Biocide enforcement in EU

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ISS ITALY

The BPR enforcement in EU

- On 29 September 2016 a Biocidal products Regulation, Biocides, Enforcement, Europe was created
- A biocides subgroup to Echa's Enforcement Forum is now part of the Reach, CLP, enforcement group (Forum).
- The previous Biocide Enforcement group was set up as a transitional working group to kick start member state cooperation on enforcement, until the CAs would agree on how best to harmonise national controls at EU level.
- This group has the duty to:
- fully integrate the previous Biocide Enforcement group into the forum;
- make it a subgroup; or keep it as a separate group, chaired and supported by the European Commission.
- The member states unanimously agreed to settle enforcement activities in a forum subgroup, according to CA meeting
- The BPR group will be fully independent from the part that deals with REACH and CLP. Meetings will be held back to back with the forum plenaries and Echa will provide the secretariat.
- Next, Echa and the European Commission have to discuss the most efficient way to implement the subgroup,

The BPR enforcement in EU

- The Forum coordinates various enforcement projects, one of the main ones being the REACH-EN-FORCE (REF) projects which are designed to harmonise enforcement in each Member State and check the current level of compliance with regard to particular obligations imposed on industry by the REACH, CLP , BPR and PIC regulations.
- The REF-projects are carried out by inspectors based in the national authorities in the participating Member States.
- The resulting information is collected by ECHA and the Forum Working Group. A final report on the findings of the REF-project is then produced. Ultimately, the goal of the REF-projects is to improve the quality of enforcement in the Member States but also to improve the compliance of registrants with the REACH, CLP, BPR and PIC regulations.

Italy Enforcement

- Enforcement in Italy is made at Central (State) level and at regional level.
  - An enforcement body is already in force for general chemicals, mostly for Reach and CLP regulations.
    - Now, additional training for Inspectors has been made also fo Biocides.

National decree issued by Ministry of Health 10.10.2017

Also applicable to products authorized according to transitional period requirements

«Disciplina delle modalità di effettuazione dei controlli sui Biocidi immessi sul mercato, secondo quanto previsto dall'Articolo 65 del Regolamento (UE) N° 528/2012 del Parlamento europeo e del Consiglio del 22 maggio 2012, relativo alla messa a disposizione sul mercato e all'uso dei Biocidi»

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SOMMARIO

Several institutions involved:

- MoH
- ISS
- Regional Inspectorates
- Reach/CLP Enforcement
- Laboratory control

The national decree on control and enforcements is aimed to:

- a. To exercise control over compliance with the conditions of authorization as set forth in art. 19 of the same Regulation;
- b. To ensure the operation of the control system, constituted by administrations and institutions of the State and of the autonomous regions and provinces in the sphere of its institutional activity and without additional burdens on public finances, in order to verify the full implementation of the part of all subjects subject to compliance with the provisions of Regulation (EU) No. 528/2012;

The national decree on control and enforcements is aimed to (cont'd):

- c. To establish and maintain official relations with the EU Com;
- d. To participate in the activities of the «ECHA Forum - Subgroup BPR (BPRS group)» operating in collaboration with the Forum of the European Agency for the exchange of information between national authorities;
- e. To participate in the work of other committees of the European Chemicals Agency, with regard to the aspects of biocidal product controls;

The national decree on control and enforcements is aimed to (cont'ed):

- f. To promote control and surveillance activities on the national territory in order to ensure the correct application of the Regulation;
- g. To adopt intervention plans to encourage the implementation of training programs aimed at businesses, to be carried out in agreement with industry associations, local authorities and other public and private entities with specific competences;
- h. To adopt a plan of initiatives to meet the priority training needs of the public system, to be achieved with the active contribution of all the involved institutional levels and those with specific skills in this regard;

The national decree on control and enforcements is aimed to (cont'd):

- i. To implement, in the framework of controls of medical and surgical offices and of biocidal products, any subsidiary and emergency initiatives aimed at the protection of public health;
- l. To fulfill the information obligations of the European Commission as per art. Article 65 (3) of Regulation (EU) No 528/2012.
- m. To promote professional training in order to define qualification and licensing

In order to:

- to ensure the protection of public health;
- to allow effective control of compliance with the conditions for authorization of biocidal products and the correct and sustainable use of such products;
- to ensure the correct use of biocidal products and the protection of the health of users in any risk scenario foreseen by the authorization of a biocidal product;
- reduce future cases of poisoning and occupational disease related to the use of biocidal products.

