NGOs and others.											

### If you could add another priority to the list in Q2, what would it be?

### Q3 The following are some of the advantages of *in silico* methods. From your perspective, which are the most important?

(Please number them 1-6. **1 = most important**. You can show equal priority, e.g. 1, 2, 2, 2, 5, 6.)

<p><b>Enabling the testing of large numbers of chemicals</b> There are many thousands of chemicals being used in the EU which need to be tested under REACH. <i>In silico</i> methods make it possible to assess large numbers and/or prioritise their testing.</p>	
<p><b>Providing regulators with the information they need</b> <i>In silico</i> methods can integrate the findings from different kinds of tests to generate an understanding of the toxicity of a chemical; the quantitative results can be used directly in risk assessment.</p>	
<p><b>Reducing costs and delays</b> The additional tests required by REACH will cost industry billions of Euros in animal experiments. These costs could be reduced by using <i>in silico</i> methods. Animal tests also take time, and laboratories are limited, causing expensive delays, whereas <i>in silico</i> methods can assess thousands of chemicals quickly.</p>	
<p><b>Reducing the numbers of tests on animals</b> Reducing the numbers of animals and fish (vertebrates) used in tests for toxicity. (This is an aim of the REACH legislation.)</p>	
<p><b>Reducing the numbers of tests on invertebrates</b> Reducing the numbers of invertebrates, such as worms, used in tests for toxicity. (This is <i>not</i> an aim of the REACH legislation.)</p>	
<p><b>Pro-active planning</b> Until now, chemicals have been developed before testing their toxicity. <i>In silico</i> methods can predict toxicity, so industry could plan from the beginning to develop and use of safer chemicals.</p>	

### Q4 Is animal testing a significant issue in your life or work?

'Animal testing' here refers to the use of around a million live animals and fish every year in Europe in laboratory tests to assess chemical toxicity. (Greater numbers are used in pharmaceutical and other research.)

- Animal testing is not an issue that usually concerns me personally or professionally.
- or  Animal testing concerns me and I wish I could do something about it, but in reality it does not affect what I do in my life or work.
- or  Animal testing concerns me, and it does affect what I do: (choose any or all)
- at work, it affects my professional or commercial decisions (please explain below);
  - as a consumer, when possible I will select products which display a statement that they have not been tested on animals;
  - as a citizen, I support or would support campaigns against animal testing;
  - as a voter, these issues concern me and could affect my vote.

*Please explain if necessary*

**Q5 After reading the introductory leaflet, what further information about *in silico* methods would be useful to you?** (The leaflet is at [www.in-silico-methods.eu](http://www.in-silico-methods.eu) in four languages)

**Q6 In what media and publications would you like to see or hear information about developments in alternative (non-animal) methods?**

**Finally...**

**How did you hear about this questionnaire or the ORCHESTRA website?**

**What is your role in relation to issues in chemical evaluation?**

*(Please tick, or rank 1, 2, 3... if more than one applies.)*

<input type="checkbox"/> Citizen, inc. citizen groups and online communities.	<input type="checkbox"/> Regulator or national competent authority
<input type="checkbox"/> Media, online communicator or journalist	<input type="checkbox"/> Industry user / association / trade union, inc. SMEs
<input type="checkbox"/> Non-governmental organisations (NGO)	<input type="checkbox"/> Distributor / retailer
<input type="checkbox"/> Governmental organisation; local / national / internat.	<input type="checkbox"/> Consultant
<input type="checkbox"/> Non-university researcher	<input type="checkbox"/> Association for alternative methods
<input type="checkbox"/> University researcher	<input type="checkbox"/> Information technology user or evaluator
<input type="checkbox"/> Scientist or science associations	<input type="checkbox"/> QSAR / <i>In Silico</i> methods developer

**Would you like to be notified of events and information about *in silico* methods?**

Yes *(Please include some contact details below)*

No

**Thank you**

**Optional personal details:**

Title:	First name:	Last name:
Organisation:		
Position:		Department:
Email:		Website:
Phone:		Country:
Address:		
<input type="checkbox"/> I have given my contact details but I want my responses to be used anonymously.		
<input type="checkbox"/> I would be willing to offer comments or advice to the dissemination project in the future.		