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REVIEW

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Nanomaterials and European Novel Food law:
The uncertain path to reasonable regulation

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Access to documents: Interaction and gaps in the REACH
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Editorial

The present issue of *elni Review* (1/2011) covers a variety of recent international environmental law issues alongside two country-specific contributions on EEE-waste regulation in Zanzibar, Tanzania and chemical substances legislation in China respectively. The key focus of the current edition of the journal, is *chemical substances regulation*.

Three articles approach this topic from different points of view:

First off, *Gareth Callegy* provides an overview of the legal impacts of the “Chinese REACH” legislation; an amendment to Chinese law which recently entered into force. By comparing the legal obligations arising from Regulation (EC) No. 1907/2006 (REACH) and the Chinese pendant, he points out inter alia the legal issues which European registrants will face when marketing chemical substances to the “Middle Kingdom.”

Subsequently, *Julian Schenten* analyses the state of affairs as regards the regulation of Nanomaterials in the food sector. Focusing on Regulation (EC) No. 258/97 on Novel Food, he identifies the weaknesses in terms of health protection and points out necessary key features which reasonable regulation of such chemical substances should have.

The third article concentrating on chemicals is by *Vito Buonsante*; it creates a bridge between the REACH Regulation and access to documents claims. In this context the author examines the interaction and gaps in the REACH and Aarhus Convention systems as well as the role of the European Chemicals Agency (ECHA).

The other contributions cover a variety of up-to-date legal issues:

Head of Legal at Friends of the Earth England, Wales and Northern Ireland, *Gita Parihar*, shows the legal impacts of the Cancun UN climate negotiations which took place in December 2010. In doing so, she develops a line of reasoning which remains relevant beyond the Bangkok Climate talks in April 2011.

Asking in his title ‘A human right to a clean and healthy environment in Europe: Dream or reality?’, *Jan Van de Venis* provides an introduction to the development of a human right to a healthy environment on a global scale. He analyses the ways in which this human rights-based approach to environmental issues evolved, what tangible benefits such a right could bring, along with where it currently stands globally and, more specifically, in Europe under the European Convention on Human Rights.

The contribution that follows, *Tania Van Laer* examines whether EU law allows Member States to justify, on the basis of animal welfare, unilateral measures that impose trade restrictions. At the same time she considers the main

principles of the free movement of goods as well as the established view of the Court of Justice.

The final article outlines the electronic waste situation in Zanzibar, Tanzania. In the absence of consumer protection provisions and specific environmental guidelines to regulate the import of these products or manage their safe disposal, the small island state is failing to implement the principles of the Basel Convention. Against this background *About S. Jumbe* presents the current activities of the Department of Environment, Zanzibar, which is now in the advanced stages of preparing a legal document which contains a set of regulations on the import, handling, and disposal of used and waste electrical and electronics equipment.

Finally, the issue covers recent developments regarding the situation of access to justice in Ireland – the only EU country in which the parliament has not ratified the 1998 UNECE Aarhus Convention.

Contributions for the next issue of the *elni Review* are very welcome. Please send them to the editors by September 2011.

Julian Schenten/Gerhard Roller

May 2011

elni Forum 2011

24th May 2011
in Brussels, Belgium

“Access to Documents at European Level – Key issues and practical experiences”

Bondine Kloostra presents key issues on access to documents regarding environmental information, including a recent decision of the ECJ (Stichting Natuur en Milieu). Vito Buonsante and Ludwig Krämer will present their practical experiences in access to documents, including the access to documents held by the European Chemicals Agency (ECHA). Eva Kruzikova will provide the point of view of the EU Commission.

This event will be held at the EU Liaison Office of the German Research Organisations (KoWi), Rue du Trône 98, 1050 Brussels, 8th Floor.

For more information about participation, including registration forms, please visit <http://www.elni.org/elni-events.0.html>.

'China REACH': Assessing the implications for non-Chinese companies producing and exporting new substances to China

Gareth Callagy

1 Introduction

Legislation concerning the environmental management of new chemical substances in China was amended on October 15 2010 by the enactment of the Measures for the Environmental Management of New Chemical Substances¹ by the Chinese Ministry of Environmental Protection (MEP).²

The regulation is an amendment of the same regulation promulgated on October 15 2003 and presents new obligations and challenges for non-Chinese companies exporting and producing new chemical substances in China. In the seven years since the implementation of the 2003 measures there have been some significant changes in the global management of chemicals, most notably with the implementation of the REACH regulation³ in the European Community in 2007. Viewed in the context of the implementation of REACH and the ongoing implementation of GHS⁴ in China, the amended regulation incorporates some concepts also included in REACH such as GHS-based criteria hazard communication, registration tonnage bands, post-notification tracking and acceptance of notifications only by legal-entities within the jurisdiction of the regulation.

