

# Antifouling for leisure boats in the Baltic Sea

A review of the European Union chemicals and water legislation



Jonas Nilsson & Lena Gipperth

Antifouling for leisure boats in the Baltic Sea  
A review of the European Union chemicals and water legislation  
ISBN 978-91-87869-09-9

# Antifouling for leisure boats in the Baltic Sea

## A review of the European Union chemicals and water legislation

Authors: Jonas Nilsson ([jonas.nilsson@law.gu.se](mailto:jonas.nilsson@law.gu.se)) & Lena Gipperth  
([lena.gipperth@law.gu.se](mailto:lena.gipperth@law.gu.se))  
2015



Danish Agency for Science  
Technology and Innovation  
Ministry of Science  
Technology and Innovation

## Abstract

In this report, the EU legislation regulating antifouling measures for leisure boats in the Baltic Sea will be presented with particular focus on authorisation of antifouling biocides and on determining the extent of the Member States' autonomy in other antifouling related matters. The report outlines the important provisions of applicable legislation in both the regulations concerning harmonization of the authorisation of chemicals and the directives targeting the environmental concerns of the water bodies in the Union. The Biocidal Products Regulation provides the basis for all biocidal products authorisation, including procedural provisions and requirements for approval of active substances and authorisation of biocidal products, while the Water Framework Directive and the Marine Strategy Framework Directive regulate the marine environment and provide specific environmental quality standards and measures that must be considered in the authorisation process. Provisions in both the Biocidal Products Regulation and the regulation in combination with the water policy directives provide the possibility to impose conditions or restrictions on antifouling biocides based on local environmental conditions, but the environmental concerns must be weighed against the objective of harmonization of the internal market. The particular sensitivity and unique environmental quality of the Baltic Sea constitutes aspects that can and must be taken into consideration in the authorisation process. The water quality directives put further antifouling related obligations on the Member States, which they may achieve through various regulations and actions determined at a national level.

## Table of Contents

<b>1. Introduction.....</b>	<b>4</b>
<b>2. The legal basis for European Union environmental law .....</b>	<b>6</b>
<b>3. The European Union chemicals policy.....</b>	<b>10</b>
<b>3.1 Introduction: the European Union’s new chemicals policy .....</b>	<b>10</b>
<b>3.2 REACH .....</b>	<b>10</b>
<b>3.3 The CLP regulation .....</b>	<b>14</b>
<b>3.4 Biocidal Products Regulation.....</b>	<b>15</b>
3.4.1 Approval of active substances.....	17
3.4.2 Products authorisation.....	19
<b>3.5 Summary: Antifouling and the European Union chemicals policy .....</b>	<b>23</b>
<b>4. European Union water quality policy .....</b>	<b>25</b>
<b>4.1 Introduction: water and marine environmental legislation .....</b>	<b>25</b>
<b>4.2 The Water Framework Directive.....</b>	<b>25</b>
4.2.1 River basin management.....	26
4.2.2 Environmental objectives .....	27
4.2.3 Environmental Quality Standards .....	28
4.2.4 Programme of measures.....	29
<b>4.3 Marine Strategy Framework Directive .....</b>	<b>30</b>
4.3.1 The marine strategy.....	31
4.3.2 Regional cooperation .....	35
<b>4.4 Summary: Antifouling and the European Union water policy .....</b>	<b>36</b>
<b>5. Summary and conclusions .....</b>	<b>37</b>
<b>5.1 Introduction .....</b>	<b>37</b>
<b>5.2 Antifouling biocides .....</b>	<b>37</b>
<b>5.3 Member states’ obligations and domestic regulation.....</b>	<b>38</b>
<b>References .....</b>	<b>40</b>
<b>Annex I: Global and regional legislation and cooperation .....</b>	<b>43</b>

## 1. Introduction

The use of effective antifouling is essential for any maritime vessel as a mean to ensure the proper functioning of the vessel, as a cost-reductive measure and for environmental purposes. Antifouling is, however, far from unproblematic as the method of choice has often involved very toxic biocides with severe negative effects on the environment, even though the use of non-biocidal methods, such as mechanical cleaning, especially for leisure boats, has been more commonly used during recent years.

The aim of this report, finalised in June 2015, is to outline the European Union's legislation concerning antifouling for leisure boats and to determine which areas and to what extent each Member State can regulate antifouling domestically. The primary focus of the report will be on the use of biocidal antifouling products and the use of these in the Baltic Sea as this has been thoroughly regulated by the European Union. The Baltic Sea has unique environmental qualities and is more sensitive to the dangers of the chemicals involved in antifouling than many other waters. The report will look into the effect and flexibility of the current legislation to accommodate to these unique circumstances. Additionally, the Baltic Sea is not entirely surrounded by Member States as Russia also has coast by the waters. The regulation must therefore be able to accommodate international cooperation beyond the borders of the Community to reach the goal of a healthy marine environment.

Despite an increase in alternative antifouling methods lately, the report will focus on the biocidal alternatives, inter alia copper-based antifouling paints, due to the method's continuous dominance as the preferred method and its potential dangers to the environment. The report will only look into the Union legislation, as the national aspect will be the focal point in other CHANGE reports. A substantial part of the legislation of note consists of EU directives that need to be incorporated into national law. Without reviewing the national adaptation of the directives any definite conclusion of its practical application is going to be limited.

The report commence with an overview of the general European Union environmental legislation. The section intends to give a brief introduction to the foundation that the regulations and directives more specific to the issue at hand, presented subsequently in the report, are based upon. The main portion of the report, consisting of the presentation of applicable European legislation, will be divided into two sections, *The chemical policy of the European Union* and *The water quality policy of the European Union*. Within the sections, each legislative instrument will be handled separately and at the end the section will be summarized with focus on its impact on antifouling for leisure boats.

The section presenting the chemical policy of the European Union will focus on the approval of biocidal products. Naturally the focus of this section will be the Biocidal Products Regulation as the primary regulation for authorisation of biocides. The presentation will present the process of authorising active substances and biocidal products, particularly attending to the possibility of influence and self-determination each individual Member State possesses. A brief

overview of other applicable Union legislation within the chemical policy will be presented, including REACH and the CLP regulation. REACH is closely connected to BPR and has certain applicability on authorisation of antifouling biocides. The section will introduce the functioning of the legislation and clarify the applicability on the issue at hand. The CLP regulation does not concern the authorisation of biocides, but rather the classification and labelling of such products, and the basics of the regulation and its impact on antifouling products will be presented.

The next section, presenting the water quality policy of the European Union, will revolve around two pieces of legislation – the Water Framework Directive and the Marine Strategy Framework Directive. These two framework directives aim for all water bodies of the European Union to reach at least a good environmental status, including proper chemical balance, thus playing an important role in several different aspects of antifouling. As the national implementation of these directives will not be reviewed within this report, the section will instead detail the general process of setting up the national implementation, its potential impact on the authorisation of antifoulants and impact on other aspects of antifouling.

The report will conclude with a summary and conclusions of the overall findings. It will elaborate on the correlation between the two chemical and water quality legislations and attempt to determine the Member States' possibility to have an impact on the domestic approval of antifouling biocides to accommodate local conditions and control over other antifouling related activities. It will also determine the obligations for the Member States related to antifouling that the water quality directives create and the possibilities for domestic regulation to fulfil these obligations.

The source material of the report consists mainly of European Union legislation and official policy documents, including white papers, strategic documents, reports etc., accommodating the legislation. Due to the many aspects of national authorisation or implementation, the Commission has been keen to develop several guidelines to ensure uniform domestic application. The chosen pieces of legislation have in large part been recently adopted and/or not fully implemented yet, resulting in restricted availability of literature, case law and practical examples. Instead the visions, guidelines and detailed descriptions of the policy documents provide an insight to the potential end result of the current movement. The websites of ECHA, the European Commission and EUR-Lex have been particularly useful in finding relevant legislation and documents and providing an overview of the system.

## 2. The legal basis for European Union environmental law

When the European Union was founded in 1957, environmental policy was nowhere to be found. It was not until 1972 that the first environmental legislation, the Environmental Action Programme, was adopted and in 1987, as the Single European Act (SEA) came into force, explicit mention of environmental protection was included in the treaties. Today, the European Union is known as a leader in environmental policy, not only at a regional level, but also globally. In this chapter a brief overview of the treaty law of the European Union from an environmental aspect will be presented to determine the Union's legislative competence on such matters, with the Treaty on the Functioning of the European Union<sup>1</sup> (TFEU) as the basis. The articles cited refer to the article, or the corresponding article, in the TFEU as amended by the Lisbon Treaty, in force since 1 December 2009.

The Lisbon Treaty created two main treaties, the Treaty on the European Union (TEU) and TFEU. TEU sets out general principles and institutional arrangements, while TFEU further details the role, policies and operation of the EU and firmly establishes the legal competence of the Union in environmental matters. That has, however, not always been the case, as environmental protection was not explicitly mentioned in the treaty until the adoption of the SEA. Instead, the predecessors to Article 115 TFEU was primarily used to develop environmental legislation on the basis of approximation of national legislation directly affecting the establishment or functioning of the common (now internal) market. The SEA introduced changes to the current Article 114 TFEU making measures based on the harmonization of the internal market easier to adopt, which includes environmental measures as confirmed by the Court.<sup>2</sup> Laws adopted under Article 114 follows the *ordinary legislative procedure* as outlined in Article 294.

