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ECHA work plan with regard to testing methods

(Document submitted to the Management Board)

1. Introduction and background

The REACH and CLP Regulations do not explicitly state any specific tasks for ECHA related to test methods besides providing guidance to potential registrants on generation of information. However, ECHA has been given a number of tasks under REACH for which the conduction depends on a profound knowledge of test methods. The most prominent of these tasks is related to the dossier evaluation. In particular, the examination of testing proposals submitted by registrants for fulfilling the information requirements for substances manufactured or imported in volumes equal to or exceeding 100 tonnes/year requires that ECHA staff has the necessary knowledge of the test methods that may be used for conducting the tests proposed. Another part of the dossier evaluation is the compliance check where, in particular, the compliance of the hazard information provided with the standard information requirements specified in REACH, Annexes VII-X is to be checked. Obviously, the evaluation of the validity and relevance of any information obtained by testing requires that the assessor has sufficient knowledge on the scope and limitations of the methods that have been used for conducting the tests.

However, not only the dossier evaluation processes require knowledge on test methods. The ECHA Secretariat is also supporting the rapporteurs of the Risk Assessment Committee whenever a dossier with a proposal for harmonised classification and labelling or Community restrictions has been submitted. The criteria for classification are largely based on the outcome of experimental tests. Therefore, such dossiers contain information obtained by testing and, thus, the Scientific Dossier Managers need to have adequate knowledge of such test methods and the interpretation of their results. Also dossiers proposing substances to be identified as Substances of Very High Concern, in particular PBT and vPvB substances and substances of similar concern (e.g. proposed endocrine disrupters), need to be reviewed by ECHA staff with sufficient knowledge on the methods used for such identification. In addition, as the Risk Assessment Committee is adopting opinions and the Member State Committee is reaching agreements on scientific issues in relation test methods, also the committee members need the same level of knowledge[1].

Furthermore, in a letter of 20 August 2009, the Commission has requested ECHA to participate in and to contribute to the activities of the OECD Working Group of National Coordinators for the Test Guidelines Program and its subsidiary bodies. Thus, ECHA needs to establish procedures for this task and to allocate appropriate resources.

Finally, in particular the testing on vertebrate animals for obtaining information of the intrinsic hazards of substances was intensely debated during the negotiations of the REACH Regulation. The proposed aim of REACH was amended during the negotiations and ended up including among the aims the promotion of alternative methods for assessment of hazards of substances; however without a clear allocation of operational responsibilities for achieving this goal. Also during the practical implementation of REACH animal welfare organisations are monitoring the behaviour of both industry and ECHA and are providing comments on testing proposals published or writing to ECHA and alerting the press whenever new developments appear.

Thus, in order to ensure a consistent approach in dealing with test methods, and that assessments are based on a profound scientific knowledge on test methods including the newest developments, it is necessary to establish a Work Programme for issues relating to test methods.

[1] Nevertheless, it is outside the scope of this Work Programme to consider the expertise of committee members.

2. Objectives

Based on the brief description of ECHA's responsibilities given in the introduction, the objectives for ECHA's activities regarding test methods have been identified as follows:

- Objective 1: That the evaluation of hazard information (e.g. in registration dossiers) is based on profound scientific knowledge derived from the application of test methods (incl. alternative methods);
- Objective 2: That new standardised test methods are providing meaningful hazard information that is adequate for regulatory purposes and in line with the principle of the Three Rs, Replacement, Reduction and Refinement[2] ;
- Objective 3: That communication on available test methods, including alternative methods, is clear, unambiguous and consistent, and in accordance with ECHA's role and responsibilities under the REACH and CLP Regulations

Operational aspects related to dossier and substance evaluation (e.g. how the dossiers are evaluated, which type of documentation is required for non-standard methods, assessment of weight of evidence approaches) are not comprised by the current work programme, as these are dealt with in the criteria to be applied for the evaluation work.

3. Results and activities required

The objectives defined can be reached by conducting activities that deliver a number of results, as defined below.

