

DHI competences and selected project references **REACH**

DHI is an independent research and consultancy organisation.

DHI has a total staff of approximately 1000; mainly engineers and scientists, of which 60 are working within the area of chemicals management.

Within the REACH area DHI offers a *one stop shopping* opportunity based on our expertise within all fields required in REACH: Detailed REACH knowledge, dossier preparation, facilitation of SIEFs and consortia as well as specialised competences within risk assessment, ecotoxicology, toxicology, CLP and exposure assessment. Our experiences are based on on-going and completed services for industries across Europe some of which are listed below.

DHI key references include:

- **REACH registration and SIEF representation:** Our REACH team is currently facilitating several SIEFs and participates either as third part representative or OR in additional consortia/SIEFs. Further DHI is currently assisting in the preparation of registration dossiers on a new substance.
- **Notification of new and existing substances.** Before REACH DHI supported European manufacturers in the elaboration of notification dossiers of new substances. As the scientific principles are similar to those applied under REACH we regard these projects as key references for our technical services supporting registration under REACH.
- **REACH consultancy for industrial companies.** Based on their specific needs and REACH obligations, DHI has assisted industrial companies with import, producer, and down-stream user obligations as well as SVHC.
- **Software development.** Together with TNO, DHI is currently developing a downstream user tool *ESmodifier* that aim to assist downstream user modification of exposure scenarios and developing of Exposure Scenarios for preparations.
- **Development of technical guidance and reviews.** DHI participated in a number of RIP and related projects, e.g. the CEFIC lead RIP 3.2 and in the SPORT project. On the exposure assessment side we are currently following ECHAs development of the Chesar exposure assessment tool.
- **Capacity building and training.** DHI has conducted a number of workshops and sector projects on implementation of REACH, including an e-learning tool. DHI develop and execute training as a part of our services.

- **Biocides, pesticides, pharmaceuticals, cosmetics and laboratory services.** DHI has a long tracked record of services on development and reviewing documentation and dossiers on biocides, pesticides, pharmaceuticals and cosmetic products. DHI has in addition a fully equipped ecotoxicological GLP certified laboratory which offers the full range of ecotoxicological and degradation studies.

DHI's main office is located in Hørsholm, Denmark, and has offices located in 20 countries around the world, including a representation in Brussels. DHI has been authorised as an Approved Technological Service Institute by the Danish Minister of Science, Technology and Innovation.

REACH RELATED SERVICES

Project: **Exposure of pregnant women to mixtures of Endocrine disruptors**
Description: DHI lead a consortium that investigates the exposure of the consumer group of pregnant women to endocrine disruptors. The project will assess the risks from exposure to a combination of different substances present in consumer goods and environments. In collaboration with DTU-Food, Force and Implement.

Country(ies): Denmark
Project value: 5.3 Mill DKK
Duration: July 2011 -
Name of client: Danish Environmental Protection Agency

Project: **Workshops on ED and mixture toxicity**
Description: Workshop on developing criteria for endocrine disruptors and workshop on combination effects with focus on endocrine disruptors. DHI acted as Rapporteur in collaboration with Danish Technological University (DTU-food)

Country(ies): Denmark
Project value: 180,000 DKK
Duration: November 2010 – January 2011
Name of client: Danish Environmental Protection Agency

Project: **Alternatives to nickel in surface treatment**
Description: Assessment of alternatives to nickel in surface treatment. In collaboration with Prof. Per Møller Danish Technological University

Country(ies): Belgium
Project value: Confidential
Duration: From March 2011
Name of client: Nickel Consortium

Project: **REACH Overlaps**
Technical assistance related to the scope of REACH and other relevant community legislation to assess overlaps

Description: The main study objectives were to:

- To review and assess potential overlap, conflicts and synergies between REACH and other relevant Community legislation
- To provide recommendations to the Commission regarding relevant legal initiatives to prevent overlap.

Key results are presented and discussed with the Commission (DG ENV). In cooperation with the Milieu.

Country(ies): EU27
Project value: DHI budget: EUR 20,000
Duration: January 2010 - ongoing
Name of client: European Commission, DG Environment

Project: REACH baseline I, II, and III
Description: The main study objectives were to:

- Develop indicator for measuring the impact of REACH
- To establish a baseline result, i.e. calculate the indicators before REACH starts

Key results at each stage has been discussed with an international scientific steering committee and presented at an international workshops. In cooperation with the German partners Ökoinstitut GmbH and FOBIC.

