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Verifying the Efficacy of Biocidal Products and Treated Articles

- a comparative study of regulatory techniques

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Verifying the Efficacy of Biocidal Products and Treated articles

- a comparative study of regulatory techniques

by Per Bergman

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Summary

Efficacy of a product such as a pesticide means that the use of the product leads to a desired positive effect. The report analyses the efficacy requirements in the new EU Biocidal Products Regulation as regards active substances, biocidal products and treated articles. The rules about treated articles are new in the European legislation and are therefore of particular interest. A comparison is made with regulations and practices in the USA relating to the efficacy of biocidal products, covering treated articles in particular.

Efficacy requirements in legislation regulating other types of products are described in the report and a large number of extensive guidance documents are identified and discussed. Such efficacy requirements may be similar to rules about biocidal products, as in the regulation of plant protection products. Product regulations that require verification of efficacy also exist for medicinal products for human and veterinary use, medical devices, food and feed and cosmetics. These efficacy requirements are briefly described and discussed in the report. The requirements can be extremely detailed and demanding and include specified data requirements. Medicinal products are one example. For other products the demands are more general, such as cosmetics. Efficacy is always assessed on the basis of the claims made about what the product is capable of. In the food legislation all health claims are individually assessed by an expert authority on the basis of general principles for scientific assessment. The different regulations generally include requirements that efficacy evaluation must be based on adequate and verifiable data and be based on scientific principles.

The sector legislation is complemented by legislation with a general scope about misleading advertising or unfair commercial practises. This legislation regulates how traders (manufacturers, sellers, etc.) present their products to consumers in commercial messages such as advertising. There is an EU directive on the subject, which is implemented in national law by the member states. According to this legislation, the trader making a claim for a product is responsible for the claim being correct and has to be able to substantiate it. How the claims have to be verified is not regulated in detail in the legislation. Claims about efficacy (such as the efficacy of a biocidal product) can be seen as environmental claims, however, and there are general ISO standards for environmental claims that can guide the application of the legislation. The requirements for verification in this legislation are strict in practise, in particular for claims about health or environmental effects, which are very difficult to assess by an average consumer. It is concluded in the report that the new EU rules about biocidal product do not contain specific data requirements regarding the efficacy of treated articles similar to the requirements for biocidal products. Such requirements for verification of efficacy claims regarding treated articles could instead be based on the legislation about unfair commercial practises.

The report finally discusses some issues where further guidance would be useful when applying the legislation about biocidal products. The borderlines between sector legislations are often unclear and the application may need additional guidance on this subject. The term “primary biocidal function” in the new EU Regulation is important but seems difficult to understand and apply.

As regards the efficacy of articles treated with biocidal products it would be very helpful if guidance was developed that clarifies and compares the obligations of both the EU Regulation about biocidal products and the legislation about unfair commercial practices. In particular it

would be important to identify which efficacy data that would be needed for treated articles in addition to data already provided when the active substance used in the article was approved.

1. Objective

The EU regulations relating to biocidal products have recently been renewed. The new Regulation No 528/2012/EU incorporates existing rules about the authorization of biocidal products but also includes a number of innovations, e.g. provisions relating to the marketing of articles treated by biocidal products.

One requirement in the biocides regulation is that the efficacy of the product has to be demonstrated when applying for approval. It has to be shown that the product really has the intended effect on the harmful organism. How such a requirement will affect the marketing of articles treated with biocides is an interesting question that is discussed in this report.

The new rules will require that new guidance and practices are developed. Furthermore, the sustainable use of biocides will be reviewed and subject to a report by the Commission in 2015. This study aims at giving an overview of different types of efficacy requirements in the biocidal rules but also and in other types of neighbouring regulations, in particular as regards the verification of claims relating to positive health effects.

The report includes:

- an analysis of the efficacy requirements in the new biocides regulation as regards active substances, biocidal products and treated articles
- information on regulations and practices in the USA relating to the efficacy of biocidal products, covering treated articles in particular
- efficacy requirements in similar types of legislation (e.g. plant protection products) and other related legislation such as food and feed, cosmetics and medicinal products for human and veterinary use (when relevant)
- limitations as regards misleading efficacy claims in advertising, in general legislation as well as in legal acts for specific products types
- summary and conclusions about elements in legislation that are necessary for the verification of efficacy claims

The report covers legislation (including case-law) as well as general guidance and documented practices. It does not cover technical and/or science issues in any detail. Focus is on EU law but also on national legislation to the extent necessary (regulations about commercial practises) and US legislation in some cases.

The report is input to a Nordic project aiming at a strategy to reduce unnecessary use of antibacterial substances in articles. Biocidal products may have many different uses. The target organisms may be different (microorganisms, vertebrates) and the uses may differ. Some biocides are intended to protect a product against contamination or deterioration. Others are intended to repel or have an antimicrobial effect. The report focuses on biocides that target micro-organisms, in particular when an external health effect is claimed by the product.

Another focus of the report is the new European regulation of treated articles with biocidal claims.

2. Introduction

2.1. Biocides and other rules

Biocidal products are pesticides that are used to control harmful organisms so that they do not damage products or creates health or environmental risks. In addition to rules about biocides, there exist a large number of separate regulations in the EU to control products that have effects which in some ways are health related. It has not been possible to cover all these regulations in detail in the report.

The report gives an overview in Chapter 3 and 4 of the rules about biocidal products in the EU and USA, with emphasis on efficacy requirements and requirements for treated articles. Chapter 5 gives an overview of efficacy requirements in other sector legislation, while Chapter 7 deals with general rules about unfair commercial practises and their application for efficacy claims. Chapter 8 contains some general conclusions. Each major chapter ends with a section that summarises the most important points.

2.2. Efficacy, effectiveness and efficiency

The purpose of this study is to compare different types of legislation as regards requirements to verify claims that products placed on the market have certain positive effects, normally health related. The study is part of a Nordic co-operation project to develop strategies regarding the use of anti-bacterial substances in treated articles. The study therefore takes the European legislation about biocidal products as a starting point, in particular the new rules in that legislation about treated articles.

Different words are often used in different legal texts to express that something can produce a positive or desired effect. According to the New Oxford American Dictionary, *efficacy* and the adjective *efficacious* should be used when something produces the desired result, e.g. requirements are met for a specific result of a test. *Effectiveness* and *effective* are used when something produces a definite effect or result, while *efficiency* and *efficient* means that something is achieved skilfully or with an economic use of resources. In legislation about medicinal products efficacy means that the desired effect is achieved in a controlled situation, such as a clinical trial, while effectiveness relates to how the product functions in a real-world situation that is not tightly controlled[1]. Effectiveness is used in the legislation about biocides as being the same thing as efficacy (introduction to Annex VI in the new biocides regulation). Efficacy seems to be the term used more commonly today in practice. Both terms will be used here without making clear distinctions between the two in most cases.

The study is focused on efficacy requirements and how they relate to product claims. Any developed legislation in this area will, however, include rules to ensure that the product can be used without risks to health or the environment. It may even be the case that the same

[1] Refers mainly to US practises.

immediate benefit, such as an antibacterial effect of a disinfectant, may lead to a long-term negative effect in the form of resistance development in the organism[2]. This may lower the efficacy of the product but also result in more general health concerns.

Efficacy requirements can therefore not be studied in isolation. The specific rules may require that a product is shown to be efficacious, but the use (including recommended dosage to ensure efficacy) must not lead to unacceptable health or environment risks.

3. Biocidal Products Regulation

The EU rules about biocidal products (or biocides) are found in the Regulation (EU) No 528/2012 (referred to in the following as the Biocides Regulation or BPR), which replaces the earlier EU Directive 98/8/EC[3]. This chapter gives a short overview of the Regulation and discusses the efficacy requirements in it. These requirements are very brief but they are complemented by guidance documents that were produced mainly for the application of Directive 98/8/EC. This guidance will still be important until specific guidance for the new regulation has been developed. Guidance produced by the OECD is also important in this area. Guidance documents are not legally binding. To the extent that they are followed by authorities, however, they often function in practice as if they were. They are often very important when interpreting the legal text regarding technical or scientific aspects in particular.

3.1. What is a biocidal product?

Biocidal products are pesticides with a wide range of uses. They have to be authorised according to EU rules before they are used[4]. They may only contain active substances that have been approved and the authorisation is only valid for a particular product type. There are 22 product types in three main groups (disinfectants, preservatives and pest control). The list of product types (Annex V BPR) with their descriptions is in fact an important part of the definition of what constitutes a biocidal product.

Different rules and obligations relating to efficacy assessment apply according to BRP for active substances, biocidal products and articles treated by biocidal products. It is therefore essential to understand these terms and to identify the dividing lines between them.

A biocidal product is defined in Article 3.1 (a) first indent BPR as

"- any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,".

[2] Cf. the report from the EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR): Assessment of the Antibiotic Resistance Effects of Biocides, 2009, available at http://ec.europa.eu/health/ph_risk/risk_en.htm

[3] The regulation has been amended by regulations 736/2013 and 334/2014.

