



4FUN

“The FUTURE of FULLY integrated human exposure assessment of chemicals:
Ensuring the long-term viability and technology transfer of the EU-FUNDED 2-
FUN tools as standardised solution”

Grant agreement No.: 308440 (Collaborative Project)

Deliverable D2.3: STAKEHOLDER CONSULTATIONS

Due date of deliverable: 30.09.2014.

Actual submission date:

Start date of project: 1st October 2012

Duration: 36 months

Coordinator	EU Relations
Deliverable Leading Partner	CSIC
Contributing Partners	AEIFORIA, ENVI, ASI, UCSC, EDF, FACILIA AB, INERIS, VITO, GRES, ARCHE, CVR, BPT
Task	Stakeholder consultation
Revision	

Project co-funded by the European Commission under the Seventh Framework Programme (FP7)		
Dissemination Level		
PU	Public	X
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

Table of Contents

1. Introduction	5
1.2. Purpose of the stakeholder consultation	5
2. Scope and objectives	5
2.1. Stakeholders and end-users involved in the exposure assessment process	6
3. First consultation methodology	7
4. Analysis of the stakeholders' feedback	8
4.1. The questionnaires' answers analysis	8
4.2. Discussion of recurring key issues and lessons learned	10
5. Future plans and recommendations	11
6. Other consultations	11
6.1. Second consultation-CEN workshop	11
6.2. Third Consultation-workshop in Paris	12
7. Business, dissemination and marketing plans	13
8. References	14
9. Appendix-List of stakeholders	15

List of figures and Tables

Figure1.Total number of questionnaires by country	8
Figure2. Timetable of the stakeholder consultation	15
Table1. Stakeholders	16
Table2. Future activities in stakeholder consultation	17
Table3. Activities to interact with stakeholders	17
Table4. Details of user perception in comparison with their expectations	18
Table5. Dissemination activities	19
Table6. Stakeholders potentially involved in the exposure assessment	22
Table7. Target audience and actions	26
Table8. Estimated total number of organizations in EU	26
Table9. Stakeholders' interviews classification	28
Table10. Stakeholder's interview sheet	28
Table11. Synthesis: identified customers range from NGOs to design & engineering companies	30

Introduction

1.2. Purpose of this plan/ report

Exposure assessment is generally considered to be a critical step in risk assessment because currently available tools show major flaws (e.g. lack of integrated approach for assessment of combined stressors, use of 'worst-case' scenarios leading to over-conservative results, lack of uncertainty/sensitivity tools for identifying the important exposure drivers, output provided in terms of intake rates because environmental multimedia and PBPK models are not integrated, standardisation processes not considered).

With the goal of making a more advanced model, the 2-FUN project (<http://www.2-fun.org>), funded under the EU 6th Framework Programme produced prototype software containing a library of models, coupling environmental multimedia and pharmacokinetic models. This software, the MERLIN-Expo tool, resulted to be an innovative and useful instrument for the assessment of human health risks from exposure to chemicals. However, the 2-FUN tool was a 'prototype' and not 'standardised' software. The 4FUN project will take the results from the 2-FUN [1] project to the market following thorough standardization processes and dissemination activities. The stakeholder consultation report represents the results of the engaging a large number of stakeholders across the European Union area especially directed towards the subjects and institutions interested in being informed and being engaged in the 4FUN project [2].

The purpose of the stakeholder consultation was to engage key stakeholders, primarily from the local government sector, academy, regulators and the industry stakeholders in identifying the major issues in the current integrated human exposure assessment of chemicals in the entire EU area which ensures transparency, relevance and effectiveness of the created exposure assessment tool.

2. Scope and Objectives

The objectives of Task 2.5:

1. To involve all key stakeholders from different sectors (NGO, academy, industry, regulators) and end-users by their objectives, priorities and interest in the 4FUN project and their expectations of the project.
2. To test the MERLIN-Expo performance, project material for training and communication with relevant group of stakeholders.
3. Include stakeholders in evaluating and fine-tuning the final project outputs in line with stakeholder needs and expectations.

Specific tasks to which this Deliverable is related (DoW)

The aim of WP2 is to put in relation stakeholders' needs in exposure assessment and the current status of exposure tools, including the MERLIN-Expo tool[1]. WP2 also encompasses all the dissemination activities and the main interactions with stakeholders. Priorities for the improvement of exposure assessment will thus be identified by consultation of key stakeholders and regulatory frameworks as well as of key end-users. The aim of **T2.4** was to identify key stakeholders and official/unofficial frameworks involved in chemical exposure assessment. (See attached excel file with relevant stakeholders).

The stakeholder consultation is directly connected with task T2.6 (Analysis of marketing environment) which objective is to define different groups of potential customers, i.e. perform a segmentation of the potential market. This segmentation will yield different client groups

that have similar product needs, usage types, and degree of expertise, financial resources and willingness to pay. The different segments can thereafter be evaluated in order to select the ones that should be most actively pursued or “targeted”. The second objective of the task is to analyse the social and political trends and how they might influence the demand for the product in the medium- and long-term period.

Task T2.5 is consultation with stakeholders on priorities for improvement of the MERLIN-Expo tool. Stakeholder consultation and management forms an essential and integral part of the 4FUN project. Each group of stakeholders was assessed with respect to their attitude towards the MERLIN-Expo model and the 4FUN project, their expectations or concerns, the degree to which they are affected and finally and their power of influencing the project and the viability of the MERLIN-Expo tool.

The role of WP4 is to guarantee a high Quality Assurance level for the final tool. The final objective was to provide standard documentation for an unambiguous and transparent technology transfer to end-users. WP4 will also perform a validation process of the tool, including 1) verification of the correct implementation of models; 2) benchmarking of 2-FUN results with other tools; 3) test controls to assess whether the tool will be acceptable to its end-users [3].