The amended measures aim to control the environmental risk posed by new chemicals to ensure public health and ecological maintenance.⁵ Despite many significant differences existing between REACH and the China REACH, most notably in the registration scope and testing requirements, the comparison can be used as a frame of reference for non-Chinese companies formulating a compliance strategy.

2 New chemical substance notification in China

Since new chemical substance notification was implemented in China in 2003, over 350 registration certificates and 14,500 exemptions from notification

have been granted by the Chinese authorities⁶. In preparation for the implementation of the regulation, an inventory was assembled as the basis for determining whether a substance is considered a 'new' substance or an 'existing' one in China. The result was the *Inventory of Existing Chemical Substances in China* (IECSC inventory) which was compiled in several stages. The 45,602 substances currently listed on the inventory⁷ represent substances which were produced or traded in China prior to 2003.

2.1 Comparison between the amended measures and the REACH regulation

The Amended Measures can be broadly compared to the inquiry and subsequent registration process of a non-phase in or 'new' substance under REACH. A potential registrant of a non-phase in or 'new' substance is required to submit an inquiry to the European authorities prior to registration to inquire whether a registration has already been submitted. If one has been submitted previously, the sharing of data between previous registrants or sources is facilitated. If not, the potential registrant has to carry out the testing to satisfy his registration requirements, either alone or with other possible registrants.

Under the Chinese regulation, notifications should be made to the Chinese Chemical Registration Centre (CRC-MEP) in Beijing. New substances, irrespective of the tonnage quantity, cannot be produced, imported or processed without first being notified.⁸ Similar to the REACH inquiry procedure, confirmation of the status of the substance should be received from the authorities before preparing a notification. This is a simple procedure and does not require the submission of extensive substance identification information unlike REACH. The IECSC inventory can be partly searched online;⁹ however, a formal application for a comprehensive search should be submitted to the CRC to search the confidential substances and other substances not searchable online. If the substance is not included in the inventory but has been previously notified, the CRC can provide the potential notifier with the contact details of previous registrant(s). This would enable the previous registrant to share notification test data with potential notifier(s). This is subject

¹ 新化学物质环保管理办法' Measures for the environmental management of new chemical substances, Ministry of Environmental Protection, October 15 2010 [hereafter Amended Measures].

² The present paper is an edited and extended version of the article 'China increases cosmetics harmonisation with EU/US' which was first published in the December 2010 issue of the CHEMICALWATCH European business briefing.

³ Regulation (EC) No 1907/2006 (Restriction, Evaluation, Authorization of Chemicals) [hereafter REACH].

⁴ The Global Harmonised System of Classification and Labelling of Chemicals (GHS).

⁵ Art. 1, Amended Measures, *supra* note 1.

⁶ Baocheng, Wang, New Chemicals Notification Seminar (October 25 2010) Beijing China, CRC-MEP.

⁷ Inventory information from CRC website: www.crc-mep.org.cn/en/M006/M006_C1.aspx.

⁸ Art. 5, Amended Measures, *supra* note 1.

⁹ Inventory Search: <http://www.crc-mep.org.cn/iecscweb/>.

to the previous notifier having given consent to releasing their contact details to future notifiers, because unlike REACH, it is not a mandatory requirement for registrants to share data under 'China REACH'.

2.2 The outlook of new substance notification in China

At present, the production of base chemicals occupies the largest segment of the Chinese chemicals market. In the coming years, however, the fine and speciality chemicals sector is expected to expand from a 26% to 38% overall market share.¹⁰ This suggests that an increasing number of new substances will be marketed in China for the first time. Import growth in the fine and speciality sector is expected to grow at an annual compound growth rate of 10% in order to keep up with the growth in domestic demand.