[4] There is a long transitional period before all the EU rules become fully applicable (Article 89-95 BPR). During this time national regulations about authorisation etc. may still be applied. This report only covers the EU rules.

Substances or mixtures that function as biocides and are generated from substances and mixtures that do not fall under the biocides definition are also seen as biocides according to the second indent.

The definition of biocidal product includes the words "substance" and "mixture", which are not defined. Instead the definitions in the chemicals legislation (Reach) are referred to (Article 3.2 BPR)[5].

This definition would also work well for many other types of products with similar purposes, such as some medicinal products, preservatives in food and feed and agricultural pesticides. These products have their own regulations, however, and are therefore excluded from the BPR (Article 2.2). Excluded from BPR are the following products:

- Animal feed and medicated feedingstuffs
- Medical devices including diagnostic and active implantable devices
- Human and veterinary medicinal products
- Food additives and additives for use in animal nutrition
- Food ingredients and flavourings
- Cosmetic products
- Plant protection products
- Toys

Since the product definitions in the different regulations often overlap, defining which regulation is applicable and the exact borderline between different products has often been difficult. Extensive guidance documents exist to assist with this[6]. If a potential biocidal product falls under the definition of one of these products, for example as a medicinal product, the BPR is generally not applicable. If the product is also intended to be used for a purpose not covered by the other regulation, however, the BPR will still apply for that use. Products may therefore exist that need double authorisations, according both to BPR and to another legislation. The definition of a biocidal product include words ("..supplied...with the intention of..") that make the claims made about the product's function essential when determining whether it is a biocidal product[7].

3.2. Active substances, biocidal products and treated articles

The biocidal effect of a biocidal product is achieved by one or more active substances in the product. An *active substance* is "a substance or a micro-organism that has an action on or against harmful organisms" (Article 3(1)(c) BPR). Active substances are approved for one or

[5] The use of the word "substance" is not really consistent with Reach since a substance in a biocidal product according to BPR can include an active substance that is a micro-organism (the use of animals such as arthropods or nematodes as active substances in pesticides is not covered by BPR).

[6] Cf. Manual of Decisions for Implementation of Directive 98/8/EC Concerning the Placing on the Market of Biocidal Products and additional guidance mentioned in the list of references. The manual refers to older rules and may not be fully applicable to the new BPR.

[7] A biocidal product is in practice something that is claimed to have a biocidal effect. The EU Court has found that blocks of natural untreated cedar wood that were sold with claims of having anti-moth properties should be considered biocidal products (Case C-443/02).

more product types. To obtain an approval, data have to be provided about toxicological and ecotoxicological properties. Environmental and health risk assessments including exposure and efficacy assessments have to be included (Article 8 and Annex II BPR). A dossier satisfying the requirements for one representative biocidal product also has to be provided for the substance to be approved.

A biocidal product is something that is "supplied to the user" or "made available on the market" (Article 17.1 BPR). If a substance or mixture with a biocidal function is incorporated into something that has another function, such an object is called a *treated article* (Article 3.1 (i) BPR). This article can be a substance or a mixture (e.g. a paint) but also a more solid object (e.g. a piece of clothing). The word "article" in "treated article" is therefore really wider in meaning than an article in the chemicals legislation, where the term does not include chemical substances or mixtures.

The text also makes it clear that a treated article that "has a primary biocidal function" always shall be considered a biocidal product and subjected to the strict requirements applying for these products. It is only when the biocidal function is secondary to the main function that the object is seen as a treated article[8].

The new rules in BPR about treated articles are of particular importance for articles imported into the EU, since the biocidal products in such articles or their active substances have not been subject to authorization or approval earlier in the EU before the coming into force of the BPR. The rules are discussed further in section 3.4.

3.3. "Sufficiently effective" biocidal products and the importance of claims

Efficacy has to be shown when applying for authorization of a biocidal product. Some efficacy data also have to be provided for approval of an active substance[9]. There is no obligation in the BPR to provide efficacy data when marketing a treated article (see the following section).

A condition for authorization of a biocidal product is that it is "sufficiently effective" (Article 19.1(b)(i) BPR). Data from tests showing the efficacy against the target organism must be provided both for approval of active substances (Annex II BPR) and for authorization for biocidal products (Annex III BPR). What "sufficiently" means is not defined in Article 19, but becomes clearer in the annexes. A product must have a function that corresponds to the description of the product type in Annex V. When the product is assessed as regards efficacy, a comparison should be made with a suitable reference product or other means of control should be applied (Annex VI p. 77 BPR). Trials must include untreated controls and involve lower dose rates than the recommended rates (for assessing that the recommended rates are

[8] "Primary biocidal function" is not defined in the legal text and may be a difficult criterion to apply. According to the Commission the function has to be of "first rank, importance or value compared to the other functions of the treated article". The Commission has been given the mandate to take decisions in order to clarify the interpretation for particular products or product groups (Article 3.3). Cf. "Frequently asked questions on treated articles".

[9] Cf. the somewhat contradictory ECHA guidance on information requirements, point 2.6: "Active substance approval requires only a minimal efficacy assessment, sufficient to show an innate level of activity for the active substance. At the same time, information on the effectiveness and intended uses of the active substance must be sufficient to permit an evaluation of the representative biocidal product and to define its conditions of use."

correct and not too high). One consequence of these rules seems to be that a product must not be substantially less efficient that other similar products in order to be authorised.

Data requirements and proposed test methods are described in guidance. Guidance documents are being developed for the new BPR, but mostly documents produced for the old Biocides Directive are still in use. This is complemented by guidance documents produced by the OECD[10]. Standardized test methods for the efficacy of biocidal products are available for most of the product types in Annex V, but there are still some gaps and the guidance is not complete[11]. This means that the applicant in some cases will have to design a testing procedure that can be used to show efficacy and that is acceptable to the authorities. General requirements for testing procedures are described in the guidance that complements the Annexes in BPR.

The guidance documents about efficacy data for biocidal products include references to standardized testing protocols when available. It has not been possible to go through all these protocols for this report. However, some general principles seem to apply in the area:

- Trials must involve untreated controls and cover different dose rates
- Trials should include a reference product when available
- The test method must be relevant in relation to the label claims
- Testing must be based on sound scientific principles and practices and result in quantitative efficacy data
- A tiered approach for testing is necessary, which includes basic testing for proof of principle (Tier 1), laboratory simulation related to the specific application and label claims (Tier 2) and field testing (Tier 3)
- Human health risks have to be assessed before Tier 3 testing is done

In practice there seems to be some flexibility when applying this type of principles, in particular as regards the need for Tier 3 data.

The claims made about what the biocidal product will do are thus extremely important and govern which efficacy data that will be required for authorization. The claims must be provided when applying for authorization and are then reformulated as conditions and particulars in the authorization decision (Article 22 BPR). These conditions and particulars are then reflected in the labelling (Article 69 BPR) or in other written material that accompanies the product.

Finally, a number of provisions are intended to ensure that information that is incorrect or too vague is not given to users in the product information (labelling, instruction leaflets, etc.). Words like “harmless”, “natural” or “environment friendly” etc. are not allowed in labelling or advertising. Advertising must not be misleading regarding risks or adverse effects or efficacy (Article 72(3) BPR). Limits on advertising and product information are discussed further below (Chapter 7).

[10] For existing guidance documents and reports about test methods, see the list of references.

[11] An overview of available test methods is given in “Efficacy testing of biocidal products”, KEMI 2012. For available guidance documents that include standards for the testing of different types of biocidal products, see ECHA’s guidance on information requirements, section 6.7.

If the biocidal product is intended to be used in a treated article and claims are made in this respect, efficacy data have to be provided to support the claims[12]. Biocides are often used as preservatives to protect articles from deterioration, for example wood preservatives and products that limit odours or growth of micro-organisms and mould on materials. Biocidal products can also be used in articles to achieve an external effect and introduce new functions in the material. An example is when claims are made about hygienic benefits and that an article or material has antimicrobial properties, so that micro-organisms are killed on humans or animals that come into contact with the material. Efficacy testing regarding external effects is more difficult to perform and standardized test methods are not always available[13]. OECD has produced some guidance in "Guidance document on the evaluation of the efficacy of antimicrobial treated articles with claims for external effects". Specific guidance exist in "Quantitative Method for Evaluating Antibacterial Activity of Porous and non-Porous Antibacterial Treated Materials". This latter guidance is not complete, however, and only covers Tier 1 tests.

3.4. Requirements for treated articles

Before the new EU legislation on biocidal products came into force, the old biocides directive was sometimes applied to treated articles that were accompanied by biocidal claims, even though it could be questioned whether the legislation really covered such articles[14]. According to this earlier practice treated articles with claims to have external effects were seen as biocidal products (one example mentioned is mosquito nets treated with insect repellents). An article that was treated with a biocidal product to protect the article itself was not considered to be covered by the biocides legislation.