Even if a harmonisation measure is introduced, Member States are given the possibility to maintain existing national provisions under Article 114(4), or introduce new ones under Article 114(5). Existing national legislation may be maintained *on the grounds of major needs referred to in article 36, or relating to the protection of the environment or the working environment*, which allows individual member states to maintain a higher level of protection than prescribed by the EU. Introducing national provisions is more difficult as it is thought to be more likely to jeopardise harmonisation. The provision must be based on new scientific evidence and relate to the protection of the environment or the working environment. The problem must be specific to the Member State, thus not applicable to the entire union, but neither does it have to be within that state alone.<sup>3</sup> Any discrepancy has to be submitted to the Commission that has six months to approve or reject the provision.<sup>4</sup>

---

<sup>1</sup> The treaty was renamed by the Lisbon Treaty and was earlier named Treaty Establishing the European Community (TEC)

<sup>2</sup> Case C-300/89 *Commission v Council* (Titanium Dioxide) [1991] ECR-I 2867

<sup>3</sup> Case T-182/06 *Netherlands v Commission* [2007] ECR II-2003, para. 65

<sup>4</sup> Article 114(6)



The SEA also introduced the environmental title that now comprises Articles 191-193 TFEU. Provisions based on these articles originate from environmental aspects, in contrast to provisions based on Article 114 that originate from the internal market. In Article 191(1) the union policy on the environment is defined as the pursuit of the following objectives:

- *preserving, protecting and improving the quality of the environment,*
- *protecting human health,*
- *prudent and rational utilisation of natural resources,*
- *promoting measures at international level to deal with regional or worldwide environmental problems, and in particular combating climate change.*

Article 191(2) prescribes the environmental policies that the pursuit of the objectives is based upon. The policy shall be aimed at a high level of protection, as repeated from the common provisions in Article 3 TEU. This should not be construed as necessarily the *highest* that is technically possible, but rather what is deemed as compatible with the taken measure.<sup>5</sup> Three other general principles are explicitly stated as the base of the Union policy.

The *precautionary principle* is the risk management approach used in the environmental legislation of the EU. The principle prescribes that all the available scientific information needs to be assessed and evaluated, especially acknowledging and taking into consideration the level of scientific uncertainty, before making a decision. The level of risk to society must be deemed acceptable and is central in deciding whether to act or not to act. To do nothing may be a response in its own right.<sup>6</sup> If a measure is taken, it should be proportional to the level of protection, non-discriminatory, consistent with similar measures and based on a cost-benefit analysis. It should also be subject to review as new scientific data becomes available and the producing of new scientific data should be made to be able to make a more comprehensive risk assessment.<sup>7</sup>

The *preventive principle* prescribes that action is preferably to be taken before actual damage occurs. Having to repair damage, instead of preventing it, is most often environmentally less successful and economically more costly.

The *polluter pays principle* determines that the producer of the pollution, instead of society and the taxpayers, should bear the cost for the prevention and the reparation of it to reflect the actual cost of production. The principle works to fairly allocate the costs, but also as an incentive to reduce the environmental pollution. It can at times be difficult to determine who should be regarded as the polluter, as most parties (the consumer, the producer, the retailer etc.)

---

<sup>5</sup> Case C-341/95 *Betatti v Safety Hi-Tech* [1998] ECR I-4377, para. 47

<sup>6</sup> European Commission; *Communication on the Precautionary Principle*; COM [2000] 1 final, p. 15

<sup>7</sup> *Id.*, p. 4

contribute to the pollution,<sup>8</sup> and it may also be difficult to determine how the cost of the pollution should be quantified.<sup>9</sup>

Article 192 concerns the decision-making on the objectives set out in the previous article. In the first paragraph, an ordinary legislative procedure is prescribed with shared responsibility between the Parliament and the Council. However, an exception is available in the second paragraph for (a) *provisions primarily of a fiscal nature* or (b) *measures affecting town and country planning, quantitative management of water resources or affecting directly or indirectly, the availability of those resources, land use, with the exception of waste management* or (c) *measures significantly affecting a Member State's choice between different energy sources and the general structure of its energy supply*. The interpretation of the second paragraph has caused considerable theoretical problems concerning its interpretation, but it is seldom used in practice.<sup>10</sup>

The Member States also enjoy a certain national autonomy as prescribed in Article 193. It is free to maintain or introduce more protective measures than prescribed by the community, subject to the compatibility with the treaties, in particular the internal market.<sup>11</sup> The Commission must be notified of the measure, but it is subject to approval. In addition, Member States are also free to pursue its own policies in areas the EU has not acted in.

The choice of either Article 114 or Article 192 as the legal basis affects the modality of the regulation, but the legislator cannot freely choose the legal basis as it sees fit. The choice has to be based on objective factors. If the regulation contains elements of both harmonizing and environmental nature, it must still be based on a single legal basis if a main or predominant purpose can be identified.<sup>12</sup> The combination of two various legal bases should be seen as an exceptional measure, only used when neither purpose is secondary and the two are *indissociably linked*.<sup>13</sup>

The EU legislative process can result in two different forms of legal acts of general application, as outlined in Article 288 TFEU. A *directive* comprises a result that is to be achieved, but leaves it to national authorities to adapt their laws to achieve the result. Each directive is given a deadline for the national implementation, after which it may become directly effective for individuals if not implemented sufficiently or at all. The second legal act, the *regulation*, becomes immediately and directly enforceable in every member state. Unlike the directive, the regulation shall not be implemented into the national legislation.

---

<sup>8</sup> For example, see case C-188/07 *Commune de Mesquer v Total* [2008] ECR I-4501

<sup>9</sup> For example, see case C-254/08 *Futura Immobiliare v Comune di Casoria* [2009] ECR I-6995

<sup>10</sup> Jans & Vedder; p. 59

<sup>11</sup> Article 34

<sup>12</sup> Case C-178/03 *Commission v Parliament and Council* [2006] ECR I-107, para. 40-42

<sup>13</sup> *Id.* at 43

Hence, the competence of individual Member States to have more stringent legislation is dependent on the type of legal act.

## 3. The European Union chemicals policy

### 3.1 Introduction: the European Union's new chemicals policy

In the late 1990s, concern had risen over an insufficient EU chemicals policy. The rigorous testing requirements of new substances in contrast to the slow and ineffective assessment by several different authorities of the substances already introduced to market. Also, the lack of availability and exchange of information, leading to increased costs and unnecessary testing, was seen as another major concern. As a result, new and possibly more efficient substances were difficult to introduce to the market while existing and possibly harmful substances were difficult to remove from the market. This led to a lack of competitiveness and innovation on the substance market.<sup>14</sup>

The work on a new chemicals policy was initiated. The aim was to create a new harmonized system with progressive and interconnecting regulation, setting a new global standard for chemicals policy. This effort would develop into several new major regulations and a new official agency overseeing the chemicals system. In the following, the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and the Regulation on Classification, Labelling and Packaging (CLP Regulation) will be presented before the Biocidal Products Regulation (BPR), which has a larger extent of application on antifouling, will be examined in further detail.

### 3.2 REACH

Regulation 1907/2006/EC concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is the European Union's policy on the introduction of chemicals on the market. The European Commission first presented the REACH system in a 2001 White Paper and the final version of the regulation passed on 18 December 2006. The new system revolutionized the chemicals policy within the European Union, creating a single system with a coherent procedure for all substances. The legislation is considered one of the most ambitious ever from the European Union, but it has also been controversial and received subject of criticism.<sup>15</sup> The regulation, which replaces several earlier directives and regulations,<sup>16</sup> entered into force on June 1 2007.<sup>17</sup> A phase-in period will be applied for certain substances up until 1 June 2018.<sup>18</sup> REACH is based on the predecessor to Article 114 TFEU, making the measure based on the harmonization of the internal market.

---

<sup>14</sup> European Commission; *Commission White Paper: Strategy for a future Chemicals Policy*; p. 6

<sup>15</sup> Most notably due to the questionable conformity with the WTO Agreement on Technical Barriers to Trade

<sup>16</sup> The regulation repeals Council Regulation (EEC) No 793/93, Commission Regulation (EC) No 1488/94, Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

<sup>17</sup> Article 141

<sup>18</sup> Article 23

REACH requires firms to register all substances imported or produced in quantities above one tonne,<sup>19</sup> with some limitation to application listed in article 2, such as radioactive substances and certain food and animal feed, or substances deemed as sufficiently well-known and safe listed in annexes IV and V of the regulation. REACH is also limited in its applicability on antifouling and other biocidal products, as these were considered adequately regulated by the Biocidal Products Directive (now replaced by the BPR). Active substances that are authorised for other uses than in biocidal products, dual use substances, have to fully comply with the REACH regulation. If it is not a dual use substance, thus covered by the BPR, the substance shall be regarded as registered.<sup>20</sup>

The European Chemicals Agency (ECHA), established by the regulation,<sup>21</sup> manages the database of the registered substances. The agency<sup>22</sup> is located in Helsinki, Finland and is responsible for some of the technical, scientific and administrative aspects of the regulation, including helping companies to comply with the regulation and to provide information on chemicals. Subsequent regulations have also increased the role of ECHA and it has now assumed a similar role in the handling of the CLP regulation and the BPR.

Under the mantra “no data, no market” the registration involves the submission of a technical dossier containing formal details and *all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant* or at minimum the information prescribed in annex VII and VIII of the regulation.<sup>23</sup> However, it is still the responsibility of manufacturers, importers and downstream users to ensure that the substances do not adversely affect human health or the environment.<sup>24</sup> If there is more than one manufacturer and/or importer of the substance, the registration is made through a joint submission to streamline the register and keep the costs low. A lead registrant, on behalf of all the applicants, can submit the information, or each can submit the information separately if it would be disproportionately costly, commercially detrimental or disagreements on the information submitted would arise.<sup>25</sup> The registered substances are also subject to data sharing in order to avoid unnecessary testing, both to lower cost and to avoid inflicting harm on vertebrate animals.<sup>26</sup>

The pre-registration of phase-in substances has been divided into three phases. By 1 November 2010, registration for all substances imported or manufactured in quantities above 1,000 tonnes and substances classified as most toxic had to be submitted. On 31 May 2013, the same deadline passed for quantities of 100-1,000 tonnes and the last deadline for quantities below 100 tonnes is set for 31

---

<sup>19</sup> Articles 5-6

<sup>20</sup> Article 15(2)

<sup>21</sup> Article 75

<sup>22</sup> Referral to the *Agency* in REACH refers to ECHA; Article 3(18)

<sup>23</sup> Article 12

<sup>24</sup> Article 1(3)

<sup>25</sup> Article 11

<sup>26</sup> See Title III (Articles 25-30)

May 2018. For every substance registration, a fee is usually charged to cover the administrative expenses.<sup>27</sup>

The *evaluation* step of REACH is regulated in Title VI. It is divided in two forms; dossier evaluation and substance evaluation. The dossier evaluation is done to examine the testing proposals of the dossier, mostly to ensure that no unnecessary testing on vertebrate animals is done.<sup>28</sup> It may also serve as a compliance check of the registration, whether the information requirements in Articles 10, 12 and 13 are followed in the dossier. If necessary, ECHA may decide that further testing or other information is required.