Country(ies): EU27
Project value: DHI budget: EUR 160,000
Duration: January 2006 - ongoing
Name of client: EUROSTAT, European Commission, DG Enterprise

REACH REGISTRATION AND SIEF REPRESENTATION

Project: Nickel Institute, Consortium 1, 2 and 3
Description: Exposure assessment technical service on the preparation of Generic Exposure Scenarios to Chapter 9 and 10 of the CSR

Country(ies): Belgium
Project value: Confidential
Duration: From January 2010
Name of client: Nickel Consortium 1, 2 and 3

Project: SIEF facilitator (Man Made Vitreous Fibres 1, note Q)
Description: DHI provides services as SIEF facilitator for a Consortium /SIEF with the aim coordinate the joint registration process. The activities include secretariat and trustee function, facilitation of meetings and communication as well as technical input.

Country(ies): Belgium
Project value: Confidential
Duration: From March 2009
Name of client: Man Made Vitreous Fibres, SIEF 1

Project: SIEF facilitator (Man Made Vitreous Fibres 2)
Description: DHI provides services to a SIEF lead registrant on coordination of the registration process. The activities include secretariat and trustee function, facilitation of meetings and communication as well as technical input.

Country(ies): Belgium
Project value: Confidential
Duration: From March April 2009
Name of client: Man Made Vitreous Fibres, SIEF 2

Project: SIEF facilitator (two SIEFs)
Description: DHI provides services to a SIEF lead registrant on coordination of the registration process. The activities include secretariat and trustee function, facilitation of meetings and communication as well as technical input.

Country(ies): Denmark
Project value: Confidential
Duration: From November 2009
Name of client: FEF Chemicals

Project: Registration of new substances
Description: DHI is currently assisting with the registration of 2 new substances. The work includes setting up a test program, liaison with CRO, study monitoring, interpretation of results, preparing of IUCLID files, CSA/CSR, exposure scenarios and SDS.

Country(ies): Denmark
Project value: Confidential
Duration: From August 2009
Name of client: NOVO Nordisk

Project: SIEF Technical consultant, Consortium on Unsaturated Polyester Resins (UPR)
Description: DHI provides technical services on sameness and chemical description of reaction products, data gap analysis and monitoring of testing program.

Country(ies): Belgium
Project value: Confidential
Duration: From March 2009
Name of client: Consortium on Unsaturated Polyester Resins (UPR)

Project: Registration of intermediates, dossier preparation.
Description: DHI assisted a Danish manufacturer of intermediates in identification and collection of available information, evaluation of quality and preparation of the technical dossier.

Country(ies): Denmark
Project value: Confidential
Duration: From April-July 2009
Name of client: Confidential

Project: SIEF representation (TPR)
Description: DHI provides REACH services as third party representative (TPR) for a German registrant. The services have included identification of substances and associated requirements under REACH, pre-registration of selected substances, and third party representation in SIEF.

Country(ies): Germany
Project value: Confidential
Duration: From June 2008
Name of client: Confidential

Project: Only Representative (OR)
Description: DHI is acting as OR for 7 non EU suppliers and in total 46 individual substances. The services include pre-registration, communication with SIEF and EU importers, SIEF participation, review of technical dossiers and CSRs as well as submission of individual registration dossiers.

Country(ies): US; Japan; Singapore; Kazakhstan
Project value: Confidential
Duration: From May 2008
Name of clients: Confidential

NOTIFICATION OF NEW AND EXISTING SUBSTANCES

Project: Notification of new chemical substances

Description: DHI has assisted nine major Danish companies with notification of their chemical substances according to (before REACH) EU legislation (and legislation in other countries). In total 21 substance have been adopted at reduced level, base level and 10 – 100 t/y level. A number of testing programmes were completed covering physical-chemical, toxicological- and ecotoxicological endpoints. The DHI services included set-up of testing programmes, liaison with CROs, study monitoring, interpretation of the test results, compilation of the data in dossiers and communication with the competent authorities.

Country(ies): Denmark

Project value: DHI budget EUR 1,500,000

Duration: 2004 - 2008

Name of client: Danish industries

Project: Development of RAR and Risk Reduction Strategy on Nickel and nickel compounds

Description: DHI developed together with RPA (UK) a risk reduction strategy on nickel and nickel compounds. The strategy was the last element finalizing the Risk Assessment Report on nickel with Denmark as rapporteur. The conclusion of the RAR was finally approved in the spring 2008.

Country(ies): Denmark

Project value: EUR: 50,000

Duration: January 2007 - 2008

Name of client: Confidential

REACH CONSULTANCY FOR INDUSTRIAL COMPANIES

Projects: Identification of presence of SVHC substances in articles, import and producer obligations, down-stream user obligations, and specific action plans for the single company based on their activities and obligations according to REACH.