The issue of treated articles has been clarified in the new regulation. A number of requirements have been introduced for such articles. These requirements apply when the biocidal property is claimed as secondary purpose for the article (an article is seen as a biocidal product if the biocidal function is primary, see above).

The most important requirement is that treated articles may not be placed on the market unless all active substances contained in biocidal products that the article was treated with or incorporates have been approved in the EU for the relevant product type and use and are placed on the list of approved substances or listed in Annex I as substances requiring simplified authorisation procedure (Article 58.2). This requirement is limited as compared to what is required for authorization of a biocidal product, since it does not mean that the biocidal product which was used to treat the article has necessarily been authorized or risk assessed when used in the article. In particular, no assessment of the efficacy of the biocidal treatment is required (approval of an active substance only involves efficacy assessment for one reference biocidal product). If the EU approval of the active substance contains restrictions that apply to treated articles, such restrictions must be adhered to, however.

The words "relevant use" is obviously important in Article 58.2. If the use in a treated article is not covered by the "relevant use" for which the active substance is approved (in addition to

[12] Cf. Annex III p. 6.5-6.7 BPR.

[13] See also Askew, Efficacy Assessment of Treated Articles.

[14] See "Manual of Decisions for Implementation of Directive 98/8/EC Concerning the Placing on the Market of Biocidal Products", Section 3.

being the same product type), the article is not allowed on the EU market. According to the Commission's FAQ for treated articles, a limitation in an approval for particular uses for an active substance is possible for certain product types such as wood preservatives. For other product types such limitations may not exist, but the approval of an active substance could include restrictions for uses in certain article categories[15]. For example, an active substance may be allowed in biocidal products used for treating textile materials, but not for treating textiles in clothes.

The second requirement for treated articles is that they under certain conditions have to be labelled (Article 58.3). Labelling is required if the manufacturer of the article makes a claim about biocidal properties. Responsible for labelling is the person who places the article on the market. Conditions in the approval of the active substance involved may also lead to that labelling is required. In addition, a consumer has the right to information within 45 days, free of charge, about the biocidal treatment of the article (Article 58.4), even if labelling is not required. All suppliers are obliged to provide this information, not just the person who places the article on the market.

The label shall include a statement that the article incorporates biocidal products, the active substances contained in the product (including nano-materials) and relevant instructions about precautions. In addition the label shall include "where substantiated, the biocidal properties attributed to the treated article".

The new rules about treated articles have been in force a very short time. They seem difficult to interpret in some respects. Such difficulties may influence how effective they will be in application. Some helpful interpretations are given in a guidance note mentioned above that has been published by the Commission.

The rules in Article 58.2 apply for treated articles, meaning that the article has been treated with or intentionally incorporates a biocidal product and that the biocidal function is not the primary function of the article. The ban on the placing on the market of articles with non-approved active substances applies regardless of whether the person placing the article on the market in the EU makes a biocidal claim regarding the article or not. However, it may clearly be very difficult to ascertain whether an imported article to the EU has been treated with the purpose of achieving a biocidal effect unless a specific biocidal claim is made.

The labelling requirements in Article 58.3 state that information is required about the biocidal properties of the article "where substantiated". According to the FAQ published by the Commission, this means that the label shall not provide information on the biocidal property of a treated article unless the claim can be supported through appropriate data. Such substantiation is even more important in cases where an (external) biocidal function is claimed. A reference is made in the FAQ to rules about unfair commercial practises.

This labelling obligation in Article 58.3 cannot be interpreted as a new obligation introduced by the BPR to produce data in order to substantiate a claim for a biocidal effect of the article, additional to information and data that are already required for the approval for the active substance involved. Such a new obligation would have to be more clearly expressed in the legal text. The words "where substantiated" is translated slightly differently in different

[15] Note for guidance: Frequently asked questions on treated articles, European Commission September 2013, point 22.

language versions. If one looks at the Danish version, for example, it seems clear that the purpose is not to introduce a new obligation to show efficacy: "hvis der foreligger documentation herfor". However, this does not mean that there is no obligation to show that a treated article is efficacious. As pointed out by the Commission, the wording can be seen as a reference to general principles about the unacceptability of unsubstantiated product claims in rules about misleading advertising and unfair commercial practises. These rules include strict demands about the substantiation of claims, in particular environmental and health claims. The requirements in the two legal frameworks have to be read together, which leads to a conclusion that efficacy data have to be provided or at least be available not just for active substances and biocidal products, but also for treated articles. This question is further discussed in Chapter 7.

According to the Commission's FAQ, it is particularly important that claims are not misleading or exaggerating when the claim has public health relevance (such as a claimed action against pathogenic organisms). In such cases the biocidal action may be considered to take higher rank than other, non-biocidal functions according to the Commission. The article would then have a primary biocidal function and be seen a biocidal product rather than a treated article, with the corresponding requirements to verify efficacy and assess risks etc. This conclusion seems far-reaching and is questioned by one Member State (UK). It would in any case be helpful if guidance was developed which could clarify with examples the dividing line between biocidal products and treated articles. It is also foreseen that additional implementing legislation may be needed for the rules about treated articles (Article 58.7).

It should finally be noted that the specific rules in the BPR intended to limit misleading claims on the label or in advertising for biocidal products do not apply for treated articles (Articles 69 and 72).

3.5. Summary

- Biocides are pesticides that are placed on the market with claims of having an effect against harmful organisms through a chemical or biological action. They are regulated in the EU by the Biocidal Products Regulation (BPR). If a product falls under the definition of certain other regulated products (medicinal products, food and feed, cosmetics etc.), the BPR is generally not applicable. Pesticides used in agriculture (plant protection products) are also excluded.
- Biocidal products need an EU authorisation and can only contain active substances that have been approved for the relevant product type. Articles treated with biocidal products do not need authorisation, but they are only allowed if they use active substances that have been approved for the relevant product type and use. If the article's primary function is biocidal, however, it is seen as a biocidal product that needs authorisation.
- For authorisation of a biocidal product data has to be provided about health or environmental risks. It must also be shown that the product is efficacious and has the biocidal effects which are claimed. For an active substance to be approved, data has to be provided for one representative biocidal product that uses the active substance. This requirement includes efficacy data.

- Articles treated with biocidal products that are allowed on the EU market have to be labelled, if claims are made about biocidal properties or labelling is required in the approval for the active substance. The label must inform about any biocidal properties, where substantiated. This provision should not be seen as a new obligation in the Regulation to provide new data on biocidal efficacy, but rather as a reference to other legislation that forbids misleading claims in commercial messages such as advertising.
- BPR contains some special provisions about the labelling of biocidal products and about advertising. These provisions do not apply to treated articles.
- Data about a biocidal product's efficacy have to be based on sound scientific principles and practises and result in quantitative efficacy data. Standardised testing procedures may exist for some product types but are not generally available. Treated articles may be particularly difficult to assess regarding efficacy. General principles for testing are discussed in EU guidance and in guidance documents developed by the OECD.

4. Registration requirements for biocidal products in the USA

4.1. Background

Pesticide registration in the USA is governed by federal rules in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) which is complemented by rules laid down by the EPA (CFR Title 40, Part 152, "Pesticide registration and classification procedures", also parts 153-162). The registration requirement applies to pesticide products in the form sold on the market (section 152.15). Additional rules may be issued at state level.

A pesticide product is registered (registration is approved) if a number of conditions are fulfilled (Section 3 FIFRA):

"(A) its composition is such as to warrant the proposed claims for it;
(B) its labelling and other material required to be submitted comply with the requirements of this Act;
(C) it will perform its intended function without unreasonable adverse effects on the environment; and
(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

A number of products are exempted from registration because they are covered by other legislation. Examples are chemical sterilants, human or animal drugs or animal feed (section 152.6, 152.20). Further exemptions apply for some products that are not excluded by EU rules, such as embalming fluids and natural cedar (section 152.25). Minimum risk pesticides are also excluded. These must contain active substances that are listed (some essential oils etc.).

For a product to be registered, data have to be provided about the product, about toxicological and ecotoxicological properties and about efficacy. Data requirements are complemented by testing guidance issued by the Office of Chemical Safety and Pollution Prevention (OCSPP).

Guidance for efficacy testing is found in "OPPTS Series 810 - Product Performance Test Guidelines". Efficacy data only need to be submitted as part of a registration, however, if the product has public health claims, as explained by the EPA:

"The Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pests that may pose a threat to human health. Data for termiticides are required because the user cannot determine if they have performed their intended function. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices." (OPPTS 810.1000).

Such a waiving of data requirements is not part of the EU system.

4.2. Treated articles

Articles treated with pesticides have to be registered, but with the following important exemption:
"(a) Treated articles or substances. An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use."