The second form, the substance evaluation, is based on Article 44 and evaluates whether the substance itself poses a risk to human health or the environment. The evaluation is based on the three criteria listed in the article; *hazard information, exposure information and tonnage*. Evaluating risks based on these criteria, ECHA compiles a draft *Community rolling action plan* (CoRAP). The CoRAP covers a period of three years and specifies which substances are to be evaluated each year.<sup>29</sup> A competent authority from a Member State does the evaluation, with ECHA responsible for coordinating the evaluation process and ensuring that each substance in the CoRAP is assigned to a competent authority and evaluated. The Member State Committee<sup>30</sup> may propose amendments to the draft plan and the final plan is to be decided upon in unity.

The *authorisation* of chemicals is made *to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative[s]*.<sup>31</sup> The substances of very high concern (SVHC) are substances considered to have serious and often irreversible effects. They are identified and listed in Annex XIV based upon the criteria in Article 57, including substances meeting the criteria for classification in the hazard class carcinogenicity, mutagenicity, reproductive toxicity, PBT, vPvB and/or endocrine disrupting properties.

While ECHA is responsible for including substances in the Annex XIV-list, the Commission is responsible for taking decisions on applications for authorisations of such substances. This division is made to balance ECHA's responsibility to ensure human health and the environment under the precautionary principle and the Commission's interest of ensuring the functioning of the internal market.<sup>32</sup> Manufacturers, importers and downstream users may apply for authorisation of a SVHC substance for a certain use. Authorisation is granted if the risks to human health and environment are

---

<sup>27</sup> The fee is based upon Regulation (EC) 340/2008 as amended by Regulation (EU) 254/2013

<sup>28</sup> See Article 40

<sup>29</sup> Article 44(2)

<sup>30</sup> Set up according to Article 76(1)(e)

<sup>31</sup> Article 55

<sup>32</sup> Jans & Vedder, p. 452

adequately controlled and conditions may be imposed to further ensure compliance.<sup>33</sup> This does not apply to substances for which it is not possible to determine a safe threshold or substances that have PBT or vPvB properties.<sup>34</sup> If an authorisation may not be granted based upon these criteria, it may only be granted if it is shown that the socio-economic benefits outweigh the risks involved and no suitable alternatives exist.<sup>35</sup>

A substance may also pose a risk deemed as unacceptable on a Community-wide basis, hence subject to *restriction* in accordance with Title VIII of the REACH regulation. Inclusion on the list of restricted substances, found in Annex XVII, entails that the substance *shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction*.<sup>36</sup> Any decision on restriction should also take into account the socio-economic impact, including availability of alternative methods.<sup>37</sup> However, the socio-economic aspect has a smaller role in the authorisation process and cannot outweigh the risks to human health and the environment.<sup>38</sup> Also, if the environmental objectives for the river basin management plans, as referred to in Article 4(1) of the Water Framework Directive, are not met, the authorisations granted for the use of the substance concerned in the relevant river basin may be reviewed.<sup>39</sup>

Organostannic (organotin) compounds are featured on the list of restricted substances, including tributyltin (TBT). The compound was widely used as an efficient antifoulant during the mid to late 20<sup>th</sup> century, but discovery of its devastating effect on marine organisms, such as the development of imposex in marine gastropods, led to the gradual banning of the substance for use in antifouling. The European Union first included it in the list of restricted substances in Annex I of the Directive on restrictions on marketing and use of certain dangerous substances and preparations in 1989.<sup>40</sup> The restriction applied to vessels with an overall length of less than 25 metres. In 2002, Annex I was amended again and the restriction was extended to apply to all vessels regardless of length.<sup>41</sup> On 17 September 2008 the 2001 AFS Convention<sup>42</sup> entered into force, an international treaty to prohibit the use of harmful organotin compounds as biocides in antifouling. The treaty has been signed and ratified by the European Union and all the EU member states.<sup>43</sup> EU took the forefront in implementing the AFS Convention and decided, already in 2003, on a regulation (EC No 782/2003) prohibiting the use of organotin compounds on

---

<sup>33</sup> Article 60(2)

<sup>34</sup> Article 60(3)

<sup>35</sup> Article 60(4)

<sup>36</sup> Article 67(1)

<sup>37</sup> Article 68(1)

<sup>38</sup> Jans & Vedder, p. 453

<sup>39</sup> Article 61(5)

<sup>40</sup> Council Directive 89/677/EEC amending Directive 76/769/EEC, Article 1(21),

<sup>41</sup> Commission Directive 2002/62/EC, Annex

<sup>42</sup> The International Convention on the Control of Harmful Anti-fouling Systems in Ships

<sup>43</sup> See Regulation 2003/782/EC

ships. As from 1 January 2008 the ships shall *either* not bear organotin compounds which act as biocides in anti-fouling systems on their hulls or external parts and surfaces, *or* bear a coating that forms a barrier to such compounds leaching from the underlying non-compliant antifouling system. After 1 January 2008 ships with TBT antifouling was not allowed to enter European harbours. The Regulation applies to all ships including pleasure vessels. If the vessel is 24 metres or longer, it is required to have a declaration of its anti-fouling system and appropriate documentation (e.g. a paint receipt or contractor's invoice), or appropriate endorsement. This is also required if the vessel is not anti-fouled to confirm that is the case. Vessels of 400GT and above require an Anti-Fouling Systems Certificate. For ships less than 24 metres in length, it is not necessary to provide for a specific survey or declaration since these ships, mainly recreational crafts and fishing vessels, will be adequately covered under the provisions of Directive 76/769/EEC, replaced by REACH (Regulation 1907/2006/EC).

The process of inclusion in the list of restricted substances in Annex XVII is initiated by a Member State, or ECHA on the request of the European Commission, upon concern over a certain substance by the preparation of a dossier conforming to the requirements of Annex XV and containing suggestions for restrictions. The dossier is sent to two of ECHA's committees, the Risk Assessment Committee and the Socio-Economic Analysis Committee, for a check of the conformity of the dossier to the requirements in Annex XV and an opinion of the proposed restrictions.<sup>44</sup> The European Commission makes the final decision of restriction.<sup>45</sup>

### 3.3 The CLP regulation

The Regulation on Classification, Labelling and Packaging of substances and mixtures (1272/2008/EC), or the CLP regulation, is a EU regulation adopted on 16 December 2008 based on Article 95 of TEC<sup>46</sup>. It repeals the Dangerous Substances Directive<sup>47</sup> and the Dangerous Preparations Directive<sup>48</sup> and amend the REACH regulation. The CLP Regulation introduces a new system for classification and labelling of hazardous substances in the Union to comply with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), a system for an international standard of classification and labelling, created by the United Nations. The CLP regulation was introduced transitionally and fully replaced earlier legislation from 1 June 2015.<sup>49</sup>

---

<sup>44</sup> Articles 70-71

<sup>45</sup> Article 73

<sup>46</sup> Corresponding to Article 114 TFEU

<sup>47</sup> Directive on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (67/548/EEC)

<sup>48</sup> Directive concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (1999/45/EC)

<sup>49</sup> Article 60



GHS was first introduced during the United Nations Conference on Environment and Development (the Rio Conference) in 1992. The intention was to create a global standard for classification and labelling of chemicals to replace the many different standards in use worldwide. Since then several nations have implemented the system into their legislation, including the European Union and the United States<sup>50</sup>. In Chapter 4.1 of GHS, chemicals hazardous to the aquatic environment are regulated with guidance on hazards to the aquatic environment in Annex 9 and guidance on transformation/dissolution of metals and metal compounds in aqueous media in Annex 10.<sup>51</sup>

The CLP regulation is the implementation of GHS in the European Union. It requires companies to appropriately classify, label and package the substances and mixtures before placing them on the market. The regulation has been in force since 20 January 2009 and will be transitionally implemented. The obligation to classify substances according to CLP applied from 1 December 2010 and the obligation to classify mixtures according to CLP will apply from 1 June 2015.<sup>52</sup> The general obligations of the CLP regulation applies for manufacturers, importers and downstream users to substances and mixtures before placing on the market and for substances not placed on the market if they are subject to registration or notification according to the REACH regulation.<sup>53</sup> The more specific requirements on classification and labelling for substances and mixtures hazardous to the aquatic are found in Part 4 of Annex I. The Annex details the classification, testing and labelling requirements specific for hazards presented to aquatic organisms and the aquatic ecosystem.

In August 2009, ECHA released the first version of the *Guidance on the Application of the CLP Criteria* to assist in the implementation of the regulation. The non-legally binding document provides detailed guidance on the application of the new set of rules based upon the guidance given in GHS and the additional guidance documents provided by ECHA.<sup>54</sup> In Part 4 of the guidance document, the specifics regarding substances and mixtures hazardous to the aquatic environment are detailed.

### 3.4 Biocidal Products Regulation

*Regulation (EU) 528/2012 concerning the making available on the market and use of biocidal products*, or the Biocidal Products Regulation (BPR), entered into force on 1 September 2013 and changed the system for approval of biocidal active substances and authorisation of biocidal products in the European Union. The aim of the legislation is to increase safety for human and animal health and

---

<sup>50</sup> The Hazard Communication Standard was revised to be consistent with GHS in 2012

<sup>51</sup> As of the Fourth revised edition (2011)

<sup>52</sup> Article 62

<sup>53</sup> Article 4(1-2)

<sup>54</sup> *Guidance on the application of the CLP criteria*; European Chemicals Agency (version 4.0, November 2013); p. 512

the environment as well as encourage innovation of biocidal products with a better profile.

BPR is based on article 114 TFEU and part of an overall chemicals policy change within the European Union, in line with REACH and the CLP regulation, harmonizing the current EU legislation. It repeals the Biocidal Products Directive<sup>55</sup> (BPD) that has been in force since 2000. The changes were in part triggered by the report on the impact of the directive submitted by the Commission to the European Parliament and the Council after the first seven years of the implementation.<sup>56</sup> The review found that the directive discouraged the development of new active substances due to the resources being focused on the review programme and the costs and risks of non-inclusion of the substance were deemed too high.<sup>57</sup> The small and medium enterprises (SMEs) were seen as particularly affected by this, creating an unnecessary hindrance for competitiveness on the market further hampering the development.<sup>58</sup> It was deemed too early to draw any conclusion on the protection level offered by the legislation, but overall it was seen as having too few benefits compared to the high level of bureaucracy.<sup>59</sup> Combined with the more centralized approach overall in the chemical policy, an update in legislation was deemed necessary.