3.1. Scientific capacity building

The operational staff of ECHA evaluating hazard information on substances should have a sufficient knowledge of test (and non-test[3]) methods allowing them to evaluate testing proposals, compliance of registration dossiers with the information required and any other dossiers submitted to ECHA (incl. proposals from MSCAs for harmonised C&L, identification of SVHC, and restrictions). This will be achieved by conducting the following activities:

- All scientific staff receives basic training on the principles[4] of hazard assessment;
- Scientific staff, whilst maintaining a general overview, can be assigned to relevant endpoints to develop specific expertise and receive advanced training on interpretation of test results within their fields of expertise. The advanced training may include practical hands-on training in standardised laboratory test methods for selected endpoints and participation in relevant workshops and conferences for selected staff;
- Establishment of Task Forces and/or ad hoc Working Groups under the scientific platforms (see section 4.1) in which experts can obtain, develop and exchange knowledge on the relevant endpoints. This should include also the monitoring of the relevant scientific developments related to new test methods;

[2] Russell and Burch 1959: Replacement means the use of methods that do not involve the use of live animals, Reduction means to reduce the numbers of animals to achieve the same objectives, Refinement means the use of methods that reduce the pain, suffering and distress or otherwise improves the welfare of the animal."

[3] Not comprised by the current work programme. A considerable number of development activities are ongoing as briefly described in Annex 1 to the present document.

[4] Training programme already developed and first training round completed.

- Knowledge on in vitro methods will be obtained through collaboration with ECVAM, e.g. by arranging training sessions for ECHA staff on assessment of results obtained by use of existing or new in vitro methods.

3.2. Contribution to development of test methods

ECHA's support and contribution to the development and standardisation of test methods (incl. development of new in vitro methods, test methods for new endpoints, and revision of current test methods in line with the Three Rs) should be of high scientific quality and result in new standardised test methods that provide hazard information that can be used for regulatory purposes with the use of as few test animals as possible and with at least harm to the animals needed to be used. This will be achieved by conduction of the following activities:

- Establishment of Task Forces and/or Working Groups for relevant endpoints under the scientific platforms[5] for providing support to development and standardisation of Test Guidelines;
- Participation in and contribution to the OECD Working Group of National Coordinators for the Test Guidelines Programme and its subsidiary bodies in close collaboration with the Commission Services. The participation will be focused on selected expert groups for test guidelines of highest relevance for REACH and CLP;
- Participation in the sub-group on the preliminary analysis of regulatory relevance of new alternative test methods (PARR sub-group) that is under establishment by the Commission. Providing feedback on the possible regulatory relevance, including the implications for the work of the MSC and RAC, of proposed new test methods when requested.
- Co-operation with Community services such as the JRC and other international initiatives (e.g. the European Partnership for Alternative Approaches to Animal Testing) on the development of integrated testing strategies that allow reduction, replacement and refinement of animal experiments. The participation of the ECHA Committees may also be considered; particularly in initiatives linked to cooperation among Committees and Panels providing scientific advice on Risk Assessment (Meeting of Chairs and Secretariats of EU bodies involved in risk assessment).

3.3. Communication preparedness

ECHA's communications on its role in relation to test methods need to be clear, unambiguous and consistent. This can be achieved by conducting the following tasks:

- Establishment of a horizontal Communication Team that can ensure a rapid response to inquiries and discussions in the public and the media as well as a coherent and consistent communication on all issues related to test methods;
- Development of general strategy documents on various issues relating to test methods (incl. ECHA's role in relation to animal welfare[6],).

[5] Scientific platforms have been established at ECHA as transparent structures for exchange of scientific views, decisions and questions.
[6] See annex 1.

4. Organisation and Resources

4.1. Organisation

The proposed organisation of the work on test methods at ECHA needs to take into account that more than one unit and more than one directorate is affected by the outcome of the work. Moreover, although parts of the objectives should be achieved within a short timeframe, others will require constant attention and long-term commitment during the years to come. This calls for a project organisation that is independent of the current unit and directorate structure.

The scientific platforms for human health and environment that have been established at ECHA are tasked with development and horizontal coordination of scientific issues within their mandates, and will support the regular REACH and CLP operations organised through the line hierarchy. These two platforms will be the most logical organisational structure at ECHA for taking up the tasks related to Objectives 1 and 2, and also to contribute to Objective 3. The two platforms will be requested to either establish Task Forces and/or Working Groups for relevant endpoints or include the tasks into existing structures. Specific Terms of Reference for the activities incl. expected deliveries and timeframe need to be developed. Also the possibilities for obtaining scientific guidance from RAC and/or MSC on specific questions will be considered.