Articles or substances falling under this definition do not need to be registered. The registration requirement for pesticide products in the form of treated articles thus only applies for articles claimed to have an external pesticide effect. Guidance for this exemption has been developed by the EPA (Pesticide Registration (PR) Registration notice 2000-1). According to the guidance, claims about mildew or mould resistance are acceptable when applying the exemption, as are odour-resistant claims. General claims about anti-microbial effects (e.g. "Antibacterial") are not accepted. Neither may the claims state that human pathogens are affected (e.g. "Effective against E. coli and Staphylococcus") or expressly claim external effects ("Provides a germ-resistant surface"). The exemption does not apply to sterilants, disinfectants, virucides or sanitizers. The guidance includes a list of other examples.

If such a health claim about an external effect is made for the treated article, it has to be registered as a pesticide product and acceptable data have to be submitted that supports the claim.

Protocols for the development of supporting data had not been established when this guidance was published. The EPA made clear, however, that testing must reflect actual use conditions and that test protocols had to be independently validated for accuracy and reproducibility. Antimicrobial treated articles would have to live up to the same efficacy performance standards that applied for corresponding antimicrobial public health products.

An important condition for the exemption is that the pesticide in the treated article is registered for such use. This condition is interpreted very strictly in the guidance:

"To qualify under the "treated articles exemption" (assuming the article or substance otherwise qualifies), it is not sufficient that the antimicrobial pesticidal substance in the treated article merely resemble or have activity like a registered pesticide. The antimicrobial pesticide in the treated article or substance must be present in the article or substance solely as the result of incorporating an antimicrobial pesticide which is registered for treating the specific article or substance."

The requirement that the pesticide has to be registered for treating the specific treated article or substance means that a description of general use patterns is not accepted when the pesticide is registered, such as "the preservation of hard surfaces, plastics, adhesives or coatings". Uses have to be described in more detail (examples given are toys, kitchen accessories and clothing articles).

4.3. Efficacy data requirements

The development of efficacy data is regulated by a substantial number of rules and guidance documents. In addition to the rules issued by the EPA (40 CFR part 58) there is the guidance issued by OCSPP (OPPTS 810.1000 - 810.3700) which deals with antimicrobial efficacy and invertebrate control agent product performance. For antimicrobial pesticides further guidance can be found in the guidance documents DIS-TTS 01-19[16], which describe i.a. efficacy requirements for different products for which health claims are made.

4.4. Summary

- Regulations about biocidal products in USA are similar to the ones that apply in the EU. Pesticide products need to be approved on federal level, and data have to be provided about toxicological/ecotoxicological properties and about efficacy.
- Efficacy data only have to be provided to the EPA if human health claims are made for the product, but the manufacturer has to be ready in any case to provide data about efficacy on demand. Data intended to verify efficacy must strictly relate to any claims made about the function of the product. Vague and misleading claims are not allowed.
- Treated articles need to be registered as pesticides if the biocidal effect is external and not just intended to protect the article itself. Data then has to be provided about efficacy as for any other pesticide. The exemption for articles that have been treated to protect the article itself only applies if the pesticide product used in the article has been registered for treating the specific treated article or substance. The use in the article in question must have been foreseen in the registration of the biocidal product.
- The USA regulation is thus stricter than the EU rules in some respects. Treated articles with external effects are treated as pesticides and subject to full authorisation requirements, while the EU rules only require that the active substance has been approved for the same product type and use. The US rules also seem more stringent in their demands for clear and unambiguous claims. On the other hand, there are far-reaching exemptions for pesticides without health claims and for treated articles without external pesticide effects.
- Data requirements for efficacy in the USA are similar to those in the EU, but the guidance documents are more detailed and extensive. Guidance on data requirements produced by the OECD is important both for USA and EU.

[16] Available at EPA home/pesticides/Science and Policy/Policy and guidance/Antimicrobial Science Policies

5. Other legislation with efficacy requirements

This chapter discusses some examples of regulations other than BPR which deal with chemicals/products that are claimed to have certain effects because of their chemical/antimicrobial content. The number of different regulations at EU level is very large, and this report cannot cover all of them in detail but is limited to rules that have similarities to the rules about biocidal products/treated articles and that deal with similar products. Products that function as biocides, in particular those with antimicrobial effects can fall under different rules, and the demarcation lines between the different regulatory frameworks are not always easy to identify.

5.1. Plant protection products

5.1.1. Overview

Plant protection products (PPPs) are products that are mainly used in agriculture and horticulture to protect plants from pests or to influence the development of plants in other ways. In the EU such pesticides are subject to a new PPP regulation[17]. The regulatory technique is very similar to the one used for biocidal products. The active substances have to be approved at EU level (this will in the future also apply to safeners and synergists). PPPs using these substances then have to be authorised at national level. The use of PPPs is affected by different climate conditions etc. in different parts of Europe. Therefore the authorisation procedure may be limited to one of three zones (North, Centre and South) and different conditions for use of a product may apply in each zone and also in the individual countries.

When the PPP Regulation is applied to plant products that are used as food or feed, the rules are complemented by a regulation that sets the maximum residue values that are allowed in food or feed. PPPs may only be authorised for use if such residue limits have been set[18].

PPPs are defined in the following way (Article 2.1 in the Regulation):

"..... products, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for one of the following uses:

(a) protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products;

(b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient;

(c) preserving plant products, in so far as such substances or products are not subject to special Community provisions on preservatives;

(d) destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants;

(e) checking or preventing undesired growth of plants, except algae unless the products are applied on soil or water to protect plants."

[17] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

[18] See the Regulation (EC) No 396/2005 and Article 29.1 in the PPP Regulation.

The rules about biocidal products are not applicable for products that fall under the scope of this definition (section 3.1 above). Identical products can have different uses, however, and the product claims are therefore important when identifying which legislation is applicable. Rodenticides, for example, can be PPPs when used to protect growing plants and biocidal products when sold for other uses, such as in city areas. Wood preservatives are treated as biocidal products and not as PPPs[19].

5.1.2. Efficacy of PPPs

PPPs have to be safe and may not have any harmful effects on human or animal health or any unacceptable effects on plant or plant products or the environment. They also have to be "sufficiently effective" (Article 4.3 and 29.1 PPP Regulation). As regards active substances it has to be established *"for one or more representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective."* (Annex II point 3.2 PPP Regulation).

Establishing the efficacy of PPPs is a complex procedure. Assessing efficacy includes not only establishing that a product does what it is intended to do but also includes a broader analysis of other effects, such as the development of resistance, effects on subsequent crops and effects on other adjacent crops[20]. There exists an extensive set of standards for testing developed by the European and Mediterranean Plant Protection Organization (EPPO) which in principle have to be followed in the EU when applying for authorisation (Regulation (EU) No 284/2013, Section 6.2). EPPO has developed a number of general standard documents complemented by individual test protocols. Testing must include comparison with reference products and untreated samples and be conducted by officially recognised testing organisations. Testing must follow Good Experimental Practice (GEP) as described in EPPO standard PP 1/181.

The efficacy evaluation for PPPs is thus very ambitious and could perhaps be compared with the assessment of medicinal products. In particular, the fact that the products are often widely spread in the environment and that the treated products may be used as food means that they need to be evaluated very thoroughly.

5.2. Cosmetic products

5.2.1. Overview[21]

Cosmetic products are regulated at EU level by a new regulation 1223/2009 that replaces an old directive from 1976[22]. The main purpose of the regulation is to ensure that the products are safe for human health (Article 3, effects on the environment are not covered). There is no authorization requirement for cosmetic products, just a requirement to notify information

[19] Cf. the guidance for the old legislation in this area: Borderline between Directive 98/8/EC concerning the placing on the market of Biocidal product and Directive 91/414/EEC concerning the placing on the market of plant protection products, available at http://ec.europa.eu/food/plant/protection/evaluation/borderline_en.htm.
[20] For details about the extensive legislation that applies for PPPs see the list of references. Efficacy assessment is described in the Commission guidance (SANCO/10055/2013 Rev. 4). See also Regulation (EU) No 284/2013Section 6 about requirements for efficacy data and the EPPO standards for testing procedures.
[21] Cf. KemI Report No 1/12, chapter 6.4.
[22] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

about the product to a central register (Article 13). Instead the products are regulated through a number of lists. The lists enumerate substances that are banned, restricted or subjected to labelling requirements. At present more than 1300 substances are banned and more than 200 subjected to other requirements. CMR substances are banned in principle in cosmetics (Article 15). There are also three positive lists with all substances that may be used for specific purposes (colorants, preservatives, UV filters).