Initial activities will focus on:

- National control
- Art 95
- Treated articles
- Illegal trade
- Training and licensing (also accounting sustainable use requirements)
- Still missing decree on penalties/fees in case of infringements

UK Enforcement

- Health anSafety Authority (HSE), local authorities and several other bodies have roles in investigating incidents and carrying out enforcement for the EU Biocides Regulation 528/2012 (EU BPR).
- Local authority trading standards officers enforce the advertisement and sale of biocides, while the use of products is enforced by either HSE inspectors or local authority environmental health officers, depending where the product has been used.
- HSE, as the regulatory authority for biocides, can also assist other enforcing authorities through:
- advice on the legislation, and on how individual products are affected by the legislation;
- details of the approval status of individual products and the conditions that have to be met for each approval;
- copies of the approval documents;
- witness statements for use in prosecutions.

UK Enforcement

- The EU Biocides Regulation 528/2012 (EU BPR) are enforced under National Regulation 8 (1) of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 which defines the application of the Act, including enforcement powers, offences, and the allocation of enforcement responsibilities.
- Enforcement of the use of biocidal products is split between the HSE and local authorities, in-line with the Health and Safety (Enforcing Authority) Regulations 1998 (SI 1998 No 494).

If the incident involves…	It should be reported to…
Advertisement or retail sale of Biocides	Your local trading standards office – which can be found on the Trading Standards Central website
All issues arising from the use of Biocidal products	HSE or your Local Authority. You can find out who is the appropriate enforcing authority from the HSE website

Austria Enforcement

- In Austria enforcement of chemicals legislation is the competence of the State Governors of the nine Federal States acting as indirect federal administration under the supreme authority of the Federal Ministry of Agriculture, Forestry, Environment and Water Management.
- The enforcement authorities and inspectors are located in the State Government Services of the nine Laender. Besides having the competence for REACH, CLP and the export/import Regulation, the competence for enforcement of chemicals legislation comprises also other European legislation for dangerous substances / preparations, detergents, persistent organic pollutants, ozone depleting substances, flourinated gases and biocidal products.

Austria enforcement

- Inspectors have the power to perform investigation on-site at all levels of the supply chain, to force the presentation of information and to take samples.
- In case non-compliance is suspected or detected, an individual inspector as well as the nine enforcement authorities can take measures such as giving warnings, requiring corrective measures or seizing goods. Identified cases of non-compliance are also reported to judicial authorities for sanctioning.
- The nine enforcement authorities conduct regular inspections at relevant companies and perform surveillance of relevant products in the Austrian market. This also includes checking of importers. Common efforts of the enforcement authorities are focused in regular joint enforcement projects.
- Since many years authorities and institutions involved in chemicals enforcement meet regularly in a committee and in ad hoc working groups and conduct common trainings in order to ensure harmonised enforcement of REACH, CLP, BPR and the export/import Regulation based on a joint planning.

Sweden enforcement

- Sweden's chemicals agency Kemi has warned that interpretation of the scope of the treated articles provisions could hinder the next enforcement project under the biocidal products Regulation (BPR).
- This agency has told that member states are still unclear on whether some textiles with biocidal properties should be classed as biocidal products or treated articles.
- This will affect the BPR enforcement project
- The project will cover substances, mixtures or articles that have been treated with, or that incorporate, a biocidal product. It will be carried out in 2019, with a report of the outcomes published in 2020.

Sweden enforcement

- Enforcement authorities are preparing manuals, checklists and training for their inspectors, starting in the next months.
- Sweden's concerns in particular relate to impregnated clothing, bed linen and similar articles for use by people or animals. These are often treated with a biocidal product to protect the user from mosquitoes or bugs.
- This is "an enormous market in the EU" and the enforcement project will affect many companies selling such articles, the agency says.
- "It is important that the member states have consistent views of the interpretation of scope issues affecting treated articles for the project to be effective."