The communication to stakeholders and the public on issues related to test methods should be coordinated at management level in order to ensure that clear, unambiguous and consistent messages are conveyed. A horizontal Communication Team should be established with participation from Directorates B, C and A, Legal Affairs Unit, and the scientific platforms on human health and environment.

4.2. Resources

So far the resources that the ECHA Secretariat has been able to allocate to the area of test method development have been very limited. It is foreseen that in the coming years the contribution to this work area can be slightly increased. In the ECHA work programme the specific resources allocated to the test methods development is covered by activity 7 (Other scientific and technical advice on questions relating to chemicals). However, the activities and related resources covered in this document are to a large extent included under their relevant activity headings in the Work Programme (e.g. evaluation).

Attachment:

1. Animal testing under REACH & CLP: the role of ECHA

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ANNEX 1

ANIMAL TESTING UNDER REACH & CLP: THE ROLE OF ECHA

1. Introduction

ECHA was established by 1 June 2007 following the adoption of the REACH Regulation. ECHA has been given a number of tasks under both the REACH and the CLP Regulations that rely on results obtained by testing of laboratory animals and are submitted to ECHA by companies. As testing using animals, more specifically vertebrate animals, is a controversial issue in the public, it is worthwhile to discuss how animal welfare is addressed in the REACH and CLP Regulations, and how this is considered by ECHA in the daily work.

2. Aims of the REACH and CLP Regulations

The overall purpose of both the REACH and the CLP Regulations is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles. While achieving this, the objectives of REACH are also to enhance competitiveness and innovation as well as promoting alternative methods for assessment of substances.

One of the main reasons for developing and adopting the REACH Regulation was that a large number of substances are manufactured and placed on the market in Europe for many years, sometimes in very high volumes, and yet there is very little information on the hazards that they pose to human health and the environment. There is a need to fill these information gaps to ensure that industry is able to assess hazards and risks, and to identify and implement the necessary risk management measures in order to protect humans and the environment. One of the goals of REACH was indeed to fill the data gaps in knowledge on the hazards of substances that have been recognised for years. The scientifically agreed methods to fill these data gaps often use vertebrate animals to predict effects in man or in the environment. Therefore the implementation of REACH and in particular the development of registration dossiers by the manufacturers and importers of chemical substances will inevitably require new testing with vertebrate animals. To avoid unnecessary testing, it is also an aim of REACH to promote alternative methods for assessing the hazards of substances.

3. Information requirements in REACH and CLP

Information requirements in REACH

One of the most important measures for ensuring safe use of chemicals is that sufficient information on the hazardous properties is available to the manufacturers, importers and users. Therefore, REACH specifies in Annexes VII-X the standard information that is required for substances depending on the volumes of manufacture and import, as this provides an indication of the potential for exposure of man and the environment to the substances.

In general, the potential registrant should obtain and review all available and relevant information on the hazards of substances. This includes any information generated by alternative means offering equivalence to the test methods prescribed in the REACH Annexes and laid down in the Commission's Test Methods Regulation. Such alternative methods include in vitro test methods and non-testing methods as read-across and (Q)SARs as long as these methods are scientifically validated and provide results that are adequate for C&L and risk assessment.

In addition, it is possible to adapt the standard information requirements to the specific substance based on substance and exposure characteristics as described in Column 2 to the Annexes VII-X and Annex XI.

Information requirements in CLP

Contrary to the information requirements under REACH, the CLP Regulation does not prescribe that certain hazard information must be obtained[7]. Instead the Regulation provides that suppliers should obtain and evaluate all available and relevant information and, based on this information, should classify substances and mixtures. Of course, for substances subject to registration under REACH, the information obtained for that purpose should be used also for determining the classification of these substances.

Nevertheless, in cases where a supplier decides to obtain new information by use of testing, such testing shall be conducted by use of the methods laid down in the Test Methods Regulation or any other methods validated according to international procedures.

4. Legislative framework relating to animal welfare

Animal welfare directive

The main legislation relating to animal welfare is Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes. The Directive provides basic requirements for the care and accommodation of laboratory animals and stipulates that experiments shall be designed to avoid distress and unnecessary pain and suffering to the experimental animal. Furthermore, experiments with animals shall not be performed if the results can be obtained by another scientifically satisfactory method. According to Article 13(4) of REACH ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the provisions of Directive 86/609/EEC.

The Directive is under revision and the Commission's proposal for a new Directive is currently being negotiated in Council and EP.

[7] Except for physical hazards, which are outside the scope of this document.