The role of WP6 is dissemination and training for technology transfer towards end-users. This is directly connected with stakeholder consultation since it uses the collected data on stakeholders to organize the dissemination activities, workshops and training activities throughout Europe’s relevant organizations which can benefit from MERLIN-Expo tool.

A 4FUN EU Observatory was established to guarantee that the 4FUN model development and implementation is policy and SME driven and responds to the latest policy developments. In parallel, all the communication materials for training and dissemination was prepared, including a web-based platform. A special focus will be placed on training of end-users through the organisation of four 4FUN Schools in different European countries.

Finally, WP7 is dedicated to the development of a sustainable business model to ensure the long-term viability of the 2-FUN tool. Therefore, it is indispensable to have the stakeholders’ analysis and feedback in order to create the business model.

The results of the first consultation round were taken into account by WPs 2 WP4 for the further development and standardisation of the MERLIN-Expo tool. The results were used to refine the planning of the further consultation with selected stakeholders that will be taken along the time frame of the project with an additional workshop and public consultation planned in 2015. These further in-depth stakeholder consultations will deliver an important input for developing detailed plans for dissemination of the MERLIN-Expo tool (WP6). The second workshop was scheduled for month 29 in Paris, a selected set of authority stakeholders will be invited for the consultation purposes with accent on the regulators and policy makers in the fields of human exposure and risk assessment.

2.1. Stakeholders and end-users involved in the exposure assessment process

People facing the exposure assessment of chemicals, as a part of the broader risk assessment process, is a highly diverse community including all interested and affected parties. They include administration and public regulatory bodies, risk assessors, risk managers and risk communicators as well as applicants for product authorization, the wider scientific community and the general public. All of them can be either potential actors or final receptors of the exposure assessment process

The purpose of Deliverable 2.4 was the identification of the stakeholders and regulatory frameworks for the exposure assessment.

Stakeholders were grouped and assessed to their:

– Attitude towards the MERLIN-Expo tool and the 4-FUN project

- Their expectations or concerns
- The degree to which they are affected
- Their power of influencing the project and viability of the tool

5 different groups of potential clients and users were identified (by Bearing Point):

1. Regulators -international (UN), European (EU), national (State governments and agencies), local (cities, regional and local authorities)
2. Academics and research public institutions (universities, institutes), private institutions (corporate, laboratories...)
3. Professional associations (Industrial sectors, Groups and associations of companies)
4. Companies (chemical industry, hospitals, farmers, treatment facilities, design & engineering companies, insurance companies)
5. Civil society (NGOs, associations (environmental and consumers), individuals)

3. First consultation methodology

The 4FUN project consortium, with CSIC as lead in this task, established the stakeholder consultation process methodology. All Consortium members participated in the task by making the database starting from October 2013. The stakeholders were selected across different EU member states, types of institutional or group affiliation (industry, regulators, NGOs, trade unions, academy) and with different types of expertise (risk assessment, risk communication, policy). Gender was also a consideration and care was taken to include a good mix of male and female stakeholders across the different countries and types of stakeholders.

The following steps to approach stakeholders were set forward by Bearing Point and distributed to all partners in the consortium:

1. Send an introductory email + technical document
2. Call 1 day after the email, to fix an interview (prefer face to face)
3. Plan the interview in the database
4. Do the interview
5. Write a comprehensive summary of the interview
6. Send the summary to the task leader (CSIC)

The technical documentation contained the project flyer and questionnaire (see the section 9.4 in the Appendix, page 28) specially fitted for the professionals in the field of exposure assessment of chemicals. The questionnaire was written and sent out in English.

This interview pattern was conducted respectfully in every partner country and, in addition, some of the partners did the stakeholder consultation in additional countries. The agreed plan and strategy were established during telephone conferences lead by CSIC and with the active participation of all consortium members.

In the next phase of the project it is intended to improve the strategy and make additional dissemination material in the form of a short video with a demonstration of the Merlin-Expo tool. The video will be an effective presentation of the tool focused on the real case studies.

4. Analysis of the stakeholder feedback

Individual results of the stakeholder consultation in every country were collected and sent to CSIC and to Bearing Point for the analysis.

Stakeholders were collected in 11 countries in the government, industry and academy sectors. The stakeholders' list from the 2 FUN project was received and updated along with new additional stakeholders.

In total the project consortium obtained 52 questionnaires (33 in France, 4 from Italy, 2 Belgium, 3 Spain, 1 UK, 5 Serbia, 1 Czech Republic and 3 Austria)

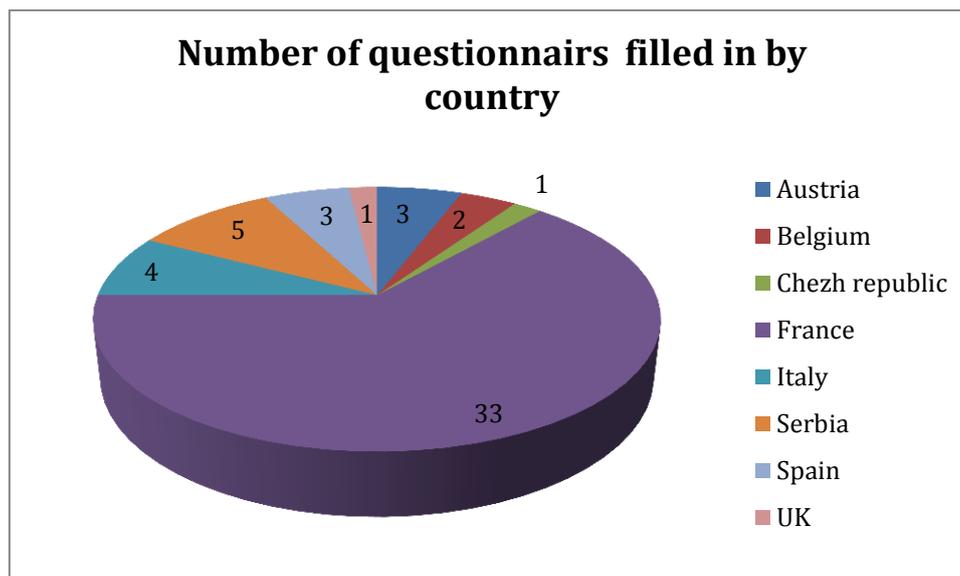


Figure 1. Total number of questionnaires collected by country

Firstly, stakeholders were ranked according to their willingness to participate in the consultation process. They were classified based on the following criteria: no answer, interested contact with date of the interview to be planned, interview via telephone and interview in person (See Appendix, table number 9).