Ireland enforcement

- An authorised officer may at any reasonable time enter any place or premises in which the authorised officer has reasonable grounds for believing that:
- (i) an active substance of a biocidal product is being manufactured, packaged, labelled, placed on the market, stored or used;
- (ii) a biocidal product is being maufactured, packaged, labelled, placed on the market, stored or used;
- (iii) a controlled product is being produced, placed on the market, processed, stored or used;
- (iv) the place or premises is to be treated, is being treated or has been treated with a biocidal product;
- (b) any railway wagon, vehicle, ship, vessel, aircraft, container or other thing in which the authorised officer has reasonable grounds for believing that an active substance of a biocidal product, a biocidal product or a controlled product is being transported, stored or used;
- (c) any premises in which the authorised officer has reasonable grounds for believing that there are any books, documents or records, including electronic records, relating to any business whose activities consist of or include:
- (i) the manufacture, packaging, labelling, placing on the market, storage, transport or use of an active substance of a biocidal product or of a biocidal product, as the case may be;
- (ii) the production, placing on the market, processing, storage, transport or use of any controlled product; and there or at any other place:

- (d) make such examinations, tests and inspections;
- (e) take samples in accordance with internationally accepted sampling procedures of any active substance of a biocidal product or of any biocidal product that the authorised officer finds in the course of the inspection and which the authorised officer believes is or may be an active substance or a biocidal product to which these Regulations apply; and
- of any controlled product, or of any article, commodity, soil, effluent or thing that the authorised officer finds in the course of the inspection and which the authorised officer believes is or may be a controlled product to which these Regulations apply or believes has or may have been contaminated with a biocidal product to which these Regulations apply;
- as the authorised officer considers appropriate and provided the quantity that a sample taken pursuant to this Regulation comprises is reasonable.

Ireland enforcement

- A person who has in any place, on any premises, or in any railway wagon, vehicle, ship, vessel, aircraft, container or other thing, an active substance of a biocidal product, a biocidal product or a controlled product to which these Regulations apply, shall at all reasonable times:
- (a) afford an authorised officer such facilities and assistance as are reasonably necessary for an inspection and for the taking of samples pursuant to this Regulation;
- (b) give an authorised officer any information which he or she may reasonably require regarding the manufacture, purchase, importation, packaging, labelling, storage, transport, sale, supply or use of any such active substance or biocidal product or regarding the production, purchase, importation, processing, transport, storage, sale, supply or use of any controlled product, which is within the person's knowledge or procurement;
- (c) produce to an authorised officer any document or any electronic information relating to the raw materials used in the manufacture of any such active substance or biocidal product or relating to the production of any controlled product which the authorised officer may reasonably require and when produced permit the officer to inspect and take extracts from or make a copy (including an electronic copy) of any such document or to make a copy (including an electronic copy) of any such electronic data.

Ireland enforcement

- Any person who carries on a business involving the manufacture, purchase, importation, packaging, labelling, sale, supply, transport, storage or use of an active substance of a biocidal product or of a biocidal product or involving the production, purchase, importation, processing, sale, supply, transport, storage or use of a controlled product, shall:
- (a) keep records of all transactions relating to any such active substance, biocidal product or controlled product;
- (b) produce at the request of an authorised officer any records, books, other documents or electronic data relating to such business which are in his or her possession or under his or her control;
- (c) permit an authorised officer to inspect and take extracts from or make copies (including electronic copies) of such records, books, other documents or electronic data and give to the authorised officer any information which is within his or her knowledge or under his or her control and which the authorised officer may reasonably require in relation to any entries therein;
- (d) afford to an authorised officer such facilities and assistance as are reasonably necessary for inspecting the stock of any active substance or biocidal product, or of any controlled product on any premises on which such person carries on such a business; and
- (e) give to such an authorised officer any information he or she may reasonably require in relation to such transactions, including, in particular, information which he or she may reasonably require regarding any active substance, biocidal product, or any controlled product specified by him or her.