Description: Identification of presence of SVHC substances in furniture and packaging for companies importing furniture to the EU. Action plan for company importing cosmetics and articles, including obligations to register in 2018 (article with a mixture). Company specific action plans for import and producer, down-stream user and supplier chain obligations for companies importing and/or producing packaging, paper, fibres, textiles, foam products, toys, pharmaceuticals, road materials, pipe systems, insulation materials and materialographic equipment and consumables.

Country: Denmark

Project value: From EUR 500 to 9,500

Duration: From a few weeks to more than 2 years. Late 2006 – July 2011

DEVELOPMENT OF TECHNICAL GUIDANCE AND REVIEWS

Project: Revision of Guidance on Intermediate use and exposure based waiving
Description: ECHA has subcontracted services on preparing examples of intermediate use and exposure based waiving (now: exposure based adaptation). DHI has together with TNO, Milieu, Oekopol and RPA prepared a number of examples based on information collected from industry.

Project: Exposure Scenario - Modifier
Description: This project is performed in collaboration with the Confederation of Danish Industries. The project aims at the development of a tool – ‘the ES-modifier’ - which was presented for the European Industry in August 2007 in relation to the ‘Arona meetings’ under RIP 3.2-2. The ‘ES-modifier’ is based on information on chemical substances and the key focus group is the DU-formulator. The tool will give the DU-formulator a possibility for re-evaluation of safe use within the boundaries given by the substance producer chemical safety assessment as presented in the exposure scenarios. The tool will be validated by involvement of relevant stakeholders in Denmark and EU. The project is performed by DHI and TNO.

Country(ies): EU27
Project value: EUR 150,000
Duration: October 2007 – September 2010
Name of client: Danish EPA

Project: Review of Annex IV of Reg. 1907/2006 (REACH)
Description: The European Commission is responsible for reviewing of Annex IV and V under REACH before 1 June 2008. DHI in association with Milieu Ltd. and PTK Ltd. has under contract with DG ENV prepared an approach and methodology to this task and conducted a technical evaluation the existing entries on Annex IV as well as new proposed entries submitted by industry

Country(ies): EU27
Project value: EUR 195,000
Duration: October 2007 - June 2008
Name of client: European Commission

Project: RIP 3.2 – Technical Guidance on preparing the Chemical Safety Report (CSR)
Description: The Technical Guidance on the Chemical Safety Report (RIP 3.2) was developed by a project consortium lead by the European Chemical Industry Council (Cefic) under a contract with the EU Commission. The main objectives of RIP 3.2 were to develop guidance for manufacturers, importers and down-stream users of chemicals on how they can

- carry out the chemical safety assessment covering workers, consumers and the environment;
- document the assessment in the report, including listing of the exposure scenarios with appropriate risk management measures;
- communicate information using the safety data sheet according to REACH.

Draft guidance documents were presented and discussed at 5 Stakeholder Expert Groups (SEG)-meetings and tested through a number of case studies.
Results published as part of the “Guidance on information requirements and chemical safety assessment” (European Chemicals Agency).

Country(ies): EU27
Project value: DHI budget: EUR 280,000
Duration: December 2006 - September 2007
Name of client: European Commission, CEFIC

Project: RIP 3.3 - Development of Intelligent Testing Strategies
Description: DHI participated in the TAPIR project preceding RIP 3.3 and was member of the RIP 3.3 Expert Working Group on Degradation. This working group developed guidance for the use of the currently available data from biodegradation studies, strategies to enable decisions in relation to further testing, and guidance for interpretation of data for the assessment of persistence (in PBT/vPvB assessment).
Results published as part of the "Guidance on information requirements and chemical safety assessment" (European Chemicals Agency).

Country(ies): EU27
Project value: DHI budget: EUR 25,000
Duration: August 2006 - October 2007
Name of client: Danish Environmental Protection Agency

Project: RIP 3.5 - Technical Guidance Document on Requirements for Downstream Users
Description: The aim of the project was to prepare a guidance on downstream user obligation under REACH. This work included case studies with European formulators and distributors and collection of experiences and tools of communication. From 2007 DHI coordinated a joint RIP 3.5-2 and RIP 3.2-2 work on development of guidance for handling of requirement for preparations.
Results published as part of the "Guidance for Downstream Users" (European Chemicals Agency)

Country(ies): EU27
Project value: DHI budget: EUR 67,500
Duration: August 2006 - October 2007
Name of client: European Commission