2.3 Significant changes in the Amended Measures

The introduction of low tonnage band notification types and tonnage bands will reduce the burden of testing for low volume quantities, especially for scientific and technological research activities. Some of the significant changes which are likely to affect non-Chinese notifiers are:

- **Notification by Chinese entity only:**¹¹ Foreign notifiers cannot directly notify under the Amended Measures and require the assistance of a Chinese legal-entity to fulfil its notification and post-notification obligations.
- **Ways to notify:** Exemptions from notification are no longer available. Scientific record notification was introduced¹² to simplify the notification process for low volume substances for process- and product-orientated research and development (PPORD) as well as scientific research. A scientific record notification (SRN)¹³ also applies for the import of test samples of new substances into China. Four tonnage bands have been established for regular notification,¹⁴ which dictate the testing requirements to be fulfilled.
- **Management categories:**¹⁵ New substances are classified into management categories by the evaluation committee of the CRC: 'general' or 'hazardous' new substances. If a hazardous substance presents persistent, bio-accumulative or other hazardous properties, it can be further classified as a hazardous substance with priority envi-

ronmental concern. The classification may also affect the level of involvement of the non-Chinese supplier in the post-notification management of the substance.

- **Requirements for inclusion in IECSC inventory:** Only 'general' new substances notified under regular notification shall be included in the IECSC. This inclusion is five years from the date indicated on the first activity report.¹⁶ Hazardous substances are added subject to review of the activity report submitted by the certificate holder six months before the five year deadline. Substances notified under simplified notification or SRN would still be considered as new substances unless otherwise included in the inventory.

2.4 Broadening the scope of new substance notification

Amending the measures from 29 to 52 articles has resulted in a broadening of the scope of notification with the inclusion of¹⁷:

- **Articles and preparations:** The inclusion of articles with intended release means that more imported products will be affected if they release new chemicals as part of their functionality, in mixtures or as pure substances. Many imported products including aerosols, paint cans, perfumes etc. could be affected. Notification would be required for substance(s) released based on the tonnage band the annual released tonnage quantity falls into. No minimum allowed release limit has been specified.
- **Raw materials and intermediates for finished products:** Although cosmetic, agricultural, pesticides and other finished products are not affected by the Amended Measures, their raw materials and transported isolated intermediates are, however, now subject to notification if not included in the IECSC. The finished products would then be subject to other licensing procedures of other relevant laws and regulations.
- **China's Free Trade and Export Processing Zones (EPZ):** These zones are included within the scope of the Amended Measures from October 15 2011 following a one year transition period. Manufacturing and import activities involving new substances require notification apart from in the case of import for re-packaging or manufacture for export only.

¹⁰ Emerging Markets Group, Ltd., & Development Solutions (2005). *Chemicals Sector: Forward-looking perspective of EU-China, 2005-2015* Brussels: European Commission External Trade.

¹¹ Art. 16, Amended Measures, supra note 1.

¹² Art. 14, Amended Measures, supra note 1.

¹³ See section 4.1.

¹⁴ Art. 11, Amended Measures, supra note 1.

¹⁵ Art. 3, Amended Measures, supra note 1.

¹⁶ Art. 41, Amended Measures, supra note 1.

¹⁷ Art. 2, Amended Measures, supra note 1.

3 Compilation of the inventory and supplementation of the IECSC by industry

One of the first major steps in the development of new chemical substance notification was the compilation of the IECSC inventory, to aid in the differentiation between existing and new chemical substances. In preparation for the implementation of the original measures, the IECSC inventory was compiled in two phases between 1994 and 2003¹⁸:

The first phase occurred between December 1994 and December 1995. During this stage, substances manufactured, imported, processed or used in China between Jan 1 1992 and December 31 1994, substances contained in other catalogues¹⁹ as well as information provided by foreign representative offices in China was included. The second phase was from March 1996 to April 2003.

In order to avoid unnecessary economic burden to industry, supplementary applications were made available in 2003 and 2007 where manufacturers, processors, importers as well as non-Chinese companies were eligible to apply for substances to be included in the inventory. Subject to justification, companies could flag a substance as confidential when submitting the supplementation application. The more than 3,000 confidential substances currently present on the inventory represent some of the substances added during this period.

The first supplementary action lasted between Jan 2002 and June 2003. The second supplementary action was announced by the MEP in 2007²⁰ for applications to include substances manufactured or imported between Jan 1 1992 and October 15 2003. Companies are thus afforded the ongoing opportunity of applying for supplementation for substances that were marketed in China during this period but have not yet been included. Supplementation may not be applicable to many non-Chinese companies due to the comparatively low presence of foreign companies in China during this period. In addition, the difficulty in preparation of documentation and time required for the application may be disadvantageous to a non-Chinese company preparing such an application.