Out of 277 people contacted 50 interviews were successfully conducted which corresponds to a response rate of 18.5%.

4.1. The questionnaires' answers analysis

1. Type of organizations

The consulted stakeholders belonged to the groups of: public or private research centres, industry, academy and regulators.

2. Use of the software

All stakeholders are active users of existing models for the exposure assessment of chemicals to human or/and environmental health. Most of them were performing the assessment in order to conduct risk assessment for the registration of chemicals under the REACH regulation, Biocidal Product Regulation, Plant Protection Product Regulation and others on a European/national/regional level where human health risk assessment is needed and their organization is asked for the service.

3. Type of chemicals used are: organic and/or inorganic.

4. The motivation for conducting human exposure assessment:

- To comply to the required regulation- risk assessment of mixtures of chemicals, risk assessment of materials with chemicals (building industry) in the framework of...?
- For local impact assessment (product and process related assessment, etc.).
- To foresee the impact of different chemicals in a given territory.
- Prioritization of chemicals
- Screening of substances

5. Type of the assessment usually performed:

- Detailed environmental and human exposure assessment of single chemicals in the framework of certain regulations.
- Assessments related to the safety of workers as well as to safety of consumers,

6. Software used

- It is noticed that the majority of stakeholders are using the exposure assessment models recommended under the REACH regulation [2]. The most frequently used model is, EUSES [6]. Other tools used are ECETOC TRA, ConsExpo (consumer exposure), Stoffen Manager, RiskofDerm (occupational exposure) and Chemges 7.

7. Price of models used

Significant number of stakeholders included in the consultation, especially highlighted the use of the free of charge models which are available online and easily accessible. It was indicated that this will also be expected from the Merlin-Expo tool. Therefore, if the model MERLIN-Expo shall be marketed /sold it needs to fulfil the expectation of the stakeholder as a competitive tool, which provides better features than the existing free-of-charge models. Large companies with sufficient funds might be interested in purchasing the tool if with its use their work would be more efficient and less time consuming. It is important to estimate if such an expectation is realistic.

8. How often exposure assessment is used

The frequency of the exposure assessment conducted in most of the interviews was from daily use to a couple of times per month depending on the requirements. Most of the organizations conduct the assessment in their own facilities without a contracted service provider.

9. Advantages in models used

As the main advantages of the tools used for the exposure assessment are the broad applicability of the model, the simple and easy use, the in-depth documentation, the strong modelling and predictive functions, the user friendliness and the availability of an online guide.

10. Drawbacks of existing models

As drawbacks of the currently used models, the professionals stated that many currently applied models are lacking certain aspects (e.g. including emission estimates according to REACH recommendations, inability to finish all the calculations and parameterization inside model, relatively scarce uncertainty analysis usually programmed as a background process, inability to handle multiple scenarios and adjust to multiple situations, inability to access different populations (e.g. age groups) and overestimation of the effect of some chemicals. Models coming from industry are less trusted.

11. Expectations

At the top of the list of important features of the models are user friendliness (clear and understandable construction of exposure scenarios, gradual approach in the model development and easy visualization of the model components), ability for tool customization, a complete database and extensive training material.

12. If asked about the organizations which are the most concerned by exposure assessment, stakeholders listed the following groups:

12.1. Industry

12.2. Downstream users

12.3. Consultants

12.4. Regulators (on a European, regional and national level).

13. Risk assessment purpose and situations where it is applied as seen by the stakeholders

Manufacturers and importers of substances and products should in certain cases perform an exposure assessment under the REACH regulation, WFD, Biocidal Product Regulation, Plant Protection Product Regulation, etc. When exposure monitoring data are not available, registrants can estimate the environmental and human exposure through exposure models. These models have to be compliant to the respective regulation.. Consultants can apply these models to support industries in this task, while national or regional regulators can apply them to check the results of previous assessments or for assessing specific relevant cases. The main motivation for conducting the risk assessment, therefore, is based on the normative requirements.

4.2. Discussion of reoccurring key issues and lessons learned

The main issues:

- 1) Identify the EU and international bodies generating regulatory frameworks for exposure assessment
- 2) Identify stakeholders and end-users (e.g. regulators, industry, SME, consultants) involved in exposure assessment, and their major areas of activity
- 3) Gather the specific relevant EU and potential EU-country specific regulatory risk assessment frameworks requiring exposure assessment; to gather regulatory frameworks for risk assessments from other major agencies outside the EU to put EU exposure assessment procedures into perspective [3].
- 4) Identify stakeholders' expectations to improve regulatory exposure assessment.

During the consultation process the biggest challenge was to achieve a proper response rate from different stakeholders. It has been shown that the email contact had a very low efficiency since most of the contacts didn't reply. The easiest way to reach stakeholders is contacting those who are familiar with the local project partner, which is conducting the interviews. People from the academic environment were more interested in cooperating compared to industry who showed much less interest. This is noted as a general trend when conducting stakeholder consultation.

The following issues were very typical for the stakeholder consultation process: difficulties to identify and reach the experts in the human or/and environmental exposure risk assessment and relatively low response rate from the industrial field.