Project: RIP 3.8 - Technical Guidance Document on Requirements for Articles
Description: The aim of the work was to develop a technical REACH guidance for article producers and importers. The work included: 1) Evaluation of current experiences, terminology and handling of already registered substances; 2) Case studies with exemplification of work processes; 3) Development of guidance document including workflow. DHI lead the with Danish Toxicology Centre, Ökopol GmbH, Umweltbundesamt Austria, Federal Environmental Agency Germany, National Chemicals Inspectorate Sweden, Danish Environmental Protection Agency and Norwegian Pollution Control Authority.
Results published as part of the "Guidance for Articles" (European Chemicals Agency)

Country(ies): EU27
Project value: DHI budget: EUR 73,300 including budget for DTC which is now a part of DHI (total budget EUR 100,000)
Duration: May 2005 - May 2006
Name of client: European Commission

Project: REACH baseline
Description: The main study objectives were to:

- Develop indicator for measuring the impact of REACH
- To establish a baseline result, i.e. calculate the indicators before REACH starts

Key results at each stage has been discussed with an international scientific steering committee and presented at an international workshop in September 2007.

Country(ies): EU27
Project value: DHI budget: EUR 80,000 (total budget: EUR 480,000)
Duration: January 2006 - September 2007
Name of client: EUROSTAT, European Commission, DG Enterprise

Project: Exposure Scenarios for preparations
Description: The project aim to develop a guidance for Danish formulators on how to make exposure scenarios for preparations The project is performed in close collaborations with Danish industry associations and include contacts at European level. Templates for exposure scenarios are developed for communication to different types of industrial formulators and end-users of substances/preparations. The final guidance will include examples of exposure scenarios for preparations.

Country(ies): Denmark
Project value: DHI budget: EUR 100,000 (total budget: EUR 220,000)
Duration: December 2007 –December 2009
Name of client: Danish Environmental Protection Agency

CAPACITY BUILDING AND TRAINING

Project: E-learning on REACH
Description: The main study objectives were to:

- Develop a web-based teaching tool to raise awareness of the new regulation and to support actors to learn how the new regulation will function.
- Develop a tool addressing employees of all kinds of enterprises including - but not limited to - function areas with little or no background knowledge on chemicals, e.g. commercial people
- Develop the tool in three languages: Danish, English, German

A public available tool is available on <http://ereach.dhigroup.com>.

Country(ies): Denmark
Project value: DHI budget: EUR 200,000
Duration: January 2006 - March 2007
Name of client: Danish Environmental Protection Agency (UBA for the German version)

Project: Training workshops on REACH for Singapore chemicals' industry
Description: DHI is contracted as consultant for facilitation of the 'REACH Series 2008 Workshop Programme' which is organised by Singapore Chemicals' Industry Council (SCIC).

Country(ies): Singapore
Project value: EUR 10,000
Duration: May 2008 – October 2008
Name of client: Singapore Chemicals' Industry Council (SCIC)

Project: Implementation of REACH within the Danish industry sector for electronics
Description: The aim of the project was development of competence and tools for implementation of REACH within the sector for electronic industry in collaboration with the sector organisation. It included training and preparing industry for REACH obligations, mapping of chemical substances, communication with suppliers, of case studies and communication of the project results.
Country(ies): Denmark
Project value: DHI budget: EUR 105,000 (total budget: EUR 228,000)
Duration: August 2006 - April 2008
Name of client: Danish Environmental Protection Agency

Project: Implementation of REACH in Danish companies for trade and distribution of chemicals
Description: This project aimed to facilitate the implementation of REACH within traders and distributors of chemicals and included:

- Development of tools for implementation of REACH
- Preparing the management
- Mapping of chemicals
- Internal communication
- Communication in the supply chain
- Training of sales people to work with REACH

The key results were presented and discussed at a workshop in January 2008.
Country(ies): Denmark
Project value: DHI budget: EUR 150,000
Duration: January 2006 - March 2008
Name of client: Danish Environmental Protection Agency

Project: Implementation of REACH within the Danish detergent and cosmetics industry
Description: The overall aim was to facilitate the introduction of REACH within the sector. This project was performed in collaboration with the Association of Danish Cosmetics, Toiletries, Soap and Detergent Industries.. The project also included development of a 'REACH manual' and an it-tool for mapping of chemical substances in relation to the industry's obligations under REACH, and updating of an existing chemical database for the sector. The results were presented at a workshop in January 2008.
Country(ies): Denmark
Project value: DHI budget: EUR 130,000
Duration: March 2006 - March 2008
Name of client: Danish Environmental Protection Agency