4 Notifying new substances under the Amended Measures

Notification applications are accepted by the CRC where they are checked for dossier completeness and that the minimum data requirements have been fulfilled. The application is reviewed by the evaluation

committee who then submits a recommendation to the Ministry of Environmental Protection. If the application is approved, registration certificates are then issued by the MEP. The procedure can take up to 90 and 60 days for regular and simplified notification respectively. Activities concerning substances notified by scientific record notification may begin once the notification has been filed with the CRC.

4.1 Ways to notify

Notifications can be made under regular, simplified and scientific record notification subject to the conditions shown in Table. 1:

Notification Type	Conditions
Regular (>1 ton/year)	Special Types: Serial, Joint, Joint-Serial, Repeat Notification, Re-Notification (increased tonnage band or use change) Four Tonnage Bands: Band I: 1-10 tons; Band II: 10-100; Band III: 100-1000; Band IV: > 1000 Tonnage Principle: 'The greater the tonnage the greater the data required' ²¹
Simplified (<1 ton/year)	Special Cases: (5 special cases concerning low volume intermediates, polymers and R&D purposes) General (< 1 ton/year)
Scientific Record Notification (SRN)	Import of test samples (for compulsory eco-toxicological testing in Chinese laboratories) R&D < 0.1 ton/year

Table 1: Notification Types and conditions under the Amended Measures

Regular notification certificates are valid from the date of issue until the substance is considered an existing substance after it has been included in the IECSC inventory. The simplified notification certificate is valid until the certificate holder applies for cancellation of the certificate, otherwise the certificate holder would be required to continue to fulfil the post-notification obligations. No registration certificate is issued for SRN; however regular announcements on SRN notifications will be published on the MEP website²².

4.2 Testing requirements and dossier requirements

The testing required depends primarily on the quantity of the substance to be notified and the notification type. The minimum testing requirements have been set and waiving requirements have been specified in the

¹⁸ Chemical Registration Center of State Environmental Protection Administration (2007), *Technical Document on Reporting for the Inventory of Existing Chemical Substances in China*.

¹⁹ For example: 'Complete Collection of Petrochemical Products' (1994 edition).

²⁰ Announcement No. 12 (2007) by the Ministry of Environmental Protection.

²¹ Art 11, Amended Measures, supra note 1

²² Art. 22, Amended Measures, supra note 1.

MEP guidance document for notification.²³ In some cases, additional testing requirements may be required for polymers in addition to the requirements of the corresponding tonnage band²⁴. Test data may be obtained from domestic Chinese laboratories or suitably accredited or GLP laboratories outside China.²⁵ Data generated using Quality Structural Activity Relationships (QSAR) or read across are now acceptable under the Amended Measures. However, endpoints generated this way can only be used as a reference²⁶.

Category	Risk Management Category	No. of Requirements	Post-Notification Obligations
1	General	6	1. Communication of MSDS to downstream users; 2. Implementation risk management measures; 3. Submission of first-activity report; 4. Storage of documents for 10 years; 5. Obligation to not sell chemicals to downstream users who are not capable of implementing their risk management measures; 6. Submission of updates if new hazard arises;
2	Hazardous	9	7. Submission of annual report (for previous year); 8. Compliance with <i>Measures for The Administration of Registration of Hazardous Chemicals</i> 9. Submission of substance flow chart
3	Hazardous new chemicals of priority environmental concern	11	10. Submission of report on disposal information; 11. Submission of annual plan (for coming year);

Table 2: Post-notification obligations introduced under the Amended Measures

²³ 'New Chemical Substance Notification Guidance Document' (2010), MEP [hereafter 'MEP guidance document'].

²⁴ Chapter 5 'Special Provisions for polymers', MEP guidance document.

²⁵ Art. 19, Amended Measures, supra note 1.

²⁶ Chapter 4 'New Chemical Substance Notification Material Requirements', MEP guidance document.

A compulsory minimum amount of eco-toxicological testing from MEP-approved Chinese laboratories is required for both general simplified notification and regular notification.