On June 12<sup>th</sup> 2009, the Commission submitted its proposal for a replacement of the BPD.<sup>60</sup> The Parliament adopted the legislation after its second reading in January 2012 and the Council adopted it in May later that year. The regulation entered into force on 1 September 2013, but it will be phased-in to allow for a transitional period and not be fully in force until 31 December 2024.

BPR applies to both biocidal products and articles treated with such products, excluding products regulated by special legislation or any explicit provision in other EU legislation listed in Articles 2(2) and 2(3), which includes REACH and the Water Framework Directive.<sup>61</sup> This is an enlarged scope of application compared to BPD as treated articles were not explicitly included in the scope and did not encompass treated articles imported from outside the EU. A biocidal product is defined in Article 3(1)(a) 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*

---

<sup>55</sup> Directive 98/8/EC concerning the placing of biocidal products on the market

<sup>56</sup> European Commission; *Study on Impact of the implementation of Directive 98/8/EC concerning the placing on the market of biocidal products*; Final Report for DG Environment October 10th 2007;

<sup>57</sup> Id. p. 5

<sup>58</sup> Id. p. 6

<sup>59</sup> Id. p. 32

<sup>60</sup> European Commission [2009]; *Proposal for a regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products*;

<sup>61</sup> Article 2.1-3

*action of, or otherwise exerting a controlling effect on, any harmless organism by any means other than mere physical*

or any other substance or mixture generated from such that does not fall under the first indent but has the same area of use. In Article 3(1)(l), a *treated article* is defined as *any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products*.

In Annex V of the regulation, the biocidal products are divided into 22 different product-types (PT) in 4 main groups; disinfectants (PT 1-5), preservatives (PT 6-13), pest control (PT 14-20) and other biocidal products (PT 21-22). The list deviates slightly from the corresponding list in BPD as PT 20, *Preservatives for food and feedstocks*, has been moved, consequently moving *Control of other vertebrates* from PT 23 in BPD to PT 20 in BPR. Antifouling products comprise product-type 21 of the fourth main group and are defined as *[p]roducts used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water*. Under which PT the product is classified as is important as some PTs are exempted from certain rules in the regulation as will be seen further on.

#### 3.4.1 Approval of active substances

The active substances in biocidal products are approved at Union level and regulated by BPR unless it is a dual-use substance and registered in accordance with REACH (see section 3.2). An active substance is defined in the regulation as *a substance or a micro-organism that has an action on or against harmful organisms*.<sup>62</sup> The European Chemicals Agency (ECHA), established in 2007 by the REACH regulation and based in Helsinki, is responsible for some of the technical, scientific and administrative aspects of the regulation, including helping companies to comply with the regulation and to provide information on biocides.<sup>63</sup> The agency is also responsible for the register for biocidal products, R4BP.

The regulation differentiates between *new active substances* and *existing active substances*. A substance regarded as an existing active substance was on the market on 14 May 2000 for purposes other than scientific or product and process-oriented research and development, while new active substances were introduced after this date.<sup>64</sup> For existing active substances certain special provisions apply for a transitional period.

All new active substances have to be approved by the European Commission and added to the list of approved substances.<sup>65</sup> The approval is, however, based on the evaluation and opinion of ECHA, which has a critical influence on the

---

<sup>62</sup> Article 3(1)(c)

<sup>63</sup> *The Agency* in the regulation refers to ECHA, see Article 3.1(x)

<sup>64</sup> Article 3(1)(d-e)

<sup>65</sup> Article 9(1)

decision. An approval can be given for a maximum of ten years and it may also be conditioned as appropriate, inter alia through the restriction to certain product types, the purity of the substance in the product or the manner and area of use.<sup>66</sup>

The approval is based on the exclusion criteria listed in Article 5, which are new compared to the BPD. An active substance should not be approved if it is considered carcinogen, mutagen or toxic for reproduction according to the CLP regulation or has endocrine-disrupting properties or meets the criteria for being PBT or vPvB according to the REACH regulation.<sup>67</sup> However, under certain circumstances an active substance may be approved despite not meeting these conditions if it is considered too important in contrast to its negative effects. An active substance may be approved despite the exclusion criteria if the active substance bears negligible risks, is essential to prevent serious danger or if a prohibition would result in disproportionate negative impact.<sup>68</sup> In deciding whether an active substance shall be approved, consideration has to be taken to the availability of suitable and sufficient alternative substances or technologies. However, such a substance may only be approved for an initial period of five years.<sup>69</sup>

An active substance that has met the criteria for exclusion may be a candidate for substitution. A candidate for substitution is considered hazardous in combination with its use, but due to the lack of better alternatives for its use it is approved as a substitute. Due to this, a candidate for substitution will be subject to a comparative assessment and also the approval or renewal of approval will be for a shorter period of time. The objective is to phase-out the substances of particular concern and to replace them with more suitable alternatives. If the active substance meets any of the criteria listed in the first paragraph, it may be chosen as a candidate. Information on the potential candidates will then be made public for a period of up to 60 days, allowing interested third parties to submit additional information, i.e. alternatives to the candidate, before ECHA forms its opinion. An approval of a candidate for substitution may not exceed seven years and not exceed five years if any of the exclusion criteria is met.<sup>70</sup>

Existing active substances, introduced on the market before 14 May 2000, are subject to a review programme.<sup>71</sup> The Commission work programme was set up by the BPD, led by the Directorate-General Joint Research Centre (DG JRC).<sup>72</sup> The programme is continued in BPR,<sup>73</sup> with the coordination of the evaluation process overtaken by ECHA. The review programme evaluates all existing active

---

<sup>66</sup> Article 4(1), 4(3)

<sup>67</sup> Article 5(1)(a-e)

<sup>68</sup> Article 5(2)(a-c)

<sup>69</sup> Article 4(1)

<sup>70</sup> Article 10(4)

<sup>71</sup> Article 90(2)

<sup>72</sup> See Article 16(2) in the Biocidal Products Directive (98/8/EC)

<sup>73</sup> Article 89(1)

substances on the effects on health and the environment, determining either the inclusion or the non-inclusion in the list of approved substances.<sup>74</sup>

According to the transitional rules in Art. 89(2) a Member State may continue to apply its current system or practice of making a given biocidal product available on the market until two years after the date of approval of the last of the active substances to be approved in that biocidal product. Products may, however, only be allowed on the market if they contain existing active substances which have been or are being evaluated at EU level, but have not yet been approved for that product-type. If an active substance is not approved, a Member State may continue to apply its current rules for up to 12 months.

### 3.4.2 Products authorisation

All biocidal products need authorisation before being introduced on the market, unless the transitional rules apply. There are several different processes available for authorisation, depending on the product and the number of intended member states the product is to be marketed in. An authorisation may be applied for at Union level and granted by the Commission for the entire market, a *Union authorisation*.<sup>75</sup> However, antifouling products (PT 21) are among the product-types excluded from this type of authorisation and are not authorised at Union level.<sup>76</sup> Instead, these products must be approved at a national level.

#### **Authorisation in a member state**

An authorisation holder applies for a national authorisation directly with the competent authority as designated by each member state.<sup>77</sup> The application consists of a dossier containing all relevant information sent to the competent authority for evaluation. An authorisation may be granted for a single biocidal product or an entire *biocidal product family*. A biocidal product family is *a group of biocidal products having similar uses, the active substances of which have the same specifications, and presenting specified variations in their composition which do not adversely affect the level of risk or significantly reduce the efficacy of the products*.<sup>78</sup> A single authorisation covers all the products in the product family. A product authorisation may be granted for a maximum of ten years.<sup>79</sup>

In Article 19 of the regulation, the conditions for granting an authorisation are defined. All the active substances in the product have to be approved as prescribed in the regulation. This also involves the conditions put in the approval

---

<sup>74</sup> List of approved substances can be found at:

[http://ec.europa.eu/environment/chemicals/biocides/active-substances/approved-substances\\_en.htm](http://ec.europa.eu/environment/chemicals/biocides/active-substances/approved-substances_en.htm)

<sup>75</sup> Article 41

<sup>76</sup> Article 42(1)

<sup>77</sup> See Article 81, a list of competent authorities is available at:

<http://echa.europa.eu/contacts-of-the-member-state-competent-authorities>

<sup>78</sup> Article 3(1)(s)

<sup>79</sup> Article 17(4)

of the active substance such as the approval for the active substance in the particular product-type.

The dossier is evaluated according to the fulfilment of the criteria in Article 19(1)(b) and the common principles of evaluation specified in Annex VI of the regulation. The evaluation is a risk assessment on the effects of the product on human and animal health, the environment and target organisms and whether the product is deemed sufficiently efficient based upon scientific principles. The regulation also specifies certain factors that should be taken into consideration when evaluating the fulfilment of the criteria, including the consequences of the use and disposal of the biocidal product and the cumulative and synergistic effects of it.

The decision-making of the environmental effects should primarily be based upon the PEC/PNEC risk assessment.<sup>80</sup> The assessment is used to indicate the likelihood of adverse effects to occur by determining the concentration level of the substance that will not lead to any unacceptable effects on organisms (**Predicted No Effect Concentration**) comparing it with the foreseeable concentration in the environment if the product is authorised (**Predicted Environmental Concentration**). The method is formulated to adapt to the actual environment where the product is to be used and data is based on the species most sensitive to the substance.<sup>81</sup> If a PEC/PNEC ratio cannot be determined, a *qualitative estimation* must be made.