The REACH Regulation

It has been known and accepted since the drafting of REACH that the need to fill the data gaps would result in an increased use of laboratory animals for the next 10 years until that goal has been reached. However, in order to strike the right balance between filling the data gaps with animal testing and avoiding unnecessary animal tests, the REACH Regulation stipulates that animal testing should only be conducted as a last resort.

Therefore, REACH provides a number of possibilities for adapting the testing requirements and for using existing data and alternative assessment approaches. Experience with for instance the OECD High Production Volume Chemicals Programme has clearly demonstrated that when substances of similar structure and toxicity profiles are assessed as a group (category), substantial savings in the number of tests can be achieved.

The CLP Regulation

In similarity with REACH, the CLP Regulation stipulates that testing on animals shall only be conducted where no other alternatives are possible. Moreover, and contrary to REACH, there are no formal requirements for performing tests for the purpose of C&L (except for physical hazards).

5. Duties of registrants under REACH

Data sharing

REACH prescribes that, in general, all substances manufactured or imported in quantities at 1 tonne or more per year have to be registered before being manufactured or placed on the market. In order to avoid unnecessary testing it also contains an obligation for sharing the results of tests involving vertebrate animals between companies registering the same substance. REACH discriminates between non-phase-in substances and phase-in substances, i.e. essentially new substances and substances that are already manufactured and marketed.

Before registration of a non-phase-in substance, a potential registrant is obliged to submit an inquiry to ECHA whether that substance has already been registered and, if so, whether any new information required by the potential registrant is already available (see Article 26 of the REACH Regulation). If the substance has already been registered, ECHA shall inform both the previous registrant and the potential registrant about this and available studies shall be shared between the parties. In particular, studies involving tests on vertebrate animals shall not be repeated. The previous registrant and the potential registrant shall make every effort to reach an agreement on the sharing of the data, and ECHA is only obliged to interfere if the two parties cannot reach agreement on the sharing of the study (see also section 6 below).

For phase-in substances, the registration deadlines are prolonged if the manufacturer or importer pre-registered the substance before 1 December 2008. The main purpose of the pre-registration was to set up the Substance Information Exchange Forums (SIEFs) consisting of potential registrants of the same substance, in which the potential registrants can collaborate on obtaining and sharing data on the substance ensuring that duplication of animal testing is avoided. Thus, REACH prescribes that available studies involving tests on vertebrate animals shall be shared among the potential registrants, while other types of studies may be shared. Essentially, members of the SIEFs shall make every effort to reach agreements on the data sharing and as long as the SIEF members are able to do so, ECHA has no role in the data sharing process within the SIEFs. ECHA is only obliged to step in, if an owner of a study is not willing to share the

study, if the SIEF members cannot agree on sharing the costs, or if the SIEF members cannot agree on who should carry out a new study for filling data gaps (see also section 6 below).

Generation of information and joint registration

Potential registrants are required to obtain data on the hazards of their substances as specified in the Annexes VII-X of REACH. Annex VI of REACH provides a basic four-steps procedure for fulfilling the information requirements. The procedure comprises the following steps: (i) Gather and share existing information; (ii) Consider information needs; (iii) Identify information gaps; and (iv) Generate new data/Propose testing strategy. Furthermore, as mentioned above, testing on vertebrate animals should only be undertaken as a last resort. In order to minimise the number of unnecessary animal tests, REACH Annex XI as well as column 2 of Annexes VII-X provide a number of possibilities for adapting the testing requirements and use existing data and alternative assessment approaches instead. Before embarking on testing for fulfilling the data requirements specified in Annexes IX and X (which include those tests requiring the largest number of vertebrate animals and which are most expensive), the registrants have to submit a testing proposal to ECHA (see 6).

Thus, it is clearly specified in REACH that potential registrants are obliged to utilise non-testing methods and in vitro test methods as well as data sharing to the fullest extent in order to avoid unnecessary animal testing for obtaining the data, which are necessary for the assessment of hazards and risks. However, every adaptation to the standard information requirements in column 1 of Annexes VII to X needs a valid justification. This justification has to be based on the provisions in column 2 of the Annexes or on the provisions in Annex XI.

In order to avoid redundant testing for specific long-term hazard end-points ECHA has published in September 2009 legal clarification of the provisions in REACH Annexes VIII-X.