The minimum requirements for regular notification include physicochemical, toxicological and eco-toxicological test reports and a risk assessment report²⁷. Recommended classification and labelling and a safety data sheet are required according to the relevant GHS-based national standards.²⁸

For simplified notification, information on the substance and its exposure and use is required. Basic eco-toxicological data is required for general simplified notification but is not required for the special cases. Companies making a notification may also need to prepare a SRN for the import of test samples of the new substance(s) into China for the compulsory eco-toxicology testing. This may especially be the case for non-Chinese companies notifying new substances which require import because of difficulty sourcing them in China. Once the SRN has been filed with the CRC the samples can be imported in order for the testing to be performed. The SRN requires only minimal information to be submitted such as information regarding its scientific use and disposal. Unlike the other notification types, no registration certificate needs to be obtained prior to import, which can begin once the SRN is filed. Although this notification is a relatively simple process, it is however an additional step to be completed in the general simplified and regular notification processes.

4.3 Confidentiality and protection of CBI

Introduction of attempts to protect some confidential information of companies can be seen as a positive development in the amended regulations. Confidential claims are available for the substance name, molecular formula, molecular structure and uses provided the sufficient justification is provided. The substance name can be masked by providing a generic name²⁹ generated by replacing structural groups or descriptive parts of the substance name. Use categories for the substance use can be provided by the applicant, if the exact use is flagged as confidential.

Sensitive information may also be protected by appointing a third-party representative to act as a trustee. The third-party representative can submit the

²⁷ A semi-qualitative report is needed for Band I and quantitative report for Bands II-IV (MEP guidance document).

²⁸ These standards include 'General rules for the classification and hazard communication of chemicals' (GB 13690-2009), 'General rules for preparation of precautionary label for chemicals' (GB 12528-2009), 'Safety data sheet for chemical products – Content and order of sections' (GB/T 16483-2008).

²⁹ Guidelines for the generic name of new chemicals (HJ/T 420-2008).

data directly to the CRC with a matching submission reference to that of the Chinese legal-entity appointed for submission of the notification application. In spite of these safeguards for confidentiality, the public publication of notification information by the MEP³⁰ has raised concerns regarding the disclosure of confidential business information.³¹

4.4 Risk Management Category Classification and post-notification obligations

The CRC evaluation committee will review the self-classification of the notifier and further classify the substance into a general or hazardous risk management category. The risk management categorisation will affect the post-notifications obligations (Table 2) and the inclusion of the substance in the IECSC inventory.

The substances included in the inventory are managed as existing substances and are no longer subject to the Amended Measures unless the use of a hazardous substance of priority environmental concern changes. In this case, a re-notification would be required.

5 Business impacts for non-Chinese companies

Due to the requirement of a Chinese legal-entity to act as a notifier, a non-Chinese company needs the assistance of a Chinese entity to submit its notification. Approved notifiers include Chinese manufacturers, importers, representative agents and downstream users (in the case of re-notifications). The notifier would be the certificate holder and would be responsible for fulfilling the application submission requirements, downstream hazard communication, report submissions and other post-notification obligations. A non-Chinese company could rely on a representative agency or its importer to act as the notifier on its behalf.

The operation of representative agency is similar to that of an Only Representative under REACH³² and may be an external representative agent or a Chinese branch of the foreign company. Unless acting as the physical importer, the subsidiary or representative agent would need to fulfil all the capital and technical requirements specified in the MEP guidance document.³³

The name of the non-Chinese company would appear on the registration certificate unless its importer is performing the notification on its behalf. Other information to appear on the registration certificate includes the substance name, registered use(s) and man-

agement category³⁴ although the substance name and use can be masked to a certain extent.

Strong contractual agreements are recommended between the Chinese notifying entity and non-Chinese company as the Chinese legal-entity would be largely reliant on the foreign company for notification information. Nevertheless, it seems that the third-party submitting sensitive information directly to the CRC could be the non-Chinese company itself, as the Amended Measures or guidance documents do not specify that the third-party must be a Chinese legal-entity. The signing of the application documentation by the legal representatives of the non-Chinese companies may inconvenience and delay the notification procedure.

The success of enforcement of the Amended Measures can be considered as largely dependent on the supervision by regional environmental protection agencies (EPAs) and the compliance of domestic manufacturers. Domestic manufacturers producing unregistered new substances could place compliant foreign exporters at an unfair disadvantage, as the cost of the product from domestic manufacturers is likely to be more attractive to potential buyers. However, the requirement for the registration certificate to be included in the Environmental Impact Assessment³⁵, required for production or processing approval, may assist with compliance supervision by regional EPAs. The requirement for downstream users to request registration certificates may aid in exposing companies who do not hold registration certificates. Penalties can be enforced by the MEP or regional environmental protection bureaus and include fines and published breaches by the MEP.