It is identified that throughout the EU member states there exist many different approaches in risk assessment policies and it is agreed that it is needed to develop a common approach[8].The development of user-friendly software tools is recommended for this purpose especially because monitoring is expensive and is a time-consuming process requiring intensive efforts: field sampling campaigns, development and validation of analytical methods,, etc. Currently, software tools of this kind are only established in the EU for operator exposure assessment. The shortcomings of the existing models are the exposure levels (e.g., the use of closed transfer systems for loading, the type of nozzle used for spraying, the use of personal protective equipment). REACH legislation ("Registration, Evaluation and Authorisation of Chemicals") (Regulation 1907/2006) makes industry responsible for assessing and managing the risks posed by chemicals and providing

appropriate safety information to their users. In parallel, the European Union can take additional measures on highly dangerous substances, where there is a need for complementing action at EU level. Therefore, consortium has decided to focus the stakeholder consultation on regulation bodies throughout the EU which is more explained in the future plan and recommendations section of this document.

5. Future plan and recommendations

The future efforts to be put into the stakeholder consultation are intended to be conducted in part 2 of the process which started in October 2014. It is planned to invest another month in collecting more stakeholders this time focusing more on the industrial sector and on regulators since they are the ones who define the exposure assessment guidelines followed by the industrial stakeholders. At the Stockholm Consortium meeting (15-17 of October 2014) the strategy for the further consultation process was defined and the main points were:

1. To establish the model strengths in order to present it to the stakeholders .The main identified strengths are:

- It is a user friendly and, easy to use tool
 - It has a good predictive and modeling function
 - It has the possibility of covering multiple scenarios
 - The tool is profoundly described in the extensive accompanied standardized documentation
2. To identify practical advantages of the tool from which the end user will have financial benefits
4. To determine how to use the model in the framework of current legislations
5. To present the case studies to show the flexibility and broad field of use of the tool.
6. To develop new dissemination material (newsletter, flyer and video of the model with the emphasis on the model strengths
7. To choose the workshop locations convenient for participants and instructors (first one Barcelona, SETAC, in May 2015).

In the next period the training workshops are planned to be organized in several cities in the European Union.

It is planned to invite the stakeholders to workshop intended especially for a face-to-face discussion about the model MERLIN-Expo and to come up with new conclusions which should provide useful information on the model development and its commercialization especially after the end of the 4FUN project. As suggested in the DOW in order to minimize the risk, the reimbursement for the stakeholders which are participating in the workshops might be offered.

6. Other consultations

6.1. CEN workshop

Workshop title: "Business Plan for the CEN Workshop on Standard documentation of chemical exposure models WS Acronym: MERLIN-Expo"

6.1.1. Scope and objectives

The objective of the workshop is to specify minimum requirements for the amount and type of information to be provided on exposure models along with guidelines for the structure and presentation of the information. The document will include a terminology for describing the elements of models based on European and International Standards and propose a structure for presenting these elements. It is expected to facilitate a more rigorous formulation of exposure models, to improve the comparability between different exposure models, the transparency and the understanding by users. Excluded from the scope of this workshop are issues of model coding/translation into software.

6.1.2. Workshop programme

The MERLIN-EXPO Workshop will embed the findings of 4FUN on standard documentation of large exposure models into a CEN Workshop agreement (CWA). This will allow all parties interested in the activity to discuss and to contribute to the development of the CWA.

Specifically, the "standard documentation framework for large exposure models" which has been developed in the course of the 4FUN project will serve as the initial input to the workshop. The framework is based on a review of academic literature together with recommendations made by official European and International bodies on the topic. The findings have been condensed into a list of items that must be covered by a standardized documentation framework clustered around topics. To tailor the communication to the needs of different users, 3-4 separate levels of information have been identified, from basic knowledge to process knowledge to numerical knowledge and mathematical knowledge, which will allow structuring of the required documentation according to the needs of different end-user groups.

The working language will be English. The CWA will be a single work item and will be published in English.

It is proposed to complete the CEN Workshop agreement within a period of 10 months. The CEN Workshop will have 1-2 plenary meeting after the kick off meeting to consider the draft. A 60-day public commenting period is proposed. The workshop will give full consideration to the comments expressed. The CWA will be approved by the registered members, to satisfy the objectives stipulated by the Workshop Business Plan.

Workshop proposers are the following partners of the 4FUN collaborative project:

- AEIFORIA SRL, Italy
- ARCHE, Belgium
- AUSTRIAN STANDARDS INSTITUTE; Austria
- ELECTRICITE DE FRANCE S.A., France
- FACILIA AB, Sweden
- INSTITUT NATIONAL DE L ENVIRONNEMENT ET DES RISQUES INERIS, France
- UNIVERSITA CATTOLICA DEL SACRO CUORE, Italy

6.2. Third Consultation: Workshop in Paris

The first regulators workshop is set to be in Paris on March 26th and 27th, 2015 organized by EDF. The invited stakeholders will be collected from the existing project's database and consortium members' contacts and participants to the CEN workshop.

Scope and objectives

1. Organize a workshop with regulators from different countries (members of EFSA, ECHA, EPA and other relevant European institutions and bodies)
2. Get feedback on the MERLIN-Expo and possibility of the tool application in the risk assessment regulation processes

The consortium concluded that that it is of utter importance to consult the authorities since they are the ones that create regulations which the industrial sector needs to follow. The first consultation confirmed that the industrial stakeholders conduct the exposure assessment mostly to follow the regulation procedures. So the task in the next couple of months will be the work on getting the regulators to assess the model and if approved to support it as one of the recommended tools for exposure assessment. The representatives of the authorities will be contacted at European, local and regional level, and will be invited to the workshops and interviewed face-to face.

7. Business, dissemination and marketing plans

1. Dissemination activities should focus on the business goal of the project – not on scientific dissemination.
2. After the second stakeholder consultation is decided to collect information and keep the business and marketing plan open
3. Organize and direct training towards possible customers especially to companies which use similar models.

7.1. Customer engagement

Future efforts will be put in the commercial side of the project and in the possibilities of making a competitive tool, which will be of interest to all sectors where stakeholders were identified. This is the key issue identified so far and it will reflect on the entire 4FUN project. Since, the upcoming scientific publications and book will cover the academic sector it is important to concentrate the future stakeholder consultation to the non-academic sector interested in the tool, not in its scientific development.