The clarification is specific. It applies to companies manufacturing or importing substances at quantities greater than or equal to 100 tonnes (and 1000 tonnes) per year who need to provide information in their registration dossiers on the repeated dose toxicity or reproductive toxicity of their substance. Put simply, companies who need to provide information based on long term toxicity studies (a 90 day repeated dose toxicity study or a pre-natal developmental toxicity study), do not need to also submit the results of screening or short term studies (a 28 day repeated dose toxicity study or a screening for reproductive/developmental toxicity study) in order for their submission to be considered “complete” by the European Chemicals Agency. Potential registrants should consider this clarification as part of an integrated approach to obtaining the information necessary to determine the hazards and risks that their substances may present for human health and the environment.

6. ECHA’s role in avoiding unnecessary testing

Inquiries on non-phase-in substances

As described in chapter 5.1 the potential manufacturers and importers of non-phase-in substances are obliged to inquire whether the substance has already been registered at ECHA (cf. REACH, Article 26). The purpose of this obligation is to allow sharing of information, in particular results of tests with vertebrate animals, between a registrant and a potential registrant. The primary role of ECHA is to bring the potential registrant into contact with a previous registrant of the same substance, which will then allow the two parties to agree on sharing their data.

In case the two parties are not able to agree on data sharing, the potential registrant shall inform ECHA on this fact. ECHA will then give the potential registrant permission to refer to the relevant information present in the registration dossier already submitted by the previous registrant provided that the potential registrant can document that he has paid a share of the costs of obtaining the data.

Thus, the role of ECHA is to bring a potential registrant into contact with a previous registrant and, if these two parties cannot agree on sharing the data, to allow the potential registrant to refer to relevant data present in the registration dossier of the previous registrant.

Pre-registration of phase-in substances

ECHA was responsible for receiving the pre-registrations of phase-in substances from potential registrants under REACH. Based on the pre-registrations received, ECHA has as far as possible[8] grouped the pre-registrants into pre-SIEFs and ensured that pre-registrants can identify and communicate with each other.

Although not a task prescribed for ECHA in accordance with REACH, considerable support is provided to potential registrants on setting up their SIEFs, e.g. by awareness raising, registration of prospective lead registrants, participation in lead registrant workshops and webinars, etc. This facilitates the data sharing process among the potential registrants in the SIEFs.

In case members of a SIEF decide that a new study needs to be carried out and they cannot agree to whom of the members that should carry out the test on behalf of the other members, the SIEF members should inform ECHA about this fact. ECHA will then decide whom among the SIEF members that should carry out the test on behalf of the other members.

In conclusion, the main role of ECHA in relation to data sharing and avoidance of unnecessary animal testing on phase-in substances was to establish the pre-registration procedures and forming the pre-SIEFs. During the practical data sharing activities within the SIEFs, ECHA only has a relative limited role by solving potential conflicts on who should carry out the necessary tests on behalf of the SIEF members.

Examination of testing proposals

Registrants have to submit a testing proposal prior to undertaking testing for obtaining information defined in REACH Annexes IX and X. The testing proposal is submitted with the registration dossier, in which the need for the test is justified. When a testing proposal concerns a study involving vertebrate animals, ECHA publishes the name of the substance and the hazard endpoint for which testing is proposed for public consultation with the aim of obtaining scientifically valid information and studies on the endpoint. Following the end of the consultation period, ECHA will draft a decision on whether the proposed test (eventually amending the conditions, e.g. test species, route of exposure) needs to be carried out. The decision is based on the registrant's justification for the testing proposal and takes into account all information contained in the registration dossier as well as any scientific valid information obtained from third parties. ECHA's decision involves consultation of the registrant that submitted the testing proposal, the Member States' competent authorities and, if necessary ECHA's Member State Committee (MSC). If the MSC does not reach an agreement, ECHA refers the draft decision to the European Commission which takes the decision after further consultation with the Member States. This procedure was established to make

[8] The grouping of pre-registrants into pre-SIEFs was depending on the substance identity, which in many cases was difficult and time consuming to interpret.

sure that the best possible use is made of existing information, and that animal testing is required only when there is a broad consensus that such testing is indeed necessary.