Ireland enforcement

- Where a sample is taken pursuant to this Regulation, the authorised officer concerned shall:
- (a) either:
- (i) divide the sample into three or more parts, each of which he or she shall seal and mark, or
- (ii) where the procedure specified in subparagraph (i) would or could result in the division of individual units, identify 3 or more units of the batch of material to be sampled, or 3 or more packages or containers containing material from the batch of material to be sampled, as appropriate, each unit, package or container of which shall constitute a part which he or she shall seal and mark;
- (b) give, deliver to, or send by registered post one part thereof to a designated analyst for analysis in accordance ;
- (c) leave with, deliver to, or send by registered post to the defendant or prospective defendant or his or her agent, a second part thereof;
- (d) where there is more than one defendant or prospective defendant, leave with, deliver to, or send by registered post to such defendant or prospective defendant or agent of such defendant or prospective defendant, one or more further parts thereof; and
- (e) leave with, deliver to, or send by registered post to the State Chemist the remaining part thereof for analysis

Ireland enforcement

- 6) (a) In any proceedings for an offence under these Regulations, the result of any test, examination or analysis of, or any report on, a sample taken pursuant to this Regulation shall not be adduced unless, before the proceedings were instituted, one of the parts into which the sample was divided (as required by paragraph (4)) was left with, delivered to, or sent by registered post to the defendant or his or her agent.
- (b) In any proceedings for an offence under these Regulations, evidence of the presence of traces of an active substance of a biocidal product or of a biocidal product to which the Regulations apply, in or on machinery, plant or other equipment capable of use for application of the biocidal product or for treatment of a controlled product with the biocidal product, shall be evidence, until the contrary is proved, of the use of the biocidal product by the owner or person in possession or in charge of the machinery, plant or equipment;
- (c) In any proceedings for an offence under these Regulations, evidence of the presence of a residue of an active substance of a biocidal product or of a biocidal product to which the Regulations apply, in or on a controlled product, article, or any other thing which may have been treated with or exposed to a biocidal product, shall be evidence, until the contrary is proved, of the use of the biocidal product by the owner, occupier or person in

Ireland enforcement

- (d) In any proceedings for an offence under these Regulations, a certificate in the form set out in the Fourth Schedule showing the results of an analysis shall, until the contrary is shown, be sufficient evidence of the facts certified therein in relation to:
- (i) the presence in a biocidal product of any active substance, impurity or formulant, and the level of any such presence;
- (ii) the presence of a residue of a biocidal product and the level of such residue in or on any controlled product, article, commodity, soil, effluent or other thing; and
- a document purporting to be such a certificate shall be deemed, until the contrary is shown, to be such a certificate.
- (e) In any proceedings for an offence under these Regulations, each of the documents referred to in subparagraph (1) (f) may be proved by the production of a copy thereof purporting to have been published in the Official Journal of European Communities, or by the Food and Agriculture Organisation of the United Nations, as

Germany enforcement

- The German government implemented the First Amendment to the German Chemical Penalties Ordinance (Chemikalien-Sanktionsverordnung – ChemSanktionsV) (Federal Gazette I, p. 951) with respect to penalties. Since 23 April 2016, fines can now also be imposed for breaches of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.
- The EU Biocides Regulation, which has essentially applied in Germany directly since 1 September 2013, contains provisions concerning the approval of active substances and authorisation of biocidal products, as well as their classification, labelling and packaging, and supplemental notification, information, communication and documentation obligations.
- Breaches of the directly applicable provisions of the EU Biocides Regulation have to date only been subject to fines to a limited extent, e.g. if companies have breached enforceable orders of competent enforcement authorities. With a new catalogue of penalties included as Section 14 of the German Chemical Penalties Regulation, the option of imposing fines has now also been created for other breaches of the EU Biocides Regulation.