With the introduction of more ways to notify and clear data waiving conditions, costs can be saved by notifying companies. Several substances with similar molecular structure or properties can be notified simultaneously under serial notification saving numerous separate notifications. Other subsidiaries and companies can also be included in the joint notification of a substance and to each receive registration certificates. Joint-serial notification is also possible and allows for several substances to be notified at the same time by multiple notifiers. Notification could also be taken as a strategic business move to notify research or innovative substances with future market potential in China. As a registration certificate holder it would offer the company a certain amount of exclusivity and although data sharing with potential registrants is encouraged, it is not mandatory. The longest time period of five years before inclusion in the inventory would mean the substance would still be considered as a new substance and the registration certificate could even be

³⁰ Art. 23, Amended Measures supra note 1.

³¹ *Information letter 876 (2010)*, International Fragrance Association (IFRA).

³² Art. 8, REACH, supra note 3.

³³ Requirements include registered capital of 300,000RMB and technical staff familiar with new chemical substance notification.

³⁴ Art. 25, Amended Measures, supra note 1.

³⁵ Art 29, Amended Measures, supra note 1.

cancelled before inclusion in the IECSC provided no manufacturing or import activities occurred during this period.

6 Conclusion

With China taking an increasing share of global chemicals production, the amended regulation demonstrates steps are being taken by the Chinese authorities for establishing a better chemical management regulatory framework. The enactment of the Amended Measures represents a significant development in safe management and use of new substances in China.

The reference to national GHS-based standards for hazard communication for new substances demonstrates the active implementation and incorporation of GHS into Chinese chemical regulations. Substances classified as hazardous will come under the control of *Measures for the Administration of Registration of Hazardous Chemicals*, regarded as the most important regulation for GHS implementation. The introduction of low-level notification introduces less resource-intensive notification and shows the encouragement of the scientific and technological use of new substances. The clarification of waiving requirements may reduce unnecessary animal testing as well as reduce costs for industry. However, as data sharing is not mandatory and substances are not immediately added to the inventory following notification, the possibility of repeat animal testing is likely.

Imprint

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The Öko-Institut (Institut für angewandte Ökologie - Institute for Applied Ecology, a registered non-profit-association) was founded in 1977. Its founding was closely connected to the conflict over the building of the nuclear power plant in Wyhl (on the Rhine near the city of Freiburg, the seat of the Institute). The objective of the Institute was and is environmental research independent of government and industry, for the benefit of society. The results of our research are made available of the public.

The institute's mission is to analyse and evaluate current and future environmental problems, to point out risks, and to develop and implement problem-solving strategies and measures. In doing so, the Öko-Institut follows the guiding principle of sustainable development.

The institute's activities are organized in Divisions - Chemistry, Energy & Climate Protection, Genetic Engineering, Sustainable Products & Material Flows, Nuclear Engineering & Plant Safety, and Environmental Law.

The Environmental Law Division of the Öko-Institut:

The Environmental Law Division covers a broad spectrum of environmental law elaborating scientific studies for public and private clients, consulting governments and public authorities, participating in law drafting processes and mediating stakeholder dialogues. Lawyers of the Division work on international, EU and national environmental law, concentrating on waste management, emission control, energy and climate protection, nuclear, aviation and planning law.

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The University of Applied Sciences in Bingen was founded in 1897. It is a practiceorientated academic institution and runs courses in electrical engineering, computer science for engineering, mechanical engineering, business management for engineering, process engineering, biotechnology, agriculture, international agricultural trade and in environmental engineering.

The *Institute for Environmental Studies and Applied Research* (I.E.S.A.R.) was founded in 2003 as an integrated institution of the University of Applied Sciences of Bingen. I.E.S.A.R. carries out applied research projects and advisory services mainly in the areas of environmental law and economy, environmental management and international cooperation for development at the University of Applied Sciences and presents itself as an interdisciplinary institution.