5.2.2. Cosmetics and biocidal products

A cosmetic product is defined as follows in Article 2 in the cosmetics regulation:

'cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;

This definition clearly covers some products that also fall under definitions for biocidal products in Annex V of BPR, in particular disinfectants for human hygiene purposes. Products within the scope of the rules on cosmetic products fall outside BPR, however (cf. Article 2.2 (j) BPR). Preservatives in cosmetic products are also expressly excluded from BPR according to Annex V. It follows that many products with claimed antimicrobial effects are cosmetic products and not biocides (they may also be medicinal products). The Commission mentions in its guidance[23] two examples: a leave-on product which is presented as "anti-septic" or "anti-microbial" and a mouthwash with similar claims. Such products may be biocidal products, cosmetic products or medicinal products depending on the main purpose of the product and of how the claims for effects are worded. Since the definition for cosmetic products mentions in particular the correction of body odours, it follows that the cosmetic products regulation often will be the legislation that applies for products of this type, i.e. products that contain chemicals with antimicrobial properties. But it still has to be clear that the cosmetic function is the main function of the product.

5.2.3. Efficacy of cosmetic products

Claims that a cosmetic product is effective and produces a certain effect (such as reducing skin wrinkles) are of course essential in the marketing of many cosmetic products. There are no efficacy requirements for verifying such claims in the cosmetic products regulation, similar to the rules that apply for biocidal or medicinal products. Exaggerated such claims are often questioned by authorities when applying the rules about unfair commercial practices (see below). But the issue is also dealt with by the new cosmetic products regulation in Article 20:

1. *In the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have."*

The person responsible for placing the product on the market must ensure that this requirement is followed (Article 4). Furthermore, the Commission has issued a Regulation

[23] Manual on the scope of application of the cosmetics regulation (EC) no 1223/2009 (art. 2(1)(a)), Version 1.0 (November 2013). See also the manual of decisions for implementation of directive 98/8/EC.

about common criteria for the justification of claims and complemented this by guidance on the subject[24]. The following criteria should be fulfilled according to the Annex of the Regulation as regards evidential support for claims:

1. *"Claims for cosmetic products, whether explicit or implicit, shall be supported by adequate and verifiable evidence regardless of the types of evidential support used to substantiate them, including where appropriate expert assessments.*

2. *Evidence for claim substantiation shall take into account state of the art practices.*

3. *Where studies are being used as evidence, they shall be relevant to the product and to the benefit claimed, shall follow well-designed, well-conducted methodologies (valid, reliable and reproducible) and shall respect ethical considerations.*

4. *The level of evidence or substantiation shall be consistent with the type of claim being made, in particular for claims where lack of efficacy may cause a safety problem.*

5. *Statements of clear exaggeration which are not to be taken literally by the average end user (hyperbole) or statements of an abstract nature shall not require substantiation.*

6. *A claim extrapolating (explicitly or implicitly) ingredient properties to the finished product shall be supported by adequate and verifiable evidence, such as by demonstrating the presence of the ingredient at an effective concentration.*

7. *Assessment of the acceptability of a claim shall be based on the weight of evidence of all studies, data and information available depending on the nature of the claim and the prevailing general knowledge the end users."*

These general criteria are made somewhat more concrete in the guidelines, where best practices applying to experimental studies and consumer perception tests are discussed. However, there are no detailed and concrete guidance with references to standardized test methods etc. A more detailed guidance has been produced earlier for one type of products: sunscreen products[25]. This guidance includes criteria for minimum efficacy and procedures for the verification of effect.

These general provisions regarding the substantiation of claims in the cosmetic products legislation are very similar to the provisions in the legislation about misleading advertising and unfair commercial practises (see below). Both legislations apply in parallel without limitation, however[26], even though the cosmetic product rules should take precedence as being *lex specialis*[27] to the extent that detailed provisions are developed in these rules.

[24] Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products. This is complemented by guidelines.
[25] Commission Recommendation 2006/64/EC of 22 September 2006.
[26] Point 51 in the preamble of the cosmetic product regulation and point 5 in the preamble of the Commission implementing regulation.
[27] Specific and detailed legislation for a product type takes precedence over general legislation.

5.3. Health claims for food

5.3.1. The food legislation

The EU has a very extensive harmonised legislation about food, the purpose of which is to ensure that food is safe, i.e. that food products are not injurious to health or unfit for human consumption[28]. Similar rules apply for animal feed. There is a separate legislation about additives to food (colorants, preservatives etc.) with positive lists covering the additives that are allowed (Regulation (EU) No 1333/2008). Additives which are not listed may not be used. There are also rules about the addition of vitamins and minerals and of certain other substances to foods (Regulation 1925/2006).

Food supplements are foodstuffs that supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, marketed in dose form, such as capsules or pills. Supplements in the form of vitamins and minerals are subject to specific rules regarding allowed content[29]. For other supplements the rules are limited to labelling requirements. No assessment of efficacy or risk is required. The claims about the products that can be made in advertising etc. are strictly limited, however. The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties. Neither may it be stated or implied that a balanced and varied diet cannot provide appropriate quantities of nutrients in general (Directive 2002/46 Article 6-7).

Maximum levels of residues of pesticides (plant protection products) in food are specially regulated in Regulation (EC) No 396/2005. There are a number of other EU legal acts that regulate special types of food and food contact materials[30]

5.3.2. Efficacy and health claims

One aspect of the evaluation of additives is of course to assess the efficacy of substances that are claimed to have a specific effect, such as preservatives. This evaluation is performed by the EU Food agency (EFSA) and national agencies. Of particular interest to the subject of this report, however, are the rules in the Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. The rules apply to commercial communications relating to foods (advertising etc.). Claims about health effects must follow a number of general conditions and be based on and substantiated by generally accepted scientific data. In addition, all health claims have to be authorized and placed on a list of permitted claims published by the Commission. The list is already extensive but not complete at the time of writing[31]. It now covers ca 100 pages of permitted health claims with conditions and more than 700 pages of claims that are not in compliance with the Regulation and that may not be used. To give an example, unauthorised health claims are often related to products that are claimed to promote the development of beneficial gut bacteria ("probiotics").

[28] Article 14 in the general food law - Regulation (EC) No 178/2002.

[29] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements

[30] Cf. KemI Report Nr 1/12, Section 6.2.

[31] See http://ec.europa.eu/nuhclaims/

EFSA has published guidance on applications for authorisation of health claims[32]. The guidance is general and does not include specific requirements about tests etc. According to the guidance, all available scientific data relating to the claim has to be submitted (in favour or not in favour). Animal data can only be used as complement to human studies, which must live up to the quality required by peer-reviewed journals. The Agency takes a decision in the form of a scientific opinion, which is submitted to the Commission for a final decision.

The legislation about nutrition and health claims for food is interesting as an extension of general requirements about misleading advertising and other commercial communications (see Chapter 7), where the ambition is raised to a level where all commercial messages have to be authorised beforehand.

5.4. Medical devices

5.4.1. Overview

Medical devices are regulated in the EU by the directive 93/42/EEC, which sets harmonised standards for the products. It is complemented by two other directives for special cases (active implantable devices and in vitro diagnostic devices). A Commission proposal for a new regulation about medical devices has not yet led to a final decision by the Council and Parliament[33].

Medical devices are defined as follows in Directive 93/42 (Article 2.2):

"(a) 'Medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,

- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

- investigation, replacement or modification of the anatomy or of a physiological process,

- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;"

Medical devices are not subject to authorisation before being placed on the market. Instead they must fulfil the essential requirements set by the directive (Article 3 and Annex I). The conformity of the product with the essential requirements has to be assessed by the manufacturer according to procedures that are defined in the directive (Article 11). The stringency of these procedures differs depending on the type of device.

5.4.2. Medical device or biocidal product?

Products that fall under the definition of medical devices are excluded from the application of the rules about biocidal products. Disinfectants for general use are not seen as medical devices but as biocidal products (unless claims are made that identify them as medicinal products).

[32] EFSA Journal 2001;9(5):2170.
[33] COM(2012) 542 final.

Disinfectants that are used specifically to disinfect medical devices are seen as medical devices, however, since they are mentioned in the rules for classification of such devices[34].

5.4.3. Efficacy requirement for medical devices

A medical device has to achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that it is suitable for one of the functions mentioned in the definition of a device (Annex I point 3). This has to be verified as part of the conformity assessment performed by the manufacturer before the product is placed on the market (Directive 93/42 Article 11). This procedure includes a clinical evaluation (Annex X), which shall verify that, under normal conditions of use, the performance of the devices confirm to the efficacy requirement in Annex I.

The clinical evaluation can include clinical trials. Sometimes data from a literature search or comparison with similar product is sufficient for an assessment[35].

5.5. Medicinal products

5.5.1. Overview

A medicinal product for human use is defined in the following way (Directive 2001/83/EC, a similar definition applies for products for veterinary use):

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

A "substance" according to this definition may refer to a chemical but also to substances of human, animal or vegetable origin. According to the first part of the definition the decisive factor for determining whether a product is a medicinal product is the claims that are made about healing effects, while the second part requires a more objective evaluation of the product as such.

A medicinal product has to be authorised before it is marketed within the EU. An authorisation can be national or decided at EU level according to Regulation (EC) No 726/2004.