Germany enforcement

- The total of 21 fineable offences not only cover the requirements relating to the making available of biocidal products on the market and their use, but also for the first time the provisions for treated articles, i.e. for products which are not themselves to be classified as biocidal products, but which have been treated with, or intentionally incorporate, one or more biocidal products.
- Although no separate criminal offences have been anchored in the Chemical Penalties Regulation with respect to the EU Biocides Regulation, unlike the penalties imposed on breaches of Regulation (EC) No 1907/2006 (REACH), heavy fines can result for the companies affected from the catalogue of penalties which has now been created.
- Penalties for intentional or negligent breaches of the EU Biocides Regulation can be up to EUR 50,000.00 in individual cases (Section 14 Chemical Penalties Regulation in conjunction with Section 26 (1) No. 11 (2) German Chemical Act (Chemikaliengesetz – ChemG)).
- In light of these supplementary penalty provisions, companies affected should on their part ensure that any gaps in product compliance for biocidal products and treated articles are promptly closed.

Hungary enforcement

- The authorities primarily responsible for the enforcement of REACH/CLP/BPR in Hungary are the Public Health Departments of the District Offices, gathered under twenty County based Government Offices which are reporting to the Prime Minister's Office.
- The work of the chemical safety inspectors is coordinated at regional level and supported by the Hungarian REACH, CLP and Biocides National Competent Authorities operating within the Ministry of Human Capacities (EMMI).
- The company visits may take the form of both spot and targeted checks. In case of non-compliance the inspectors take a binding decision and/or impose a fine (chemical load penalty) on the companies concerned.
- It is foreseen that other authorities will also be responsible for other aspects of the chemical regulations, such as environmental protection (National Inspectorate for Environment, Nature and Water), occupational safety (Hungarian Labour Inspectorate), consumer protection (National Authority for Consumer Protection) and customs control (Hungarian Customs and Finance Guard).

Hungary enforcement

- Authorities responsible for REACH/CLP/BPR enforcement
- National Institute of Chemical Safety (OKBI) - Useful information materials and the text of the national enforcement legislation are available on the OKBI website.
- Hungarian National Public Health and Medical Officer Service (ÁNTSZ) - This body is responsible for the professional management of enforcement of the REACH, CLP and BP Regulations.
- Joint website of the Governmental Offices

Spain enforcement

- In Spain, the Competent Authority (CA) for Biocides Regulation is the the Ministry of Health, Social Services and Equality and acts as the Point of contact between Autonomous Communities Authorities, the European Commission and other European BPR competent authorities. The BPR enforcement authorities (EA) are the "Autonomous Communities". They conduct regular projects on monitoring, control and sanctions tasks in Spanish market.
- It has established a Rapid System on Information Exchange on Chemicals (SIRIPQ), which allows regional inspectors (EA) and the Competent Authority (CA) to exchange information.
- In Spain, the BPR Enforcement is under the responsibility of the individual Autonomous Communities Authorities (EA) (17), but to facilitate and centralise communication with the relevant EA, we provide below the link to the central BPR Competent Authority:

- The Ministry of Health, Social Services, and Equality - BPR Competent Authority responsible for the coordination of human health related Spanish enforcement authorities.

Belgium enforcement

- Belgium has an enforcement structure composed of several federal and regional authorities acting on their own competency. Direct surveillance of compliance and law enforcement is executed by inspection services and legal authorities while indirect enforcement of compliance is executed by permitting authorities.
- Inspection services: organise proactive inspection campaigns and report on non-compliance to the public prosecutor or to an administrative legal authority which can then be followed by legal proceedings, leading eventually to criminal or administrative penalties; sanctions can be imposed to force compliance
- Permitting authorities: these regional authorities can refuse a demand for an operating license or impose special conditions

Belgium enforcement

- Inspectors, when conducting control visits have the power, for example, to force the presentation of information and take samples. When non-compliance is suspected or detected, they can take measures such as giving recommendations or warnings, reporting to judicial authorities, seizing goods, stopping activities, banning imports.
- In principle, all the recommendations of ECHA's Forum with regard to harmonized campaigns throughout the EEA are followed in Belgium.
- Enforcement authorities, including Customs, liaise via a national forum to maximize the useful effect of enforcement initiatives while minimizing the efforts required from public authorities and from legal persons.
- Authorities responsible for Biocides enforcement
- Environment and Federal Inspection