Further points of attention are:

1. Explore 'in house' knowledge about the tool with colleagues not directly involved in the project.
2. Make sure that the interaction with potential users is kept simple and not overcomplicated so that it remains easy to reply and therefore does incentivise people to communicate with you.

8. References

1. European Union 6th Framework Programme (thematic priority 6.3 "Global Change and Ecosystems", contract n° FP6-2005-GLOBAL-4-036976). Duration: Feb 2007 - Jan 2011. Read Project Summary, <http://www.2-fun.org/#>, -. 2. <http://4funproject.eu/>.
3. Annex I - "Description of Work" , 4FUN project.
4. Lynn Frewer, et al., *Deliverable 4.2.BROWSE,Bystanders, Residents, Operators and WorkerS Exposure models for plant protection products*. 2011.
5. Spanish National Scientific Council.
6. The European Union System for the Evaluation of Substances (EUSES) is a decision-support instrument which enables government authorities,
7. The European Chemicals Agency (ECHA).
8. EFSA, *EFSA (2009). Draft Scientific Opinion: Preparation of a Guidance Document on Pesticides Exposure Assessment for Workers, Operators, Bystanders and Residents. Published for public Consultation on 7 August 2009 at: www.efsa.europa.eu/en/calls/consultation.htm*. 2009.

9. Appendix

This document is delivered with the Excel file where the entire stakeholder list is included. The Excel file will be delivered separately and can be found on the following link: <https://docs.google.com/spreadsheets/d/1-P2UkpyeutokX2FjjJxFMdOEYN-Y705fCZtFncJhtKo/edit#gid=1269711919>

9.1. Timetable of the stakeholder consultation

4FUN project Stakeholder consultation timeline										
Activity	2013			2014			2015			
	March	October	November	October	November	December	March	June	October	November
Deliverable report 2.4. ¹										
Stakeholder consultation 1										
Deliverable report 2.3. ²										
Stakeholder consultation 2										
Stakeholder workshop in Paris ³										
Special issue STOTEN										
Book special issue STOTEN										
Final consultation workshop in Brussels ⁴										
1. Identification of stakeholders and regulatory frameworks for exposure assessment										
2. Stakeholder consultation										
3. 2 day workshop in March										
4 To be planned in final months of the project										

Figure 2. Timetable of the stakeholder consultation

9.1. Stakeholders classification and activities

Table1. Stakeholders

Stakeholders	Subgroups	Key domains / sectors
Regulators / legislators	European (European Commission) Central (Ministries) Regional (regional agencies, delegations) Public organizations (National agencies, institutes, etc.)	<ul style="list-style-type: none"> • Environment • Health • Security at work
Research organizations	Specialized in calculation models (toxicology, environment) Specialized in epidemiology studies providing scientific data	<ul style="list-style-type: none"> • Epidemiology • Toxicology • Atmosphere, water and soil pollution
Academics	Universities	<ul style="list-style-type: none"> • Epidemiology • Toxicology • Atmosphere, water and soil pollution
Professional organizations	Sectorial federations	<ul style="list-style-type: none"> • chemistry (including pharmaceuticals, cosmetics, biotechnologies) • oil and gaz • construction and infrastructure • metallurgy
	Specialized professional associations in pollutions issues	<ul style="list-style-type: none"> • site pollution • waste treatment • water treatment • risks assessment and management
Specialized consultancy companies	Consultancy companies	<ul style="list-style-type: none"> • Risk assessment and management • Environmental engineering
Industries (companies)	SME Large companies	<ul style="list-style-type: none"> • Chemicals (including pharmaceuticals, cosmetics, biotechnologies) • Oil and gaz • Waste treatment • Water treatment • Construction and infrastructure • Metallurgy
Civil society	NGOs	<ul style="list-style-type: none"> • Environmental-oriented NGOs • Health and safety-oriented issue NGOs • Consumer-oriented issues

Table2. Future activities in stakeholder consultation

	Roles	Actions to implement
1.	Customers ✓ professional organizations – paying for their members ✓ specialized consultancy companies ✓ industries	→ Marketing & dissemination → Customer relationship activities
2.	Users ✓ regulatory and legislators (experts on chemical assessment / risks assessment) ✓ research organizations ✓ academics (researchers) ✓ specialized consultancy companies (expert on chemical) ✓ industries (expert in HSE, chemical R&D).	→ Marketing & dissemination → Customer relationship activities → Training
3.	Prescribers ✓ regulatory and legislators ✓ professional organizations ✓ industries ✓ NGOs	→ Marketing & dissemination
4.	Funders ✓ regulatory - legislators	→ Marketing & dissemination → Lobbying
5.	Scientific contributors ✓ research organizations ✓ academics	→ Marketing & dissemination

These stakeholder groups can be described as: customers, users, prescribers, funders and scientific contributors.

Target prioritizations

- Business users: gathering experts at specialized consultancy companies, industries and also more widely professional organizations
- Regulators and the local/regional level
- Scientific users: gathering researchers at research organizations and academics (sector covered already with the scientific publications and the book)

Table3. Activities to interact with target stakeholders:

Service	Users expectations
Training	End-users are expecting training on the tool to be able to use it in total autonomy. Such services must be delivered to end-users in order to make sure the tool is used in a correct manner and leads to valuable scientific results. Potential certifications may be linked to this training offer.

Table4. Details of user perception in comparison with their expectations

Perceived benefits	Details of user perception in comparison with their expectations
3.3 Quality user support	The possibility of delivering training with the tool has been identified as a key benefit for the tool. The possible of online training has been mentioned by several stakeholders as a real benefit. Such training would make them understand how to use the tool. The identified benefit has been taken into account in the training definition.