In marine environments, the conditions laid down in Article 19(1)(b), criterion iv, are especially central in the evaluation. It states that the biocidal product must not have any unacceptable effects itself having particular regard to

- *the fate and distribution of the biocidal product in the environment,*
- *contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,*
- *the impact of the biocidal product on non-target organisms,*
- *the impact of the biocidal product on biodiversity and the ecosystem;*

These conditions must also ensure that the authorisation of the product does not undermine the compliance of standards laid down in any of the Union's directives on water policy or marine environment, including the Water Policy Framework, the Marine Strategy Framework Directive and the Priority Substance Directive,<sup>82</sup> nor the international agreements on the protection of river systems or marine waters from pollution.<sup>83</sup> If the conditions in Article 19(1)(b), criterion iv, are not fully met, the product may be made available on

---

<sup>80</sup> Annex VI, para 65

<sup>81</sup> See European Commission Joint Research Centre [2003]; *Technical Guidance Document on Risk Assessment*; p. 99-106

<sup>82</sup> These two directives are detailed in Section 4 of this report

<sup>83</sup> Annex VI, para 67

the market anyway if not authorising it would lead to disproportionate negative impacts for society in comparison to the risks. The product may be subject to appropriate risk mitigation measures to minimise exposure to humans and the environment.<sup>84</sup>

A biocidal product containing an active substance that is a candidate for substitution in accordance with Article 10(1) is also subject to a comparative assessment before authorisation. The comparative assessment is carried out to ensure that no unnecessarily hazardous products are made available on the market when suitable, less-hazardous alternatives are already available. Article 23 prescribes that the competent authority should prohibit or restrict the product's availability on market if another authorised biocidal product or non-chemical control or prevention method already exists with significantly lower overall risk and with no other significant economic or practical disadvantages.<sup>85</sup> The alternative must have *the chemical diversity of the active substance to minimise the occurrence of resistance in the target harmful organism*.<sup>86</sup>

Some products must be used in practice to acquire experience before a comparative assessment can be made. For these *exceptional cases*, the biocidal product may be granted an authorisation for a period up to four years to gather the experience before the comparative assessment is made.<sup>87</sup> A product that has been subject to comparative assessment in accordance with Article 23 may be granted authorisation or renewal of authorisation for a period of up to five years.<sup>88</sup> As with the active substances that are candidates for substitution, these biocidal products are intended to be phased-out and replaced by safer alternatives.

### **Authorisation through mutual recognition**

As Union authorisations are not available for antifouling products (PT 21), a product intended to be marketed in several member states must be authorised through the process of mutual recognition. The concept of mutual recognition in the European Union first emerged in the *Cassis de Dijon* case<sup>89</sup> and has since evolved both in subsequent court cases and legislation. In Chapter VII of BPR, specified regulation for mutual recognition of biocides is included. There are two processes for mutual recognition of biocides - *mutual recognition in sequence* and *mutual recognition in parallel*.

*Mutual recognition in sequence* is regulated in Article 33. It concerns extending the authorisation of a product already granted authorisation in a Member State into other ones. It requires the applicant to submit an application to each of the states' competent authorities it wishes authorisation in, *Member States*

---

<sup>84</sup> Article 19(5)

<sup>85</sup> Article 23(3)(a)

<sup>86</sup> Article 23(3)(b)

<sup>87</sup> Article 23(4)

<sup>88</sup> Article 23(6)

<sup>89</sup> Case 120/78 *Rewe-Zentrale AG v Bundesmonopolverwaltung für Branntwein* (*Cassis de Dijon*) [1979] ECR 6

*concerned* (CMS) and the original granting Member State, *the reference Member State* (RMS), to forward the original national authorisation, in a translated version if required, to the competent authorities. If the Member State agrees with the RMS's evaluation, it will grant authorisation to the product.

*Mutual recognition in parallel* is regulated in Article 34 and instead used for a biocidal product that is not currently recognised in a Member State, but the applicant intends to seek authorisation for the product simultaneously in several Member States. The application is sent to the competent authority of a Member State of its choice, also referred to as *the reference Member State* (RMS), containing both the information required for the regular authorisation process and a list of all Member States where authorisation is sought, *the Member States concerned* (CMS). The application is then evaluated by the RMS concerning the risks involved to environment and human and animal health as well as establishing any potential conditions or restrictions to the use of the product. The assessment report is thereafter sent to the applicant for a chance to issue written comments taken into consideration in the final evaluation before forwarding it to the CMS. The Member States (RMS and CMS) will then agree on a summary of the products characteristics and either grant or deny the application.

However, in both processes disagreements between the RMS and CMS on the mutual recognition may exist, leading to the refusal of a CMS to authorize a product already authorised in another Member State or the inability of Member States to agree on a summary in a mutual recognition. To solve this, the disagreement is first sent to a Coordination Group that has 60 days to get the parties to reach an agreement.<sup>90</sup> The coordination group is a body formed by representatives of the Member States and the Commission. If the Coordination Group is unable to reach an agreement, the matter is sent to the Commission to make a final decision.<sup>91</sup> The Commission, if necessary using the scientific and technical expertise of ECHA,<sup>92</sup> will make a binding decision on the matter that the parties must comply within 30 days.<sup>93</sup>

A Member State may derogate from mutual recognition by refusing to grant authorisation or adjust the terms and conditions of the authorisation provided that it is done on justifiable grounds. These grounds are listed in Article 37(1) as:

- (a) *the protection of the environment;*
- (b) *public policy or public security;*
- (c) *the protection of health and life of humans, particularly of vulnerable groups, or of animals and plants;*
- (d) *the protection of national treasures possessing artistic, historic or archaeological value; or*
- (e) *the target organisms not being present in harmful quantities.*

---

<sup>90</sup> Article 35(3)

<sup>91</sup> Article 36(1)

<sup>92</sup> Article 36(2), see also Article 38

<sup>93</sup> Article 36(4)



Additionally, biocidal products that contain active substances that have met any of the exclusion criteria in Article 5 or are candidates for substitution in accordance with Article 10 the Member States have extended control over and increased possibility to derogate. The Member State must communicate with the applicant and inform it on the grounds of derogation. The two must then seek to reach an agreement within 60 days of the communication. If an agreement cannot be reached, the Commission is again involved and delivers a decision the Member State must comply within 30 days.<sup>94</sup>

### **Simplified authorisation**

For products that have less need for monitoring, *the simplified authorisation procedure* may be an alternative to the mutual recognition process. The purpose is to encourage the use of biocidal products that are less harmful to the environment and to human and animal health. A product that is granted such an authorisation can freely be made available throughout the Union, provided each Member State that the product is made available in is notified at least 30 days prior.<sup>95</sup> In Article 25, the conditions for eligibility for the simplified authorisation procedure are listed. The biocidal products must comply with all of the following conditions:

- (a) all the active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex;*
- (b) the biocidal product does not contain any substance of concern;*
- (c) the biocidal product does not contain any nanomaterials;*
- (d) the biocidal product is sufficiently effective; and*
- (e) the handling of the biocidal product and its intended use do not require personal protective equipment;*

Annex I of the BPR contains active substances of low toxicity, including weak acids, alcohol and vegetable oils. The list of substances was initially carried over from the BPD, but is open for applications to expand the list. Due to the nature of the active substances included in the list, it is unlikely that any antifouling product will be considered eligible for the simplified authorisation procedure.

### **3.5 Summary: Antifouling and the European Union chemicals policy**

The chemical policy in the European Union is currently undergoing major changes with the aim of both harmonizing to global standards and centralizing the processes involved. The many changes have led to the current transitional period. The legislation is not fully in force yet and there is a limited number of practical examples to draw any conclusions from.

The authorisation of antifouling biocides can largely be divided into two parts, the authorisation of the active substances used in the antifoulant and the authorisation of the antifouling biocide itself. The authorisation of the active substance is made at a Union level, regulated either by BPR or REACH depending

---

<sup>94</sup> Article 37(2)

<sup>95</sup> Article 27(1)

on the uses of the substance. Active substances used exclusively for biocides (single-use substances) are regulated by BPR, while substances used also for other chemical products (dual-use substances) have to be registered according to REACH.

The authorisation of biocidal products can usually be made both at a Union level and a national level. However, antifouling products are one of the product-types that are not granted Union authorisation, thus allowing for increased national influence on which products are approved and ability to adjust to local conditions. The refusal of authorisation or derogation from mutual recognition must be based upon the criteria set in the regulation, found in Annex VI and Article 37(1). For biocidal products approved in other Member States, the European Commission ultimately decides disagreements on the mutual recognition.

For biocidal products affecting the water environment, such as antifouling products, referral is also made to the Water Framework Directive, the Marine Strategy Framework Directive and the Priority Substance Directive. The approval of a product should not jeopardise the conformity with these directives, making them central in the authorisation process. In the following section, these directives will be presented.

## 4. European Union water quality policy

### 4.1 Introduction: water and marine environmental legislation

In the following section, the two major water quality directives will be examined. The water environmental legislation has during the 21<sup>st</sup> century moved from dispersed specific legislative measures to larger framework directives ensuring a coherent application of environmental standards for all types of water bodies. Additionally, with the introduction of the Marine Strategy Framework Directive the Union got its first legislation regulating the marine environment. The ultimate goal of the legislative measures is to create a safe, clean, healthy and productive water and marine environment. Reaching the chemical standards is vital to comply with the directives; hence the close connection and importance to the regulation of biocidal antifouling products.

### 4.2 The Water Framework Directive

Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, or the Water Framework Directive (WFD), is an integrated Community policy on water. The directive entered into force on 22 December 2000 and was to be implemented by the Member States by 22 December 2003.<sup>96</sup> The directive streamlines the Community legislation on water policy and repealing seven *first wave*<sup>97</sup> water directives.<sup>98</sup> The key objective of the Directive is to achieve good status for all the water bodies within the Community by the year 2015.