The claims made about curative effects of a product are essential in determining whether it shall be seen as medicinal or other type of product, such as a biocidal, cosmetic or food product. This seems to some extent be true also for part (b) of the definition, which is more objectively worded than part (a). Since the action of the product has to be pharmacological, immunological or metabolic, products functioning through physical action (as a barrier etc.) are excluded. Such products may instead be medical devices. On the other hand, if it can be

[34] Directive 93/42/EEC Annex IX section 4.3.

[35] Guidance by the Commission in Clinical Evaluation: a Guide for Manufacturers and Notified Bodies, MEDDEV. 2.7.1 Rev.3, December 2009. Available at http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm

shown that a product has no pharmacological, immunological or metabolic effect (and no purpose of medical diagnosis), the product is not a medicinal product[36].

The very strict authorisation requirements which apply for medicinal products may be avoided if a product is marketed as a food supplement, with the corresponding strong limitations about the health claims that can be made for these (see above).

5.5.2. Efficacy of medicinal products

An authorisation of a medicinal product requires that an extensive documentation is provided about the efficacy of the product. Results are required from tests in three stages (pharmaceutical tests, pre-clinical tests and clinical trials). A risk/benefit analysis is performed based on the results of the tests and other documentation.

These requirements apply in principle for all products that are medicinal products according to the definition cited above. For traditional herbal medicinal products, documentation about efficacy is not required if the product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community (Directive 2001/83 Articles 8 and 16a-16i).

Similar rule apply for veterinary medicinal products according to Directive 2001/82/EC.

5.5.3. Summary

- A number of products are covered by separate sector legislation in the EU. Examples are plant protection products, substances in food and feed, medical devices, medicinal products and cosmetic products. The Regulation about biocidal products usually does not apply for such products, even in cases when the products also fall under the biocide definition in the Regulation.
- Disinfectants, for example, are seen as biocidal products if the product claims relate to general use. If a disinfectant is claimed to prevent diseases, it can be a medicinal product. Some disinfectants are seen as medical devices. The formulation of the product claim is often very important for identifying to which category a product belongs.
- The sector legislation usually has some kind of provisions that relate to claims that are allowed about the efficacy of the product.
- As regards health claims for food, every individual claim made must be approved before it can be used for products on the market. For some food supplements, the only limitation is general requirements to avoid exaggerated claims.
- Plant protection products and medicinal products have efficacy requirements similar to biocidal products. Efficacy has to be shown as part of the authorisation procedure. Medical devices also have to be proven efficacious by the manufacturer before they can be CE marked. Cosmetic products are not authorised or CE marked, but their efficacy must still be verified by adequate and verifiable evidence.

[36] ECJ judgement in Case C-140/07.

- The efficacy requirements can be extremely detailed and demanding and include specified data requirements (medicinal products). Plant protection products and medical devices are also subject to strict requirements. For cosmetic products the demands are more general. Health claims for food are individually assessed by an expert authority on the basis of general principles for scientific assessment. The legislation generally includes requirements that efficacy evaluation must be based on adequate and verifiable data and be based on scientific principles.

6. General Product Safety

The general product safety directive[37] deals with safe products and measures to be taken when products lead to risks to human health. For example, there is a general obligation to ensure that products put on the market are safe. There are rules about information to users, rapid intervention procedures when products are found to be unsafe (recall etc.), as well as rules about market surveillance and exchange of information between authorities in the Member States (RAPEX system).

The general product safety directive does not apply (Article 1.2) to products subject to specific safety requirements imposed by Community law insofar as concerns the risks or categories of risks covered by the specific legislation. For example, if a specific directive regulates chemical risks related to a type of product but not other types of risks (such as mechanical risk, noise) the general product safety directive only applies for the latter type of risk.

The general product safety directive has nothing to say about the efficacy of products and is therefore of limited interest for this report.

7. Misleading advertising and unfair commercial practices

7.1. Background

It is easy to understand that claims about the positive effects of products of the type covered in this report may be exaggerated in advertising and other market communications, while negative side effects may not be mentioned or downplayed. It is very difficult for both consumers and professional users to evaluate the products themselves if the advertising and labelling etc. is not correct and comprehensive. Most of the legislative systems referred to in the report have specific rules about marketing and labelling with rules about the information that has to be provided. Claims have to be verified by the manufacturer and specified claims may be forbidden in advertising. In some cases, such as some food supplements, the fact that health claims are forbidden is the only substantive element in the legislation. The claims that are made about what the product can do and its effectiveness are also often crucial for determining which sector legislation is applicable, since the uses and claimed effects are often part of the product definitions.

[37] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety

Specific rules about certain types of products are complemented, however, by general legislation about commercial communications and advertising that exist in all developed legal systems. The EU rules discussed in the following have similar counterparts in USA, Japan and other countries.

7.2. EU legislation

The EU has two legal instruments with a general scope that regulate commercial practices such as advertising. The Directive 2006/114/EC concerning misleading and comparative advertising is a consolidation of an older Directive from 1984. It protects professional actors ("traders") against false or misleading claims in advertising. This directive does not cover advertising aimed at consumers. Such advertising or other types of information to consumers is instead covered by the unfair commercial practices directive 2005/29[38] . Both directives include bans on false or misleading claims in advertising. The following comments concern the second directive (in the following referred to as "the Directive"), but should generally be valid also for the application of Directive 2006/114[39].

According to Directive 2005/29, unfair commercial practises are prohibited. Practises are seen as unfair if they materially distort or are likely to materially distort the economic behaviour of an average consumer. Material distortion of economic behaviour occurs when the commercial practise appreciably impairs the consumer's ability to make an informed decision, thereby causing the consumer to take transactional decision that he or she would not have taken otherwise. A transactional decision could be a decision to buy or not to buy something, but could also refer to other related actions (Articles 2 (c), 2 (k) and 5.1-2). Such a test of how a business practice may influence an average consumer is not necessary for a number of misleading practises that are listed in Annex I of the directive, which are always seen as unfair. Two of these are

- claiming that a product has been approved, endorsed or authorised by a public or private body when it has not,
- otherwise creating an impression that a product can legally be sold when it cannot, for example when an advertised product subject to an authorisation requirement has not in fact been authorised.

These provisions stem in part from ECJ case law, according to which the question whether a statement is misleading must be answered taking into account the presumed expectations of an average consumer who is reasonably well informed and reasonably observant and circumspect (case C-210/96). The Court found in another case that the well known phrase "dermatologically tested" was acceptable, since an average consumer would not be misled into thinking that these words meant that the product had a specific beneficial health effect (case C-99/01).

[38] Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council

[39] For guidance about the application of the directive, see Commission staff working document "Guidance on the Implementation/application of Directive 2005/29/EC on Unfair Commercial Practises", December 2009.

An unfair commercial practise could be an action that is misleading by providing information that is false or in other ways likely to deceive the consumer. This could involve information about the existence or nature of the product or its characteristics, which inter alia could include its benefits, fitness for purpose, results expected from its use or the results and material features of tests or checks carried out on the product (Article 6.1).

The trader (seller etc.) making a claim is responsible for the claim being correct and has to be able to substantiate it. How the claims have to be verified is not regulated in detail in the directive and has to be decided on a case-by-case basis. This is often a contentious issue in the cases before the national courts, where fairly strict requirements are set (see below). There are also standards for environmental claims that can guide the application of the legislation[40]. A claim that a biocidal product has a positive effect, for example antibacterial, is an environmental claim[41].

Environmental claims are separately discussed in the Commission's guidance to the Directive. The requirements on the traders about such claims are summarised as follows:

"*a) Based on the Directive's general clause, traders must, above all, present their green claims in a specific, accurate and unambiguous manner;*

(b) Traders must have scientific evidence to support their claims and be ready to provide it in an understandable way in the case that the claim is challenged."

In an earlier report from the Commission about environmental claims the verification requirement is discussed further on the basis of the ISO standard[42]:

"Principle 2 states that "environmental claims shall be based on scientific methodology that is sufficiently thorough and comprehensive to support the claim and that produces accurate and reproducible results'. This principle should prevail when selecting an evaluation method."

The Directive on unfair commercial practises thus stipulates that any claim that a product is effective in producing certain benefits has to be correct. If such a claim is false, it is considered misleading and is banned if it can influence the economic behaviour of a consumer or if it is of a particularly serious nature. The Directive does not regulate in detail what is required of a trader in the form of verification of claims. This is left to national implementing legislation, but general guidance can be found in the ISO standard for environmental claims.

If specific aspects of unfair commercial practises are also regulated in sector legislation and the regulations overlap, the sector legislation is seen as *lex specialis* and takes precedence (Article 3.4). Annex II in the Directive contains a non-exhaustive list of EU legislation that includes specific rules for advertising and other commercial communications. Even though such rules exist in most examples of sector legislation mentioned in this report, for some reason only medicinal products for human use is mentioned in the annex.