9.2. Dissemination activities

9.2.1. Deliverable 6.1 – Dissemination plan

International conferences

- SETAC and SETAC Europe annual conference (possible submission of one additional training session)
- EUROTOX annual conference
- ISEE (International Society for Environmental Epidemiology) annual conference
- ISES (International Society of Exposure Science) annual conference
- IUPAC annual conference
- SRA-Europe Society for Risk Analysis Annual meeting
- International conference on the science of exposure assessment
- EuCheMS International Conferences on Chemistry and the Environment
- Pesticide Behaviour in Soils, Water and Air - York conference

National conferences

- Annual meetings of relevant national societies

This list will be updated according to other conferences/events that come up during the course of the project.

Table5. Dissemination activities

Date	Event & Location	Type of activity* and Topic	Size and type** of audience	Partner	Short explanation of dissemination activities	Countries addressed
20-21 February 2013	4FUN training course, Paris (France)	Internal training course	20 4FUN consortium	EDF, FACILIA		

March 2013	Website launched	4FUN website	All	AEIFORIA	Website	
12-16 May 2013	SETAC Europe Annual Meeting, Glasgow (UK)	Poster presentation. Title: Review and evaluation of exposure models in the 4FUN projects	500+ Scientific community	ARCHE		EU/ international
17 -19 June 2013	SRA-E Conference (The Society for Risk Analysis – Europe), Trondheim (Norway)	Oral presentation. Title: Demonstration and exploitation of the 2-FUN human exposure model identified as a promising tool derived from European research activities; A case study on Pb in the environment	250+ Scientific community	VITO	Oral presentation on scope and aims of 4FUN case study on Pb	EU
30 June - 2 July 2013	ICESEC 2013 - First International Conference on Environmental Safety and Ecological Criteria (co-organized by SETAC Asia-Pacific), Nanjing (China)	Platform presentation. Title: Assessment of Children Lead Exposure in a Smelter Site Area in China: Approaches for the Identification and Ranking of the Most Relevant Exposure Routes	300+ Scientific community	CVR		China/ international
19 - 23 August 2013	Conference of the International Society of Environmental Epidemiology (ISEE), the	Oral presentation. Title: Demonstration and exploitation of	500+ Scientific community	VITO	Presentation on scope and aims of 4FUN case study on As	EU

	International Society of Exposure Science (ISES), and the International Society of Indoor Air Quality and Climate (ISIAQ), Basel (Switzerland)	the 2-FUN human exposure model identified as a promising tool derived from EU research activities; A case study on Arsenic.				
02-04 September 2013	Pesticide behaviour in soils, water and air, York (UK)	Poster presentation. Title: Review and evaluation of exposure models in the 4FUN project	200+ Scientific community	AEIFORIA		EU
March 2014	Press release	Press release describing the project distributed via CORDIS wire and Apogee system	500+ All	AEIFORIA		EU/ international
11-15 May 2014	SETAC Europe Annual Meeting, Basel (Switzerland)	Poster presentation. Title: Linking exposure models to regulatory and sustainability driven frameworks	500+ Scientific community	ARCHE		EU/ international
14 May 2014	Press release	Press release on the CEN workshop distributed via CORDIS wire	500+ All	AEIFORIA, ASI		EU/ international
02 July 2014	CEN Workshop (WS MERLIN-Expo) ,	New CEN Workshop on Standard	30+ All	ASI		EU

	Brussels (Belgium)	documentation of large chemical exposure models (WS MERLIN- Expo)				
4-5 July 2014	International Symposium on Environment and Health (co-organized by SETAC Asia-Pacific and Society of Environmental Geochemistry and Health), Beijing (China)	Accepted as platform presentation. Title: Comparison of modelling approaches for the assessment of children exposure to lead in a smelter area in china	300+ Scientific community	CVR		China/International
10-14 August 2014	13th International Congress on Pesticide Chemistry (IUPAC), San Francisco, USA	Poster presentation. Title: Evaluation of exposure models and their link to regulatory frameworks within the 4FUN project	500+ Scientific community	AEIFORIA		International
10-14 August 2014	13th International Congress on Pesticide Chemistry (IUPAC), San Francisco, USA	Poster presentation. Title: MERLIN- Expo – an integrated advanced chemicals exposure assessment tool for legislation requirements	500+ Scientific community	UCSC		International

9.3. Stakeholders involved in the exposure assessment process

This table was included in the Deliverable 2.4. on the regulatory framework on exposure assessment and stakeholders identification.

Table6. Stakeholders potentially involved in the exposure assessment process

Sector	Sub-sector	Class
Public Administration	World (WHO)	Environmental (air, water, waste) Health (Food safety, Drinking water, Drugs etc.)
	European Commission	Industry Food
	State	Health and Safety
	Local	
Industry	Chemical	<u>Basic organic chemicals</u> Petrochemical (extractive, cracking, reforming etc.) Chloro-alkali Chemical commodities Plastics (polymers, synthetic fibers, synthetic rubbers etc.) <u>Transformation products</u> Dyes and pigments Surfactants Fine chemicals Additives Adhesives <u>Specialties</u> Pharmaceuticals Cosmetics and Personal care products Biocides and plant health products Paintings and coatings Inks and printing products
	Tanning	Skin and hide preparation
	Surface treatment	Surface treatment of goods, objects or products using organic solvents (dressing, printing, coating, degreasing, waterproofing, sizing, painting, cleaning or impregnating)
	Paper	Pulp mills Paper production
	Water Treatment	Wastewater treatment Drinking water production
	Waste treatment	Waste treatment and recycling Landfills

		Incineration
Services	Professionals Insurance companies	Risk assessors Consultants Communication professionals Safety Professionals
Academic and Research	Public Private	Universities Research Institutions
Citizenship	NGOs Consumers' Associations	Environmental Health Food Safety

Groups / companies list (derived from EG's various list of attendees).