WFD is based on Article 174 of TEC<sup>99</sup> and establishes a framework for the protection of inland surface waters, transitional waters, coastal waters and groundwaters.<sup>100</sup> The application of the Directive on antifouling may also affect the application of antifouling paint, cleaning of the hull and alternative antifouling methods due to the exposure of hazardous substances and metals to waters that the activities may cause. To ensure coherent and successful process, a common strategy for the implementation of the Directive was developed by the Member States, the European Commission and Norway.<sup>101</sup> Following the context of this common strategy, several working groups and joint activities developed

---

<sup>96</sup> Article 24-25

<sup>97</sup> The term was used by the European Commission to describe the Community's first legislation on water policy emerging during the 1970s, see *Introduction to the new EU Water Framework Directive*, available at:

[http://ec.europa.eu/environment/water/water-framework/info/intro\\_en.htm](http://ec.europa.eu/environment/water/water-framework/info/intro_en.htm)

<sup>98</sup> See Article 22

<sup>99</sup> Corresponding to Article 191 TFEU

<sup>100</sup> For definitions of the different water types, see Article 2(1-3, 6-7)

<sup>101</sup> See EU Water Directors [2001]; *Common Implementation Strategy for the Water Framework Directive (2000/60/EC) – Strategic Document as Agreed by the Water Directors under Swedish Presidency 2 May 2001*

several non-legally binding guidance documents to aid the Member States in the implementation.<sup>102</sup>

#### 4.2.1 River basin management

The Directive applies the river basin management system, described as a holistic approach to water.<sup>103</sup> The river basin is the *area of land from which all surface run-off flows through a sequence of streams, rivers and, possibly, lakes into the sea at a single river mouth, estuary or delta*.<sup>104</sup> This approach allows for the water to be divided as a natural geographical and hydrological unit, instead of according to administrative or political boundaries. The Member States shall identify the individual river basins within their national territory and assign them to individual river basin districts.<sup>105</sup> A river basin district comprises of an *area of land and sea, made up of one or more neighbouring river basins together with their associated groundwaters and coastal waters*.<sup>106</sup> Due to the holistic approach, the river basin may cover the territory of more than one Member State and thus form an *international river basin district*.<sup>107</sup> For such districts, the Member States shall together ensure coordination and preferably use existing international agreements to achieve this.<sup>108</sup> A district may also extend beyond the territory of the Community. The Member State(s) concerned shall strive to establish coordination with relevant non-Member States, aiming to achieve the objectives of the Directive throughout the entire river basin district.<sup>109</sup>

Each water body is the subject of an initial characterisation in accordance with Article 5. The characterisation requires an analysis of the water body's characteristics, a review of the human activity impact and an economic analysis of the water use. The technical specification for the three requirements is included in Annex II, for the two first requirements, and in Annex III, for the economic analysis. It is subsequently used for the river basin management plan and the programme of measures, and was to be reported by 22 December 2004.<sup>110</sup> The characterisation was subject to review in 2013 and thereafter to be reviewed every six years.<sup>111</sup>

In Article 13, the Directive prescribes that a river basin management plan shall be produced for each river basin district to identify all actions to be taken in the district to reach the objectives set in WFD. For international river basin districts

---

<sup>102</sup> All guidance documents are available at:

[http://ec.europa.eu/environment/water/water-framework/facts\\_figures/guidance\\_docs\\_en.htm](http://ec.europa.eu/environment/water/water-framework/facts_figures/guidance_docs_en.htm)

<sup>103</sup> Jans & Vedder, p. 392

<sup>104</sup> Article 2(13)

<sup>105</sup> Article 3(1)

<sup>106</sup> Article 2(15)

<sup>107</sup> Article 3(3)

<sup>108</sup> Article 3(4)

<sup>109</sup> Article 3(5)

<sup>110</sup> Article 5(1)

<sup>111</sup> Article 5(2)

falling within the Community, the Member States concerned should aim to produce a single river basin management plan. If unsuccessful, the Member States shall produce plans for the territory falling within their borders.<sup>112</sup> The same approach applies to districts exceeding the Community borders with the aim of producing a plan in coordination with non-Member States for the entire river basin district. If unsuccessful, the Member State concerned must produce a plan for the territory within its borders.<sup>113</sup>

The expected content of each river basin management plan is detailed in Annex VII of WFD. The information requested includes, inter alia, mapping of the location and boundaries of the water body, the information required under Article 5, the chemical status of surface water and groundwater and a summary of the programmes of measures adopted under Article 11 (see below). As the plans are updated, they must also contain assessment of progress and summary of, and explanation for, planned measures that have not been undertaken. The construction of the river basin management plans is also subject to public information and consultation as the plans shall be published and made available for comments to the public.<sup>114</sup>

The completion date for the river basin management plans were set to 22 December 2009 and reported to the Commission within three months of publication,<sup>115</sup> with a review planned for 2015 at latest and every six years after that.<sup>116</sup> In 2012, in accordance with Article 18, the Commission published its first report on the implementation of the Directive. It was reported that 75 % of all expected river basin management plans had been adopted and reported. None of the Member States surrounding the Baltic Sea failed to report their plans.<sup>117</sup>

#### 4.2.2 Environmental objectives

The environmental objectives of WFD are found in Article 4. The general objective of the WFD, the achievement of, at least, good ecological status and good chemical status for all surface waters and groundwaters by 2015, is formulated in the first paragraph of the article.

All the surface waters are subject to classification and assigned a status according to their quality. The Directive uses five different ecological status classes: high, good, moderate, poor or bad. A high ecological status for surface waters, the best possible, is defined as having no or very low human pressure to the chemical, morphological and biological qualities of the water. For the lowest

---

<sup>112</sup> Article 13(2)

<sup>113</sup> Article 13(3)

<sup>114</sup> Article 14

<sup>115</sup> Article 13(6), 15

<sup>116</sup> Article 13(7)

<sup>117</sup> European Commission; *Report from the Commission to the European Parliament and the Council on the Implementation of the Water Framework Directive (2000/60/EC) – River Basin Management Plans*; p. 4-5

acceptable status, *good status*, there shall be low human impact and only a slight deviation of what is considered undisturbed condition.<sup>118</sup>

Article 4 also contains exemptions to achieving the set environmental objectives. Exemptions include the deadline for good status extended beyond 2015, the application of less stringent objectives or breach as a result of exceptional circumstances and may be applied providing that the conditions for the exemptions are met.<sup>119</sup> A body of water that has been created or altered by human activity may also be designated as artificial or heavily modified by a Member State if the achievement of good ecological status would have significant adverse effects on important sustainable human development activities and the beneficial objectives for the water body cannot reasonably be reached by environmentally friendly means.<sup>120</sup> An artificial or heavily modified water body is subject to separate environmental objectives and instead of achieving a good environmental status these waters shall achieve good environmental potential. The exemptions to the environmental objectives were the subject of a separate guidance document from the European Commission.<sup>121</sup>

#### 4.2.3 Environmental Quality Standards

Environmental Quality Standards (EQS) applies to contaminant concentrations in water, sediments and/or biota.<sup>122</sup> These become key tools in assessing and classifying the chemical status for each water body. The EQSs are established both by the European Commission and by each individual Member State depending on whether the substance is considered a priority or not.

Article 16(1) outlines the steps to be taken to develop the strategies against chemical pollution of surface waters. It states that the European Parliament and the Council were to *adopt specific measures against pollution of water by individual pollutants or groups of pollutants presenting a significant risk*. The first list of priority substances, becoming Annex X of the WFD,<sup>123</sup> was presented on 20 November 2001.<sup>124</sup> The list was subsequently updated by the Directive on Environmental Quality Standards in 2008 and again reviewed and updated, as prescribed in Article 16(4), in 2012-2013.<sup>125</sup> The list currently contains 45 priority substances considered to present a significant risk to or via the aquatic environment. Of these, 21 are identified as priority *hazardous* substances, including the aforementioned tributyltin (TBT) compounds.<sup>126</sup> Other antifouling

---

<sup>118</sup> Annex V, 1.2

<sup>119</sup> See Article 4(4-6)

<sup>120</sup> Article 4(3)

<sup>121</sup> See European Commission; *Common Implementation Strategy for the Water Framework Directive (2000/60/EC) – Guidance Document No. 20 – Guidance Document on Exemptions to the Environmental Objectives*

<sup>122</sup> Article 3, Directive 2008/105/EC

<sup>123</sup> Article 16(11)

<sup>124</sup> See Decision 2455/2001/EC

<sup>125</sup> See Directive 2013/39/EU

<sup>126</sup> See Annex X, point 30

related substances on the list are diuron and cybutryne (also known under trade name Irgarol), both formerly used in antifouling biocides. The hazardous substances are considered toxic, persistent and liable to bio-accumulate or other substances that give rise to an equivalent level of concern.<sup>127</sup> Each priority substance has a quality standard applicable to the concentration of the substance in surface water and/or biota. These standards must be complied with to reach good chemical status for the body of water.<sup>128</sup>

For other pollutants, *identified as being discharged in significant quantities into the body of water*,<sup>129</sup> the Member States themselves are responsible to develop EQSs. The Member States must also identify which substances are to be regarded as such significant pollutants. An indicative list of the main pollutants is included in Annex VIII. The list contains several pollutants of interest regarding antifouling biocides, including organotin compounds (no. 3), metals (no. 7) and biocides and plant protection products (no. 9). The principles for the development of the EQSs are established in section 1.2.6. of Annex V and for further guidance to ensure coherent implementation, *Guidance Document no. 27*<sup>130</sup> on the derivation of the EQSs was developed.

Copper is among the metals generally considered being such a significant pollutant by the Member States. After the restrictions on the use of TBT in antifouling products, the copper-based antifoulants have been reinstated as the most widely used. Copper is, however, also harmful to aquatic organisms, mainly affecting the respiratory organs,<sup>131</sup> and as such in need of monitoring. The levels of copper in the Baltic Sea have seen an increase during recent years.<sup>132</sup>

The EQSs for the specific pollutants contribute to the parameters for ecological status. If these standards are not met, a water body cannot be classified as having either good or high status.<sup>133</sup>

#### 4.2.4 Programme of measures

The programme of measures contains the actions to be taken during the river basin management plan to achieve the objectives of the Directive. The setting up of the programme of measures is outlined in Article 11 of the WFD. The measures shall be based upon the analysis and review made based upon Article 5 and the environmental objectives created based upon Article 4. The programmes

---

<sup>127</sup> Article 2(29)

<sup>128</sup> Annex V, section 1.4.3.

<sup>129</sup> Annex V, section 1.1.1.-1.1.4.

<sup>130</sup> European Commission; *Common Implementation Strategy for the Water Framework Directive (2000/60/EC) – Guidance Document No. 27*;

<sup>131</sup> Id. p. 54

<sup>132</sup> *Hazardous substances in the Baltic Sea – An integrated thematic assessment of hazardous substances in the Baltic Sea*; Balt. Sea Environ. Proc. No. 120B; HELCOM (2010), p. 69

<sup>133</sup> European Commission; *Common Implementation Strategy for the Water Framework Directive (2000/60/EC) – Guidance Document No. 27*; p. 13



consist of mainly two different types of measures – the basic measures and the supplementary measures.

The *basic measures* are defined in Article 11(3). These measures consist of the minimum requirements that have to be complied with and the different types of measures falling under this category are listed in the article. Included in the list are measures to prevent or control input of pollutants from diffuse sources, also known as non-point sources. The control forms are exemplified in the article as *prohibition on the entry of pollutants into water, prior authorisation or registration based on general binding rules* provided that these measures are exceeding Union legislation.<sup>134</sup> Also listed in the article are, inter alia, measures based upon the characteristics of the river basin district and to eliminate pollution by substances identified as priority substances or other substances.<sup>135</sup> The measures are to be periodically reviewed and, where necessary, updated.