The Institute fulfils its assignments particularly by:

- Undertaking projects in developing countries
- Realization of seminars in the areas of environment and development
- Research for European Institutions
- Advisory service for companies and know-how-transfer

Main areas of research

- **European environmental policy**
 - Research on implementation of European law
 - Effectiveness of legal and economic instruments
 - European governance
- **Environmental advice in developing countries**
 - Advice for legislation and institution development
 - Know-how-transfer
- **Companies and environment**
 - Environmental management
 - Risk management

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The Society for Institutional Analysis was established in 1998. It is located at the University of Applied Sciences in Darmstadt and the University of Göttingen, both Germany.

The sofia research group aims to support regulatory choice at every level of public legislative bodies (EC, national or regional). It also analyses and improves the strategy of public and private organizations.

The sofia team is multidisciplinary: Lawyers and economists are collaborating with engineers as well as social and natural scientists. The theoretical basis is the interdisciplinary behaviour model of homo oeconomicus institutionalis, considering the formal (e.g. laws and contracts) and informal (e.g. rules of fairness) institutional context of individual behaviour.

The areas of research cover

- Product policy/REACH
- Land use strategies
- Role of standardization bodies
- Biodiversity and nature conservation
- Water and energy management
- Electronic public participation
- Economic opportunities deriving from environmental legislation
- Self responsibility

sofia is working on behalf of the

- VolkswagenStiftung
- German Federal Ministry of Education and Research
- Hessian Ministry of Economics
- German Institute for Standardization (DIN)
- German Federal Environmental Agency (UBA)
- German Federal Agency for Nature Conservation (BfN)
- Federal Ministry of Consumer Protection, Food and Agriculture

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sofia



NATUUR
& MILIEU



elni

In many countries lawyers are working on aspects of environmental law, often as part of environmental initiatives and organisations or as legislators. However, they generally have limited contact with other lawyers abroad, in spite of the fact that such contact and communication is vital for the successful and effective implementation of environmental law.

Therefore, a group of lawyers from various countries decided to initiate the Environmental Law Network International (elni) in 1990 to promote international communication and cooperation worldwide. elni is a registered non-profit association under German Law.

elni coordinates a number of different activities in order to facilitate the communication and connections of those interested in environmental law around the world.

Coordinating Bureau

Three organisations currently share the organisational work of the network: Öko-Institut, IESAR at the University of Applied Sciences in Bingen and sofia, the Society for Institutional Analysis, located at the University of Darmstadt. The person of contact is Prof. Dr. Roller at IESAR, Bingen.

elni Review

The elni Review is a bi-annual, English language law review. It publishes articles on environmental law, focusing on European and international environmental law as well as recent developments in the EU Member States. elni encourages its members to submit articles to the elni Review in order to support and further the exchange and sharing of experiences with other members.

The first issue of the elni Review was published in 2001. It replaced the elni Newsletter, which was released in 1995 for the first time.

The elni Review is published by Öko-Institut (the Institute for Applied Ecology), IESAR (the Institute for Environmental Studies and Applied Research, hosted by the University of Applied Sciences in Bingen) and sofia (the Society for Institutional Analysis, located at the University of Darmstadt).

elni Conferences and Fora

elni conferences and fora are a core element of the network. They provide scientific input and the possibility for discussion on a relevant subject of environmental law and policy for international experts. The aim is to gather together scientists, policy makers and young researchers, providing them with the opportunity to exchange views and information as well as to develop new perspectives.

The aim of the elni fora initiative is to bring together, on a convivial basis and in a seminar-sized group, environmental lawyers living or working in the Brussels area, who are interested in sharing and discussing views on specific topics related to environmental law and policies.

Publications series

elni publishes a series of books entitled "Publications of the Environmental Law Network International". Each volume contains papers by various authors on a particular theme in environmental law and in some cases is based on the proceedings of the annual conference.

elni Website: elni.org

The elni website www.elni.org contains news about the network. The members have the opportunity to submit information on interesting events and recent studies on environmental law issues. An index of articles provides an overview of the elni Review publications. Past issues are downloadable online free of charge.

elni Board of Directors

- Martin Führ - Society for Institutional Analysis (sofia), Darmstadt, Germany;
- Jerzy Jendroska - Centrum Prawa Ekologicznego (CPE), Wrocław, Poland;
- Isabelle Larmuseau - Vlaamse Vereniging voor Omgevingsrecht (VVOR), Ghent, Belgium;
- Marga Robesin - Stichting Natuur en Milieu, Utrecht, The Netherlands;
- Gerhard Roller - Institute for Environmental Studies and Applied Research (I.E.S.A.R.), Bingen, Germany.

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