It has to be realised that for some hazard endpoints covered by testing proposals (e.g. repeated dose toxicity, reproductive toxicity, mutagenicity), the current scientific status is still that animal testing may be needed for providing the information requested by REACH. This does, however, not mean that such tests have to be conducted for each substance or by each registrant. The data sharing provisions require that data on animal tests are shared between the registrants of the same substance. It is also possible to submit existing data (i.e. from studies not carried out according to GLP or in accordance with the prescribed standard methods) adequate for the purpose of C&L and/or risk assessment. In addition, read across from scientifically valid data for similar substances may be appropriate and the building of chemical categories is another possibility.

Compliance check of registration dossiers

ECHA is obliged to check at least 5% of all registration dossiers within each tonnage band for compliance with the information requirements of REACH. In case ECHA consider that the dossier is not in compliance with the information requirements, ECHA will draft a decision requiring the registrant to submit the missing information.

A part of the compliance check is to check that the hazard information provided complies with the requirements of REACH. In case the information requirements specified in REACH Annexes VII-X have been adapted, ECHA is checking the scientific validity of the adaptation justifications. If, for example, the information required has been provided by use of alternative methods, the documentation for the use will be evaluated in accordance with the basic specifications provided in REACH Annex XI and explained in the ECHA guidance on Information Requirements. In any case, it is up to the registrant to justify that alternative data are adequate for the purpose of C&L and for risk assessment.

Substance evaluation

Substance evaluation aims at verifying whether a substance constitutes a risk for human health or the environment. This information can be used in other REACH or CLP processes to promote the safe use. Substance evaluation is performed by Member State Competent Authorities (MSCAs) and involves an assessment of all available information and requesting further information from industry to confirm whether or not the suspected risk is there. ECHA is coordinating and facilitating the work, in particular through drawing up the list of substances to be evaluated (Community Rollin Action Plan). The formal outcome of the substance evaluation is a request for further information following the same decision making process as in dossier evaluation. Substance evaluation may also lead to testing with vertebrate animals, and therefore the above considerations in relation to dossier evaluation about using alternative or non-testing methods are equally valid.

Other ECHA activities

In addition to the above listed specific tasks ECHA is promoting, directly or indirectly, the avoidance of unnecessary animal testing through various other activities. Particularly important is development of guidance documents (e.g. the guidance for information requirements and for chemical safety assessment) but also helpdesk activities, and training and awareness raising will support industry to better implement the legislation in a way that will avoid unnecessary animal testing. Finally, the operational staff at ECHA are being trained to be aware of the latest scientific developments regarding test methods and non-testing methods.

Finally, the ECHA Committees may be required to give advice on issues relating to test methods; for example, on whether the use of specific alternative methods will provide sufficient information for fulfilling the regulatory aims.

7. ECHA's involvement in development of alternatives

Testing methods

The development of new and revision of existing standard test methods is a continuously ongoing activity that is mainly carried out at international level under the auspices of the OECD. Animal welfare is one of the aspects typically considered and used for justifying such initiatives. The three R principles (Replacement, Reduction, Refinement) are in focus when new test methods are developed and validated and when their regulatory relevance is considered. One of the most radical changes to animal testing is the development of in vitro methods when these can fully, as a test battery, or as part of an integrated testing strategy replace existing animal tests. However, also modifications of existing animal tests that allow obtaining similar information with use of fewer animals have a positive impact on animal welfare.

In the EU, the ECVAM at JRC is responsible for the scientific validation[9] of new alternative testing methods. However, this alone is not a sufficient pre-condition for introducing a new test method, as it also has to provide a result that is meaningful for regulatory use. The Commission is responsible for the regulatory acceptance of new methods and their adoption and inclusion in the Test Methods Regulation. To this end, the Commission has established a working group tasked with pre-evaluation of the regulatory relevance of proposed new test methods (the so-called PARR sub-group) at an early stage of the development of new test methods. ECHA is providing scientific and technical support to these activities.

Alternative non-test methods

In some cases, non-testing methods can be used for filling data gaps instead of using traditional test methods. Such methods include (Q)SARs, grouping and read-across, which may be used when their scientific validity has been established as well as their regulatory relevance, i.e. that the results provided are adequate for C&L and/or risk assessment. These methods can be used not only for direct filling of data gaps, but also in integrated testing strategies and as weight of evidence.