Regulator / Government

- UK: HSE (Health and Safety Executive), FERA (Food and Environmental Research Agency), CRD (Chemicals Regulation Directorate), PHE (Public Health England), VMD (Veterinary Medicines Directorate), BCPC (British Crop Production Council), NERC (Natural Environment Research Council), HPA (Health Protection Agency, Chemical Hazards and Poisons Division)
 - Netherlands: RIVM, Rikswaterstaat
 - Sweden: KEMI
 - France: ANSES (French Agency for Food, Environmental and Occupational Health and Safety)
 - Denmark: Danish EPA
 - Norway: Norwegian Food Safety Authority
 - Switzerland: Agroscope Chengins-Wädenswil
 - Lithuania: The State Plant Service under the Ministry of Agriculture
 - Poland: Institute of Environmental Protection – National Research Institute, Ministry of agriculture and rural development,
 - Germany: UBA
 - Austria: AGES (Austrian Health and Food Safety Institute)
 - Netherlands: CTGB
 - Czech Republic: Water research institute
 - Turkey: Ankara Food Control Lab
 - Spain: Spanish Veterinarian National Corp
 - Italy: National Institute of Health
 - Belgium: Federal public service, health food chain safety and environment.
 - Croatia: Croatian centre for agriculture, food and rural affairs
 - Ireland: Department of Agriculture, Food and the Marine
-
- EFSA (European Food Standards Authority)
 - JRC (European Commission, Joint Research Centre)

Other groups / organisations:

- OECD (The Organisation for Economic Co-operation and Development)
- ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals)
- ECMS (European council for Modelling and Simulation)
- SETAC (Society of Environmental Toxicology and Chemistry)
- IOM (Institute of Occupational Medicine, UK)
- SEGH (Society for Environmental Geochemistry and Health)
- FOCUS (Forum for Coordination of pesticide fate models and their Use)
- PFMODELS.org (site dedicated to pesticide fate modelling)
- WHO (World Health Organisation)
- ICPS (International Centers for Pesticides and Health Risk Prevention, Milan)
- ECCA (European Crop Care Association)
- FISABIO (Foundation for the Promotion of Health and Biomedical Research of Valencian Region)
- ISES (International Society of Exposure Science)
- HEIMTSA (Health and Environment Integrated Methodology and Toolbox for Scenario Assessment) [Is an EU 6th framework project, has got links to 2FUN project?]

Academia/Research

- UK universities: Cranfield, York, Reading, Bangor, Sunderland, Surrey
- Germany: University of Giessen, Alterra (part of Wageningen university), Fraunhofer, Institute of AgroEcology (IfA) RLP AgroScience, Forschungszentrum Julich
- Sweden: SLU (Swedish University of Agricultural Sciences)
- Belgium: VITO Belgium
- USA: University of California, Riverside
- Netherlands: Netherlands Environmental Assessment Agency
- Italy: Università Cattolica (UCSC), Istituto di Chimica Agraria e Ambientale (UCSC), University of Pisa,
- Slovenia: Jozef Stefan Institute

Industry

- Syngenta, Syngenta Italia
- Bayer CropScience
- Monsanto
- Agria
- Belchim
- Nufarm
- Makhteshim AGAN
- Dow AgroSciences
- Oxon Italia
- Mabeno
- SAPEC, SAPEC Agro
- ISK Biosciences Europe
- Isagro Spa
- FMC chemical
- Sumitomo Chemical Agro Europe
- Agrifar group
- UPL (United Phosphorus Limited)
- Neudorff
- Rotam Agrochem

- Chemtura, Helm AG
- AkzoNobel,
- BASF SE
- DuPont
- Clariant Produkte

Industry Associations:

- CEFIC (European Chemical Industry Council)
- Institut für Zuckerrubenforschung (university of Göttingen)

Consultants / service providers:

- Nufarm,
- Alterra,
- Smithers-Viscient,
- Harlan
- AEIFORIA,
- JSCI,
- Batelle,
- Waterbourne Environmental,
- CEA,
- Exponent International,
- Arcadis,
- RifCon,
- Footways,
- Knoell Consult,
- Eurofins,
- Informatica Ambientale,
- SCC GmbH,
- TSGE,
- ADAS,
- GAB Consulting GmbH,
- LKC Switzerland Ltd.,
- Expedia MRCC,
- LSR associates,
- Oxford Agricultural Consultants Ltd.,
- DHD-Consulting GmbH,
- Innovative Environmental Services (IES) Ltd.
- German Agency for International Cooperation (GIZ)
- SGS Institut Fresenius, SGS UK, SGS Agricultural Services
- Kwizda Agro
- WSC scientific
- Redebel
- The lifeline group (Canada)

Table7. Target audience and action

Action	Tool	Target audience*	Timing	Responsibility
Exchange information with existing networks	Identify and contact other existing networks, projects, etc... working in the same field	All	Entire project	All partners

Get effectively in practice the use of the tool	Training for end-users "4FUN-schools"	Modellers	Apr/2015 – Aug/2015	WP6
Assist trainers in using the 4FUN training materials in their work	Train the trainer	Modellers; SC; I	Sep/2014	WP6
Keep interested people up-to-date	Mailing lists	Modellers; SC; I; Org	Apr/2013 – Sep/2015	WP1 and WP6

* All= all target audience; Modellers= End-users/modellers; SC= scientific community; I= intermediaries; Org= organisations with exposure modelling need

Table8. Estimated Total number of organizations in EU

Stakeholders	Sub groups (of necessary)	Estimated number of organizations in Europe	total of in
Regulatory - ministries	Ministries	27	
Regulatory - regional entities	Regional entities	281	
Regulatory - public organizations	Public organizations	90	
Research Organization	NA	tbd	
Academics	NA	931	
Professional organizations	NA	135	
Consultancy companies	NA	180	
Industries - chemicals	NA	321	
Industries - oil and gaz	NA	386	
Industries - metallurgy	NA	225	
Industries - waste and water treatment	NA	56	
Industries - construction and infrastructure	NA	250	
NGOs	NA	NR	
TOTAL	NA	2882	