The *supplementary measures* are to be taken in addition to the basic measures.<sup>136</sup> These are designed and implemented to achieve the environmental objectives pursuant to Article 4. In part B of Annex VI a non-exhaustive list of such supplementary measures has been included. The list contains 17 different types of measures, including adopting legislative instruments, administrative instruments, negotiated environmental agreements and emission controls.<sup>137</sup> Supplementary measures may also be adopted to provide additional protection or improvement of the waters covered by WFD. A third type of measures, *additional measures*, is available for exceptional cases when the environmental objectives for the body of water are unlikely to be achieved. These measures include investigation of the possible failure, examination and review of existing permits and authorisation, review of the monitoring programme and the establishment of stricter environmental quality standards.<sup>138</sup>

The programme of measures follows the time plan of the river basin management plans. The programmes were to be established by 2009, operational by 2012 and reviewed every six years.<sup>139</sup>

### 4.3 Marine Strategy Framework Directive

The Marine Strategy Framework Directive<sup>140</sup> (MSFD) was adopted on 17 June 2008. It is an environmental EU directive, part of the Sixth Environmental Action

---

<sup>134</sup> Article 11(3)(h)

<sup>135</sup> See Articles 11(3)(i, k)

<sup>136</sup> See Article 11(4)

<sup>137</sup> See Annex VI, part B, measures i, ii, iv and v

<sup>138</sup> Article 11(5)

<sup>139</sup> Article 11(7-8)

<sup>140</sup> Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive)



Programme,<sup>141</sup> based on Article 175 TEC<sup>142</sup>. Part of the expanding EU environmental legislation, the Directive addresses the marine environmental concern by aiming to achieve *good environmental status* GES by 2020 through national initiative and regional cooperation. The Directive was first presented in a communication, *Towards a strategy to protect and conserve the marine environment*, from the Commission in 2002, noting the lack of an overall, integrated policy for marine protection.<sup>143</sup> The plan proposed measures to, inter alia, stop the biodiversity decline, control emission of hazardous substances and combat eutrophication through the development of a coherent marine policy, improved implementation and enforcement of legislation, increased knowledge base through effective monitoring and increased cooperation between the regional sea conventions and agreement and the official agencies of EU and other relevant bodies. By request of the Council, the strategy<sup>144</sup> detailing the new Marine Environmental policy was presented by the Commission in 2005 and later resulted in the MSFD.

The Directive is applicable to *all marine waters*.<sup>145</sup> This includes waters, the seabed and subsoil of the territorial waters within the jurisdiction of any member state. To define the jurisdictional rights of the member states, the Directive refers to the United Nations Law of the Sea Convention (UNCLOS). The Convention defines the territorial waters as sovereign territory of the state reaching up to 12 nautical miles from the baseline.<sup>146</sup> The Directive is, however, limited in its application to coastal waters in so far as particular aspects already covered by the EU Water Framework Directive are not subject to the provisions in MSFD.<sup>147</sup>

#### 4.3.1 The marine strategy

In Article 5 of the Directive, it is established that *each Member State shall, in respect of each marine region or subregion concerned, develop a marine strategy for its marine waters*. The marine strategy is the national implementation of the Directive, aimed at setting the targets as well as determining the measures needed to achieve and maintain GES. The strategy is divided into several different tasks and phases, starting with the initial assessments that were to be ready by 2012 to the ultimate goal of achieving GES by 2020 and the following continuous work to maintain the status. The first phase, known as the preparatory phase, is covered in Chapter II of the Directive and the second phase, the programmes of measures, is covered in Chapter III.

---

<sup>141</sup> Decision 1600/2002/EC laying down the Sixth Community Environment Action Programme

<sup>142</sup> Corresponding to Article 192 TFEU

<sup>143</sup> Para 2

<sup>144</sup> European Commission; *Thematic Strategy on the Protection and Conservation of the Marine Environment*

<sup>145</sup> Article 2

<sup>146</sup> UNCLOS, Article 2.1; The baseline is calculated according to Article 5, 7 and 14 of the convention

<sup>147</sup> Article 3(2)

All the below elements of the marine strategy are subject to public consultation.<sup>148</sup> The Member States shall ensure that all interested parties are given opportunities to participate in the implementation of the Directive. Regional Sea Conventions, Scientific Advisory Bodies and Regional Advisory Councils are explicitly mentioned as possible interested parties.<sup>149</sup>

### **Initial assessment**

In Article 8, the Member States are prescribed to make an initial assessment of the marine region. The assessment, containing three different tasks, was to be completed by 15 July 2012.<sup>150</sup>

First, an analysis of the essential features and characteristics and current environmental status is to be made.<sup>151</sup> The analysis should be based upon the list of characteristics presented in Table 1 of Annex III. The list itself is indicative; all characteristics listed may not be applicable and certain information outside of the listed may be of importance. The characteristics are divided into four sub-groups: physical and chemical features, habitat types, biological features and other features. Among the characteristics listed under the sub-group *other features*, a description of the situation with regard to chemicals is found and the Member States are asked to identify chemicals giving rise to concern.

Secondly, the analysis is to include the predominant pressures and impacts on the environmental status.<sup>152</sup> The assessment is to be based on Table 2 of Annex III, an indicative list of possible pressures and impacts. Among the eight sub-groups of pressures and impacts listed, *contamination by hazardous substances* can be found. Introduction of synthetic compounds is listed as a possible impact, also explicitly exemplifying antifoulants as a possible source of such synthetic compounds to be assessed.

Thirdly, the Member States are also prescribed to analyse the economic and social use of the waters and the cost of degradation of the marine environment.<sup>153</sup> The Directive does not further describe how this analysis is to be performed in practice, thus allowing the Member States to decide how to approach the task. To aid the Member States in the performance, the European Commission issued a guidance document presenting different approaches to the economic and social analysis.<sup>154</sup>

---

<sup>148</sup> Article 19(2)(a-d)

<sup>149</sup> Article 19(1)

<sup>150</sup> Article 5(2)(a)

<sup>151</sup> Article 8(1)(a)

<sup>152</sup> Article 8(1)(b)

<sup>153</sup> Article 8(1)(c)

<sup>154</sup> See European Commission [2010]; *Economic and Social Analysis for the Initial Assessment for the Marine Strategy Framework Directive: a Guidance Document*

## **Determination of Good Environmental Status**

The aim of the directive is to achieve good environmental status (GES), defined as

*the environmental status of marine waters where these provide ecologically diverse and dynamic oceans and seas which are clean, healthy and productive within their intrinsic conditions, and the use of the marine environment is at a level that is sustainable, thus safeguarding the potential for uses and activities by current and future generations<sup>155</sup>*

by the year 2020.<sup>156</sup> The GES is determined for each marine region or sub-region separately, taking into consideration the unique characteristics of each.<sup>157</sup> The determination of GES is made by each member state relative to its own national waters. The deadline for the completion of the determination was set to 15 July 2012.<sup>158</sup>

The basis for the determination of GES is the qualitative descriptors listed in Annex I of the Directive. In the annex, eleven different qualitative descriptors are listed. For biocidal antifouling, the most relevant aspects are found in descriptor 8, *concentration of contaminants in the marine environment*, and in descriptor 9, *contaminants in fish and seafood for human consumption*. To help the Member States translate GES into practice and to ensure that GES is determined in a coherent and coordinated manner, the Commission further developed the descriptors in a decision released in 2010.<sup>159</sup> The decision contains further criteria and associated indicators for the assessment of GES, based upon existing obligations and EU legislation.

In the detailed information for descriptor 8, referral is made to the Water Framework Directive and the Environmental Quality Standards established in accordance with the Directive. The acceptable contamination limits are also determined as to ensure no significant impacts on or risk to the marine environment. For descriptor 9, it is prescribed that the maximum levels established by EU legislation or other relevant standards must not be exceeded and that the Member States are responsible to monitor edible tissues of fish and other seafood to ensure compliance.

## **Establishment of environmental targets**

The Member States are to establish environmental targets and associated indicators as prescribed in Article 10. These are used to guide the progress towards achieving GES. To establish the targets and indicators, guidance is taken by the pressures and impacts in Table 2 of Annex III, including the explicit mention of antifoulants, also used for the initial assessment. The pressures and

---

<sup>155</sup> Article 3(5)

<sup>156</sup> Article 1(1)

<sup>157</sup> Article 9

<sup>158</sup> Article 5(2)(a)(i)

<sup>159</sup> See Commission Decision 2010/477/EU

impacts are used to identify the source of the problem, thus identifying the targets in need of action.

Also, the *indicative list of characteristics to be taken into account for setting environmental targets* presented in Annex IV is used. The list contains twelve different characteristics of what is considered well-executed targets, including absence of conflicts between targets (4), setting a timescale for the achievement of targets or interim target (6) and due consideration of social and economic concerns (9).

The establishment of environmental targets was part of the first phase, with a deadline for the Member States set to 15 July 2012. The environmental targets established were then subject to the assessment and, if needed, subject to guidance in modifications of the Commission in accordance with Article 12.

### **Establishment of a monitoring programme**

After the establishment of environmental targets, Article 11 provides that the Member States shall establish and implement a monitoring programme for the on-going assessment and regular update of targets. The monitoring programme is a continuation of the assessment and foremost the targets established earlier, based on the indicative elements of Annex III and the indicative list in Annex V containing a checklist to ensure the monitoring programmes' compliance with the Directive's objectives.

The Member States shall notify the Commission of the monitoring programmes within three months of its establishment.<sup>160</sup> The Commission then assesses whether the programme constitutes an appropriate framework meeting the requirements of the Directive. The Commission may ask for additional information if it is available and necessary. Within six months of the notification, the Commission will inform the Member State concerned whether the monitoring programme is consistent with the Directive or if any modification is considered necessary.<sup>161</sup> The deadline for the Member States to establish the monitoring programmes was set to 15 July 2014.