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[40] ISO 14021:1999 Environmental labels and declarations -- Self-declared environmental claims (Type II environmental labelling)

[41] It may be discussed whether all health claims can be seen as ”environmental claims” that are covered by the ISO standard. Considering the wide definition of ”environment” that is used in different legislations the conclusion is that they are covered. See for example definitions in the Aarhus Convention on access to information in environmental matters as reflected in the EU Directive implementing the Convention (Directive 2003/4/EC). In any case, the ISO standard can always be seen as a general guide also for health claims.

[42] Commission report ”Guidelines for Making and Assessing Environmental Claims”, Report No. 67/94/22/1/00281, December, 2000

7.3. National implementing legislation and the verification of efficacy claims

The EU rules are implemented in Member State legislation in a slightly different fashion. For example, some countries (including Sweden and Germany) let the same requirements apply for professional buyers and consumers, even though the directive only applies to practices aimed at consumers. The Directive as such is fully harmonised, however, and does not allow for stricter or less strict requirements being applied nationally.

Studying the national implementing legislation (Swedish and Danish in this case), it becomes clearer that the trader has the burden of proof for any efficacy claims that are made and that claims have to be verified by documentation that the trader has to be able to provide when required. What documentation is needed must by assessed on a case-by-case basis. This is described in the following way in the guidance on environmental claims and the Danish "Markedsføringslov" published by the Danish Forbrukerombudsmannen[43] (a rough translation of the relevant parts):

*"**6.3 Documentation about claims***

It must be possible to provide documentation about any factual circumstances. (...). This requirement means that any environmental (...) claims about a product and its properties (...) has to be verifiable. The trader must ensure that the documentation is available when the claim is made in marketing for the first time.

Documentation shall be sufficient, which normally means that claims have to be substantiated by conclusions or studies made by independent bodies with known competence in the area. If there are substantial differences of opinion and doubt among specialists about environmental effects (...) , the trader must provide information about this or refrain from using the message in the marketing.

Studies conducted by the producer or the trader marketing the product must be evaluated by an independent body or it may in some other way be securely concluded that the study has been conducted correctly and that the evaluation of the result can be defended scientifically."

In Swedish case law, it is also stressed by the court (Marknadsdomstolen) that any claims have to be substantiated and that the burden of proof is on the person who makes the marketing claim. One example[44] is a case where a producer of a toothpaste had made the claim that the product was "the only toothpaste clinically proven to give instant relief from shooting pains in the teeth". This claim was questioned by a producer of another toothpaste. It was stressed by the court in its judgement that it would be very difficult for an average consumer to judge such a claim and that the documentation provided by the trader therefore had to be particularly trustworthy.

The court found that an average consumer would interpret the claim as saying that the toothpaste in question was the only one bringing relief to pain. The producer making the claim would have to substantiate this. Some studies were produced that indicated that the tooth paste made by the producer did have the promised effect to some extent. The competitor also presented studies, however, to prove that other tooth pastes had a similar beneficial effect. The value of the different studies was discussed in the judgement, in particular the use

[43] Forbrukerombudsmannens vejledning om bruk av miljømæssige og etiske påstande mv. i markedsføringen, januar 2011
[44] Marknadsdomstolen judgement MD 2011:20

of reference products for comparison. The Court found that the competitor's studies could be questioned in some respects, but that they were enough to show that the tooth paste about which the claim was made was not the only one that could relieve pain. The claim was not allowed according the Swedish legislation (marknadsföringslagen) and its future use was banned.

There are many cases tried by Marknadsdomstolen about health claims made for products. The cases are often about weight-loss products, where scientific studies proving efficacy are often non-existent or clearly inadequate[45]. Case 2010:28 was about an anti-wrinkle cream made by a large producer of cosmetics. Verification of its efficacy was produced by some simple studies (evaluations made by persons who had used the product, studies with a so called dermal-torque meter and in vitro-tests). The Court found that the user evaluations and the torque-meter tests could indicate subjective improvements but that they did not objectively show that the skin had been repaired. The in vitro tests used could be questioned and were not sufficient to prove the effect. Claims that the product reduced wrinkles were therefore banned.

There are also cases where the products were in fact unauthorised medicinal products and all commercial marketing was forbidden (MD2013:7). In one case (MD 2006:21) a publisher of a weekly magazine was seen as responsible for advertisements in the magazine about a weight-loss product. According to the court it must have been obvious to the publisher that the claims made were misleading. The publisher was therefore jointly responsible with the producer for infringing the Swedish law.

Sanctions for infringements are in Sweden most often that the trader is forbidden to use the claims in commercial messages. Court cases may be initiated by the authorities (Konsumentombudsmannen) or by competitors. The offender has to pay the other parties´ litigation costs. There is also a possibility to decide on public fines (marknadsstörningsavgift). Competitors may require financial compensation for damages, for example if their sales of a competing product have gone down as a result of incorrect claims[46].

7.4. Summary

- Sector legislation such as the Biocides Regulation often contains rules about which information about a product that may be presented to a customer in commercial messages such as advertising. Exaggerated claims about the efficacy of the product may not be allowed by the sector legislation.
- The sector legislation is complemented by legislation with a general scope about misleading advertising or unfair commercial practises that exists in most countries. The EU Directive about unfair commercial practises regulates how traders (manufacturers, sellers etc.) present their products to consumers in commercial

[45] MD 2003:26, 2004:20 and others

[46] Damage claims are more common and more important when false claims are made according to the corresponding legislation in the USA. Such cases may take the form of ”class actions”, where damages may be awarded to all consumers who have been misled into purchasing a product. One example is the use of triclosan in products to reduce bacterial contamination. The FDA in USA assessed triclosan in 2010 and found that there was no evidence that triclosan in antibacterial soaps and body washes provides extra health benefits over soap and water. This has led to class actions being initiated in USA and Canada for compensation to users who have been misled by advertising about the advantages of triclosan in health care products.

messages such as advertising. It is implemented into national law by the EU member states and has a harmonised application.

- The Directive forbids unfair commercial practises that can be misleading to average consumers and influence their transactional decisions, such as the decision to buy a product. It is misleading to provide information that is false or in other ways likely to deceive the consumer. This could involve information about the characteristics of the product, which inter alia could include its benefits, fitness for purpose, results expected from its use or the results and material features of tests or checks carried out on the product. This clearly relates to the claims about the efficacy of a product for its purpose that are discussed in this report.
- The trader (seller etc.) making a claim is responsible for the claim being correct and has to be able to substantiate it. How the claims have to be verified is not regulated in detail in the legislation. Claims about efficacy (such as the efficacy of a biocidal product) can be seen as environmental claims, however, and there are general ISO standards for environmental claims that can guide the application of the legislation.
- The requirements for verification are strict in practise, as seen in national case law and as follows from the standard. This is particularly true for claims about health or environmental effects, which are very difficult to assess by an average consumer. Scientific evidence is needed to verify claims and the documentation has to be sufficient. This would normally mean that studies have to be made and/or evaluated by independent bodies with known competence in the area. How much documentation that is needed is decided on a case-by-case basis, but the application of the legislation is made easier by standards and general guidance.

8. Analysis and conclusions

This report has covered rules in sector legislation that deals with different types of products (chemical products or other products) that have certain useful functions but that also may have negative consequences in use, in the form of health risks or risks for other unwanted effects. The legislation tries to counteract such negative effects in different ways. Registration or authorisation may be necessary before a product is placed on the market. Detailed rules may be laid down about the substances that are allowed in a certain product. Compliance with these rules may be checked as part of an authorisation procedure or may be ensured through self-certification (CE marking).

Rules about the content of products may take the form of negative lists (bans on substances) or positive lists (substances allowed in a product). The legislation may include requirements about a risk assessment and risk/benefit analysis that has to be performed either by industry (manufacturer or person responsible for marketing) or by the responsible authorities. Rules about such assessments may be extremely complex and demanding (e.g. medicinal products) or more limited in scope (e.g. cosmetic products).

The products are sold on a market. The general legislation about commercial practises is there to ensure that consumers and professional users are not mislead by false or misleading claims

about what a product can do. But the claims made about the function of a product are also important for identifying the product and the sector legislation that is applicable.

In this chapter an attempt is made to analyse and draw conclusion on the basis of the description of the efficacy requirements in the different types of legislation, taking the legislation about biocidal products as the starting point. Three issues seem important to discuss: the borderlines between sector regulations, the wording of efficacy requirements and the efficacy requirements for articles treated with biocidal products.

8.1. Identifying the applicable sector legislation

This report has taken the legislation about biocidal products as its starting point and in particular looked at products that are claimed to have antimicrobial properties, such as disinfectants. Identifying the applicable sector legislation for such products may be very difficult, since almost all the types of legislation discussed in the report have a scope that may include the products. A product with antimicrobial effects can be a biocidal, medicinal or cosmetic product or a plant protection product. The product may be a medical device. The food legislation may also be applicable (preservatives or food contact materials, for example). The formulation of claims about what the product will do is often essential in determining the applicable legislation. The application is further complicated if a product is claimed to have more than function, such a sunscreen product that also is claimed to function as an insect repellent.