9.4. FUN Project – Questionnaire (simplified version)

1. GETTING TO KNOW YOU

- Brief overview of the project context, objectives, and the purpose of this interview

- Presentation of your entity, your responsibilities among this entity

2. YOUR USE OF SOFTWARE FOR ASSESSMENT OF ENVIRONMENT AND HUMAN EXPOSURE TO CHEMICALS

- Do you or your organization **use software for environmental exposure, human health exposure** or both?
- Please qualify **your needs** in terms of **assessment of environment and human health risks** from exposure to chemicals :
 - **type of chemicals** you study (organic, inorganic, both)
 - your **motivations** for conducting such assessments? (research activity, local impact assessment, financial/economic approach, regulatory oriented assessment, zealous approach, etc.)
 - the **type of assessments** you conduct and your motivations (quick scans, detailed analysis...).
- How do you **answer to those needs** today?
 - **Tool(s)** used
 - **Access conditions** to this/these tool(s): costs, technical access (online, downloaded, time of operation...)
 - **Frequency of assessment**
 - **The way of conducting assessment** (on your own, or with a service provider, please precise the type of service provider and the role it plays in the process)
 - The advantages and drawbacks of the tools
- What are your **expectations for the next generation of exposure assessment tools** in terms of functional coverage, superior flexibility, user friendliness for model development, user friendliness for delivered results
- What **feature would you really need** to be provided by the product to **consider a purchase** (access, online supports, technical support, training, etc.)?

3. GENERAL USE OF SOFTWARE FOR EXPOSURE ASSESSMENT TO CHEMICALS

- What **type of users (companies, industries, regulators,)** are the most concerned by exposure assessments tools? Please give **names of stakeholders and examples**.
- Are there **contacts you would like to recommend** us in these companies? If so, please indicate their names and contact details.
- Do you know **which tools** these companies use for their assessments? Please give the name(s) of the tool(s).
- Can you please **qualify the needs** of these companies in terms of assessment of environment and human health risks from exposure to chemicals? Types of project, motivations, etc.)

4. OTHER CONTACTS

- Are there **other contacts** you would like to recommend us? If so, please indicate their names and contact details.

Table 9.Stakholders interviews classification

LEGEND			
No answer, or not interested or the contact gave us another contact into its entity		Interested contact, date of the interview to be planned	
Contact interviewed /met		Contacted but no answer so far	
Date of the interview is already fixed in the following days		Entity to be contacted , contact to be detailed	

Table 10.Stakeholders interviews sheet

Name	Company	Position	eld of activi	Details	ontact detai	Mail status	Phone status	Name	Organisati on	Date of the interview	Comments
<i>Companies</i>											
<i>Professional associations</i>											
<i>Academic & research</i>											
<i>Regulators/ Legislators - Agencies and institute</i>											
<i>Engineering office / Consulting office</i>											
<i>Civil society (NGO, associations..)</i>											

Stakeholders /training (EnviResearch)

Finding contacts for promotion of training program

Purpose of this document:

- Explore all possible leads for the identification of end-users potentially interested in attending the MERLIN-Expo training program.
- Use document as a framework to select appropriate targets, find contact details of appropriate individuals / groups.
- Start building a relationship with end-users in order to
 - a) promote the training program,
 - b) get their commitment to attend /ensure their availability to attend,
 - c) get the end-users involved in development of training program
 - d) set the training session agenda/content to suit their need

Steps:

- Send this document to all 4FUN consortium group, add any new leads to the list.(done)
- Use these leads to find individuals /groups / discussion forums– make contact, send them the training program promotional flyer, start a dialogue.

Sources of potentially useful contacts used to build this document:

1. Analysis of marketing environment (Deliverable 2.5, draft)
2. Business plan (Deliverable 7.1)
3. Dissemination plan (Deliverable 6.1, also text in Description of Work)
4. Existing models relevant to the 4FUN project (Deliverable 2.4 – SWOT analysis) – could have associated users' groups, conferences etc.
5. Projects related to the 4FUN project, as described on 4FUN website
6. EG's own experience (modelling conferences etc) / list of attendees. Google searches re modelling workshops, conferences etc.
7. Input from other 4-FUN partners

Other deliverables (not yet available) which may provide useful leads for promoting the training program:

1. Identified key stakeholders (Deliverable 2.3 – report on stakeholder consultation)
2. Analysis of marketing environment (Deliverable 2.5, final)
3. Previous success stories (Deliverable 2.6 – key findings from previous successes)
4. Report on involvement of other networks (Deliverable 6.7)
5. Final plan for use and dissemination (Deliverable 6.8)
6. Report on awareness and wider social implications? (Deliverable 6.9)

Other possibilities:

7. Posting on summer school websites (SETAC or other)

9.5. Deliverable 2.5 (draft) – Market analysis

1. Regulators/legislators gathering the different levels of worldwide regulators, international, European, national and even local (cities, regions, local authorities). The size of this population is estimated around several thousand users.
2. Academic and research including public institutions such as universities, institutes, etc.
3. Professional associations including industrial sectors, groups and associations of companies.
4. Independent design and engineering companies including design companies, engineering companies that are independent.
5. Companies and most specifically “polluting” companies such as: industrial installations, hospitals, depollution companies, insurance companies.
6. Civil society gathering NGOs, associations and, eventually individuals.

Table11. Synthesis: identified customers range from NGOs to design & engineering companies (Bearing Point partner)

Potential Users		Prescribers	Customers	Non-paying beneficiaries
Regulators	Provident authority		Locan and regional authorities	Citizens
	Critical Authority		Design and engineering authorities	
	Regulating Authority			
Academic and Research	Public	Authorities	University/Public Research	Students/Scientists
	Private		Private companies	
Professional Associations	Centralizing organizations		Professional association	Member companies
Companies	Compliant industry	Polluting companies	Design and engineering companies	

	Zealous producers		Polluting company	
Civil Society	Alert watchdog		NGO or associations	
	Curious individuals		Individuals?	Individuals