Project: Strategic Partnership On REACH Testing (SPORT)
Description: DHI participated as a facilitator in relation to the testing of the functioning of the registration and evaluation procedures in REACH by use of specific case substances.
Country(ies): EU
Project value: DHI budget: EUR 45,000
Duration: September 2004 - July 2005
Name of client: European Commission, CEFIC

Project: REACH consultancy for Danish Metalworkers' Union
Description: The project included REACH consultancy for Danish Metalworkers' Union and health, safety and environment units in associated companies. The project output was a guideline for the EHS units at company level regarding new actions and opportunities under REACH and a method to catch new knowledge on safety and classification of substances to be used for improvement of the workers' environment.
Country(ies): Denmark
Project value: DHI budget: EUR 42,000
Duration: December 2007 - July 2009
Name of client: Danish Environmental Protection Agency

CLASSIFICATION AND LABELLING

Project: **Chemical regulatory phrases and data**
Description: DHI provides updated regulatory data and phrases for use in the area of Environmental Health & Safety. With the increased demands on hazard communication in the supply-chain imposed by REACH, the need for good IT-solutions for authoring Safety Data Sheets and other documents is increasing. DHI provides a standard library of phrases in more than 35 languages and an extensive database of chemical lists for use in Safety Data Sheet authoring. The database includes lists on Classification & labelling, Occupational exposure limits, chemicals inventories, and various observation lists etc. This product is offered to industry directly for use in their IT-systems or as a licensed product supplied through software developed by our international partners. In addition DHI uses the data and phrases internally on a daily basis as part of the Safety Data Sheet authoring and consultancy services.
Country(ies): Worldwide
Project value: yearly turnover: EUR 160,000
Duration: Running updates and deliveries
Name of client: Various Industry companies

Project: **Safety Data Sheets**
DHI has an ongoing agreement with an industrial association in Sweden covering preparation of Safety Data Sheets and Product registration for a number of countries in Europe and USA/Canada on their chemicals products. The project contains different solutions for different markets depending on the clients wish to fulfil local national requirements or general requirements (e.g. EU or GHS guidelines). Following parts are included: Obtaining full product composition, including contact to sub-suppliers, if any. Classification and labelling based on compositional information, translations and quality assurance, preparation of Safety Data Sheets and product registrations on relevant markets.
Country(ies): Sweden
Project value: Confidential
Duration: From 2006
Name of client: Confidential

BIOCIDES, PESTICIDES AND LABORATORY SERVICES

Project: Evaluation of a pesticide active substance and products

Description: DHI provide services under a framework contract with the Danish EPA, including reviewing of dossiers on pesticide active substances and product formulations.

Country(ies): Denmark

Project value: Yearly approx. budget: EUR 60,000

Duration: 2004 -

Name of client: Danish Environmental Protection Agency

Project: Toxicological evaluation of a biocide active substance

Description: DHI provide services to the Danish EPA on evaluation of active biocide substances with the aim to be included into the Biocides Directive Annex 1. The work included evaluation and description of toxicological studies and overall evaluation of the observed effects of the active biocide substance and biocide products as well as description of exposure scenarios.

Country(ies): Denmark

Project value: DHI yearly budget, approx: EUR 50,000

Duration: 2004 - 2007

Name of client: Danish Environmental Protection Agency

Project: EU monographs on Napropamid, Tebuconazole, Dicamba and Tafluvalinate

Description: DHI evaluated human safety aspects of plant protection products. DHI has evaluated and prepared the EU Draft Assessment Report Part B6: Toxicology and Metabolism for different Plant Protection Products. The work included evaluation and description of toxicological studies and overall evaluation of the observed effects of the plant protection products.

Country(ies): Denmark

Project value: DHI budget: EUR 150,000

Duration: 2004 - 2007

Name of client: Danish Environmental Protection Agency

Project: DHI GLP laboratories (ecotoxicology)

Description: DHI conducts ecotoxicological studies in compliance with the OECD principles for Good Laboratory Practice (GLP). The studies comprise short-term and long-term testing in accordance with OECD, ISO or OSPAR guidelines and standards. DHI is able to conduct the tests related to the ecotoxicological standard information requirements in REACH, and can provide testing in relation to the requirements in Annexes VII-X on physicochemical, toxicological and ecotoxicological properties via collaboration with other laboratories. Furthermore, the laboratories conduct research and development projects in collaboration with industry and academia.

Country(ies): Denmark

Project value: DHI budget: Annual turnover - EUR 670,000

Duration: Continuous services

Name of client: Industry