A survey of the different types of legislation as in this report creates an impression that the rules about the scope of the separate regulations were not very well coordinated when formulated. This is perhaps unavoidable when the rules follow from different individual needs and are written by different groups of experts. It creates large problems of interpretation for the persons who are obliged to follow the rules, however.

There exist a substantial number of guidance documents with conclusions about which legislation that is applicable for individual products. This guidance seems generally helpful and comprehensive. It could perhaps sometimes be even more helpful if it was written taking a specific product as a starting point, instead of identifying if a particular type of legislation is applicable to a product or not. Guidance of a more general kind also exists, however.

New types of treated articles with biocidal functions are constantly created and introduced on the market. This creates new difficulties in determining the applicable legislation (the concept of “primary biocidal function” is a new problematic concept). The FAQ produced by the Commission about the new rules for treated articles is helpful but needs to be further developed, in particular as regards new uses of products and the issue of primary biocidal function. It could also be helpful if guidance was developed on multi-functional products.

8.2. How shall efficacy be substantiated?

Almost all the sector regulations discussed in this report require that claims about efficacy have to be substantiated (food supplements is an exception). The verification can be done by an expert authority on the basis of all available evidence (health claims for food), but usually has to demonstrated by the person seeking an authorisation or the person who places a product on the market. There exist a number of standards with methods for verifying efficacy for different types of products. In the area of chemicals and pesticides guidance is developed by

the OECD. There are no detailed requirements for specific testing methods etc. to be used, however (medicinal products may be an exception). If a specific testing method or standard exists for verifying efficacy, authorities may require that the standardized procedure is used or at least that convincing reasons are presented for not using it. Standardized test protocols may be available for some studies that are needed (Tier 2 tests) but not for field testing (Tier 3 tests) where testing has to be adapted to the claims made in the individual case.

Normally the legislation includes some general rules about principles for verifying efficacy. These rules may be slightly differently worded. They always express that testing must be relevant in relation to the label claims and that it must be based on sound scientific principles. Small but important differences can be identified in some cases. For example, the ISO standards for environmental claims stress that assessments or studies have to be performed by independent bodies with expertise in the area, which is not mentioned in the requirements for cosmetic products. In general, however, the demands are similar but with different levels of ambition. It is also often stressed that the amount of verification needed must depend on the type of product and whether it can have an impact on human health. A person placing a medicinal product on the market faces much stricter demands on efficacy verification that a person who sells a cosmetic product. In the legislation about unfair commercial practises an important factor is determining whether average consumers can be expected to draw their own conclusions about the properties of a product. For the type of products discussed in this report it is clearly difficult or impossible for an average consumer to judge any claims regarding efficacy.

8.3. Efficacy of articles treated with biocides

EU rules

Biocidal products must be shown to be efficacious according to EU rules. Data showing the efficacy have to be provided for each individual product to be authorised. For an active substance to be approved, efficacy data for a representative biocidal product incorporating the active substance must be provided. This regulation is logical and consistent. The fact that one product using an active substance is efficacious does not imply that other products using the same substance necessarily can do what they are claimed to do. Efficacy can depend on the amount of active substance in the product, how it is released and how the target organism is exposed etc. etc. Therefore all authorised products have to be assessed for efficacy.

The same principle applies for articles treated by a biocidal product, if the article has a primary biocidal function. If the biocidal function is not the primary function, no data about efficacy has to be provided according to the Biocidal Products Regulation (BPR). The only substantial limitation is that the active substance in the article has to be approved for the relevant product type and use. The limitation as regards use can be important for some product types where the approval of an active substance is differentiated between uses or where specific uses are expressly excluded by the formulation of the approval (section 3.4). In other cases the approval of the active substance has not been refined in such a way.

EU rules and the rules in the in USA

It is instructive to compare this regulation with the system in the USA, which is stricter than the EU rules in some respects and less stringent in others. Efficacy data are only required for products that are claimed to control pests that may pose a threat to human health (depending on the formulation of the claims, these may instead be medicinal products). Treated articles or substances that only contain biocides in order to protect the article or substance itself fall outside the regulation. In these respects the rules are less strict than EU rules. On the other hand, the biocidal product used to treat the article or substance has to be approved for the specific article or substance type in question for the exemption to be applicable. The EU rules do not require authorisation of the biocidal product used, only the active substance. The limitation to product type and use for the active substance in the EU rules can be very broad and does not guarantee that the biocidal product used to treat article has been assessed for exactly the type of product in question as regards efficacy or risk. In this respect the US rules seem to be more ambitious and consistent. Rules and guidance in the USA are also is very clear about the claims that are allowed for a certain type of products and about claims that may not be used.

Primary biocidal function

The effect of the new EU rules about treated articles depends to a large extent on the interpretation of the concept "primary biocidal function". The Commission has in its FAQ document concluded that the biocidal action may be considered to take higher rank than other, non-biocidal functions when articles are considered for which claims are made with public health relevance (section 3.2). Such articles should therefore be seen as biocidal products and not treated articles and be subject to the full authorisation procedure with data requirements. This interpretation may be contentious and the meaning of the phrase is extremely important for the application of the BPR. It seems essential to develop further guidance on this issue that looks at a number of practical examples. The alternative - to wait for the issue to be dealt with in case law – could lead to a long period of uncertainty as regards the interpretation.

Treated articles and rules on unfair commercial practises

It has been concluded in this report that the BPR as such does not require verification of efficacy for treated articles (section 3.4). Efficacy data for the active substance used in the article may not be very helpful in assessing whether the specific article is efficacious. Any claims that the article has biocidal properties have to be placed on the label, however, where such claims are substantiated. This wording is somewhat strange, since the Regulation itself does not require that claims about the properties of the article have to be substantiated. The wording makes sense, however, if it is seen as a reference to the general rules about misleading information and about unfair commercial practises which have been described in Chapter 7.

These latter rules about marketing practises should be applicable to articles treated with biocides to the extent that the BPR does not include specific provisions on the same subject. For biocidal products there are specific rules about labelling and also about advertising (Article 72) that would take precedence if there was a conflict with the rules about marketing practises. For treated articles, however, the only requirement is the labelling and the content on the label. The rules do not deal with substantiation about product claims and the rules do not lead to harmonisation in that area. Instead the provisions of the Unfair Commercial Practises Directive are applicable (these are also harmonised in the EU). The requirements for

substantiation of claims in this legislation are in fact very similar or even stricter than verification requirements for claims in BPR and other sector regulations (Chapter 8).

The conclusion is that any claims about efficacy of treated articles have to be substantiated according to general principles that have been developed in case law about unfair commercial practises. This connection between the two legal frameworks has not been made clear in guidance for the application of legislation (the Commission mentions it in the FAQ about treated articles). It would be very useful for persons placing treated articles on the market if guidance was developed that clarified the obligations in both legislations in parallel. It would, for example, be important to know to what extent and in what way one can rely on efficacy data that are part of the approval for the active substance and what additional data that would be needed to substantiate an efficacy claim.

If a seller makes efficacy claims for a treated article, a national authority may find it necessary to demand that the claim is substantiated according to the principles described in this report. Any such demand has to be based on a mandate given by the correct legislation. In some cases the Biocides Product Regulation may provide the basis, in other cases the rules about unfair commercial practices. Often different authorities have the competence to apply these different sets of rules. Such issues should also be dealt with and clarified by a guidance document.

8.4. Summary

- The borderlines between sector regulations are often unclear; making it difficult to decide which legislation is applicable for a particular product. This is particularly true for products with health related claims that fall under the biocides regulation. Some guidance exists to address these problems, but additional guidance may be needed especially where new types of articles treated with biocidal products come onto the market.
- General principles about the required verification of claims are similar in sector legislation and in the rules on unfair marketing procedures, but with some differences in level of ambition. Testing must be relevant in relation to the label claims and must be based on sound scientific principles. Standardized testing procedures are not always available, however, in particular for treated articles.
- Articles treated with biocidal products that have a primary biocidal function are seen as biocidal products themselves and are subject to the full authorisation procedure. The meaning of the phrase “primary biocidal function” is discussed, and it is extremely important to avoid ambiguity in its interpretation. More concrete guidance using examples should be developed in this area.
- Articles treated with biocidal products must contain approved active substances and must be labelled when biocidal claims are made or when required by the active substance approval. There is no obligation according to the biocidal products regulation to provide data about the efficacy of the article as regards biocidal function. Claims have to be presented on the label, however, where these are substantiated. This wording should be seen as a reference to general legislation about marketing claims, in particular the unfair commercial practises directive. This directive is applicable for treated articles and requires that product claims are substantiated. Guidance should be

developed that clarifies the obligations in both legislations in parallel, in particular which efficacy data that would be needed for treated articles in addition to data already provided when the active substance in the article was approved.

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