A prospective new tool for use by potential registrants is currently being further developed in the form of the OECD (Q)SAR Application Toolbox. The OECD is responsible for the development while ECHA is actively supporting the development of the tool by providing funding, project management and IT expertise. It is seen as an essential tool for helping industry in obtaining the relevant information of the intrinsic hazards of their substances. The Toolbox can, a.o., be used for the building of chemical categories based on test data that are contained in the database of the Toolbox. As registrants are obtaining hazard information on their substances and submitting it to ECHA, new scientific valid information (incl. test data) becomes available. Whenever this information is not claimed confidential by the registrants, it can be fed into the Toolbox and the information can then be used to fill data gaps by reading across from already tested substances.

To avoid the need to test every substance for every endpoint, the grouping concept will be further developed in the future. In addition to the tools that are already available, the methodology of grouping and read-across is also moving under the OECD umbrella. New, more flexible ways for grouping of substances are emerging (e.g. targeted

[9] Validation is the process by which the reliability and relevance of a method are established.

categories) and more science is invested in the way the similarity is perceived (mode of action approaches for profiling, adverse outcome pathways for data gap filling). The implementation of the new tools and methods in existing OECD programmes like SIAM and under REACH is improving the understanding of the non-test methods and is paying back by increase of the usefulness and the acceptance of non-test methods. To this latter point, bi- and tri-lateral collaborations, especially with US and Canada, help to bring the international experiences from hazard evaluation and priority setting from different regulatory frameworks around the world.

Considering the development of non-testing approaches, is may be expected that the main approaches that will be used for the 2010 registrations, will be building of categories and reading-across from scientific valid data within the category. The further development of (Q)SAR approaches (i.a. based on the test data provided with the first registration wave) could probably have an increasing role for the later registrations (i.e. in 2013 and 2018).

8. Monitoring and reporting

According to REACH, Article 117(3), ECHA shall every three years beginning from 1 June 2011 submit a report to the Commission on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of REACH. No similar reporting obligations apply for the CLP Regulation.

The primary sources of information that will be available to ECHA are the registration dossiers submitted by manufacturers and importers for non-phase-in substances and phase-in substances as well as the results of ECHA's examinations of testing proposals and compliance checks. ECHA has already received a number of registrations of non-phase-in substances, while the first bulk of registrations of phase-in substances will arrive in the period up till the first deadline for substances at the highest volumes and hazards at 30 November 2010. The registration dossiers are all in the IUCLID 5 database format, and tools for extracting statistical information from the dossiers are under development.

9. The way forward

The REACH Regulation is designed to balance the need for information on the hazardous properties of the substances that are manufactured, imported and used in the EU, and the need to avoid unnecessary use of animals for obtaining this information. This puts the responsibility on registrants to share the information already available to them as well as to the fullest extent utilise the possibilities for using alternative non-testing and testing data whenever possible. It also puts a responsibility to the authorities to disseminate all information that becomes available so the potential registrants will have access to such information.

Consequently, ECHA is now starting to disseminate non-confidential information contained in the registration dossiers received. At least the hazard information incl. the results of the tests carried out will be made available at ECHA's website and, to the extent that not claimed confidential, also the robust study summaries (RSS).

ECHA is also supporting the further development of the OECD (Q)SAR Application Toolbox, which is a tool for industry to build chemical categories, and develop and use read-across and QSARs. Test data from registration dossiers and other sources are important background information for use of the Toolbox.

The development of new and revision of existing test methods is a continuous process. ECHA is following such developments and is providing scientific and technical support based on our role as a regulatory agency.

Within the first years of operation, ECHA has built up and is continuing building up the expertise of the operational staff, which allows a professional and scientific evaluation of the registration dossiers including the testing proposals. The dossier evaluation focuses on the scientific validity and relevance of the data provided as well as on the documentation for any adaptation of the standard requirements proposed. To this end, it should be noted that the purpose of the dossier evaluation is to ensure that the information requirements specified in REACH Annexes VII-X are met, so the registrant has sufficient information for assessing and ensuring that any risks are controlled.

Whenever ECHA is drafting a decision as a result of the dossier evaluation, the role of the Member State Competent Authorities, the Member State Committee, or ultimately the Commission, in the decision making process needs to be remembered. Hence, these bodies need to be involved in the discussions to ensure a common and consistent line in the scientific and regulatory approach.

Finally, we can only urge all stakeholders to collaborate on obtaining the necessary information for ensuring the safe manufacture and use of the substances by use of valid and documented alternative methods, as this is the most efficient option for avoiding unnecessary use of laboratory animals. As mentioned, ECHA will as far as possible provide support and tools for this.