### **Development of measures designed to achieve or maintain GES**

The next step for the Member States is to develop a programme of measures designed to achieve or maintain GES by 2020 as outlined in Article 13 of the Directive. The measures shall be based upon the determination of GES as established in the first phase, as well as the initial assessment and the environmental targets established.<sup>162</sup> The programmes of measure should also take into account other relevant measures established through EU legislation, including measures established under the Water Framework Directive.<sup>163</sup>

---

<sup>160</sup> Article 11(3)

<sup>161</sup> Article 12

<sup>162</sup> Article 13(1)

<sup>163</sup> Article 13(2)

Each measure introduced in the programme must be appropriate and effective for its purpose and the Directive includes specific points of assessment for the proposed measures. The Member States shall give due consideration to *sustainable development* and to the *social and economic impacts* of the proposed measure in particular. It shall also be made sure that the proposed measures are *cost-effective* and *technically feasible*. For each proposed measure an *impact assessment* shall be carried out, including a *cost-benefit analysis*.<sup>164</sup> It must also be indicated in the programme how the measure will be implemented and how it will contribute to the achievement of the environmental targets.<sup>165</sup> In Annex VI, the eight different types of measures available under Article 13 are listed.

The programme of measures shall be developed by 2015 at the latest.<sup>166</sup> It shall be operational within a year of its establishment, thus by the end of 2016 at latest.<sup>167</sup>

#### 4.3.2 Regional cooperation

Due to the transboundary nature of the marine environment, the Directive puts emphasis on regional cooperation as central in achieving good environmental status. Regional cooperation is defined in the Directive as *cooperation and coordination of activities between Member States and, whenever possible, third countries sharing the same marine region or subregion, for the purpose of developing and implementing marine strategies*.<sup>168</sup> In particular, the existing institutional structures, such as the Regional Sea Conventions, are identified as important in the coordination of the environmental measures.

In Article 4, the marine waters within the Union are divided into four different marine regions: the Baltic Sea, the North-east Atlantic Ocean, the Mediterranean Sea and the Black Sea.<sup>169</sup> The Baltic Sea is not further divided into sub-regions, unlike some of the other marine regions.

The focus on regional cooperation is embodied in Article 6 of the Directive. The article prescribes the use of existing regional institutional cooperation structures, such as the Regional Sea Conventions, where practical and appropriate to achieve the cooperation aspects set out for the marine strategies.<sup>170</sup> Such structures are also prescribed as a forum for cooperation with countries outside of the Union that have sovereignty or jurisdiction in the same marine region.

In the Baltic Sea region, the Baltic Marine Environment Protection Commission, better known as the Helsinki Commission (HELCOM), is the most prominent

---

<sup>164</sup> Article 13(3)

<sup>165</sup> Article 13(7)

<sup>166</sup> Article 5(2)(b)(i)

<sup>167</sup> Article 13(10), Article 5(2)(b)(ii)

<sup>168</sup> Article 3(1)(9)

<sup>169</sup> Article 4(1)(a-d)

<sup>170</sup> Article 6(1)

existing regional institutional cooperation structure. It is also explicitly mentioned in the MSFD as an example of a regional sea convention as defined by the Directive. HELCOM works to coordinate and harmonize legislation, as well as monitor and take actions in several aspects regarding the Baltic Sea, including hazardous substances. As prescribed in the Directive, HELCOM creates a forum for cooperation outside of the Union. For the Baltic Sea, this involves the cooperation with Russia that is not a member of the EU.

The Regional Sea Conventions are also granted influence upon the marine strategies as part of the public consultation. The Member States should give interested parties, including the Regional Sea Conventions, effective opportunities to participate in the formation of the different tasks of the marine strategies.<sup>171</sup>

#### **4.4 Summary: Antifouling and the European Union water policy**

The two directives presented in this section each regulate certain types of water. The WFD regulates inland surface waters, transitional waters, coastal waters and groundwater, or essentially the freshwater, while the MSFD regulates all marine waters, except for those regulated by WFD, or roughly translated to the saline waters of the Union.

The directives share many common traits. They both require national assessment and implementation for compliance, focusing on the individual characteristics of each environmental district and regulation accommodating these local conditions. While the MSFD establishes the entire Baltic Sea as a single region for the marine strategy, the WFD divides the waters into river basin districts with environmental strategies for each district allowing specific measures, legislative or other, to be taken for local areas.

It is the national implementation of the directives that dictates its effects on authorisation of antifouling biocides. The implementation assesses the current status, sets the environmental goals and standards, points out the pressures and determines the measures to be taken to reach good status. Antifoulants are known pressures, explicitly recognized in the legislation, to be considered in the national implementation when setting up the measures to be taken. While some of the substances used in antifouling are recognized as priority substances by the European Union, for others, such as copper, a standard must be implemented by the Member States' themselves.

Central in the policy is also the need for regional cooperation to achieve the goal of good environmental status. For the Baltic Sea, the HELCOM is central for the regional cooperation. All states surrounding the Baltic Sea, as well as the European Union itself, are members of HELCOM and it provides a platform for harmonization of legislation and common monitoring and actions to jointly work on issues regarding the marine environment.

---

<sup>171</sup> Article 19(1-2)

## 5. Summary and conclusions

### 5.1 Introduction

The report's outset is to outline the most relevant European Union legislation regulating the antifouling use and through this also determine the outer limits of autonomy of the member states in antifouling matters. The material chosen for the task is the Union's water quality and chemical legislations, which must be considered central for antifouling considering the method and environment where it is primarily used. Looking at all aspects and steps of antifouling products, from production and import to the end-use, other regulation may to some degree have an effect, but this impact must be considered limited.

In the following, the different aspects of antifouling will be evaluated based on the information in the report. Firstly, the antifouling biocides will be evaluated based upon both the chemical and the water quality legislation. Secondly, other aspects, to the extent possible based upon the concerned legislation, will be evaluated. Focus for this section will be the obligations for the Member States created by the water quality directives and possible measures to be taken by the Member States to fulfil these obligations.

### 5.2 Antifouling biocides

The basis for the process of authorisation for biocidal products is provided by the BPR. It outlines the structure for the process of application and authorisation for both the active substance, with the exception of dual-use substances regulated by REACH, and the biocidal product. The exception of antifouling products from Union authorisation, as one of few product-types to be subject exclusively to national authorisation, allows for increased influence from the individual Member States and possibility to adapt to the local conditions at hand. The exception emphasizes the sensitivity of water and marine environments and the need to accommodate the unique circumstances of each environment in direct contrast to the often very toxic antifouling products. While the BPR focuses on the antifouling product, the directives concerning water policy instead regulate its counterpart – the water and marine environment where the antifouling product is released. Consideration of the local conditions is provided in the BPR, but the water policy allows for consideration of the larger movement, towards a healthy environment, provided by the implementation of WFD and MSFD. The assessments and measures based on WFD and MSFD are recognised in several ways in the chemical regulations and offers the possibility for deviations based on local environmental conditions.

The Baltic Sea offers plenty of options for such deviations. It has been classified as a Particularly Sensitive Sea Area by the IMO and has incomparable characteristics with its brackish water and low dilution of pollutants.<sup>172</sup> The introduction of hazardous substances leads to substantially more devastating

---

<sup>172</sup> For further information on the sensitivity of the Baltic Sea, see Magnusson, K. & Norén, K. [2012]; *The sensitivity of the Baltic Sea ecosystems to hazardous compounds*

effects and over a significantly longer period of time than for most other large water bodies. The sensitive marine environment not only offers the option to adapt, but foremost a responsibility to do so.

The regulations and directives presented in this report are still young. The national implementations of the WFD and MSFD are not fully done and there are steps to be taken and time to pass before the aim of good status is due to be achieved. The BPR has just recently entered into force and transitional provisions are still in effect for many years to come. Practical examples of its application are yet to be seen. As a result, the correlation between the water policy and the BPR is also yet to be tested and any conclusions based on practical examples are impossible to make.

The authorisation of an antifouling product should not undermine the compliance with WFD or MSFD according Annex VI of BPR. The two represent different core objectives of the European Union, the harmonization of the internal market and common environmental policy. The use of any antifouling biocides is by definition, due to the toxic nature of the product, undermining the objectives of the water policy. This does not, however, culminate in the Member States being able to freely dictate the authorisation by simply referring to WFD and/or MSFD and the national implementation of these, as it would undermine the entire purpose of the BPR and the general policy of the internal market. Instead it may allow the individual Member State to set a higher standard, generally applied for conditions and restrictions of all antifouling biocides, based on the specific needs created by the local conditions. This refers both to the need in antifouling, as all waters does not require the same type and level of antifouling, and the need of protection of the environment which it may affect.

### **5.3 Member states' obligations and domestic regulation**

Based on the water quality legislation provided by the WFD and the MSFD, member states have obligations related to antifouling beyond the authorisation of biocidal products. As EU directives, the member states are obliged to reach the result, but the means are not dictated by the Union. Instead the member states themselves decide upon the means they see fit to achieve these results and are given the opportunity to adapt these means to the local conditions at hand.

The chemical status of the water bodies is dependent upon the concentration of the 45 priority substances. Of these, three substances are connected to use in modern antifouling biocides. While the current concentration of diuron and cybutryne are very low in the Baltic Sea and not considered a pressing issue, the concentration of TBT is still too high to meet the environmental quality standards. The long biological half-life of the substance and the still on-going flow of the substance in to the Baltic Sea have resulted in the concentration of TBT still being an issue a quarter of a century after the prohibition of its use. This results in obligations for the member states beyond maintaining the prohibition of adding new TBT-based paint on boat hulls.



Due to the long half-life of TBT, especially in sediments with low oxygen concentration, dredging may be a necessary measure to lessen the concentration of TBT in some contaminated areas. How these measures are conducted, if at all, is up to each member state to decide upon. The continuous flow of TBT in to the water is attributed mainly to substance residues left on boat hulls. The substance may be released when the boat is in water or during washing or sandblasting of the hull. Rules for waste management, wastewater or procedures for washing or blasting the hull may be decided upon by the member state.

Copper is not included on the list of priority substances, but is generally considered a significant pollutant by the member states and as such affects the ecological status in WFD. Antifouling may not be considered a major pressure for copper overall in the Baltic Sea, but for water bodies with a high concentration of leisure boats the pressure from antifouling may indeed be significant. The Member States establish the environmental quality standards for the significant pollutants themselves based upon the characteristics of each water body. Further, the Member States must then determine the measures necessary to meet these standards. The concentration of copper in antifouling biocides is instrumental in this, but measures such as dredging and regulating waste management and wastewater may also be important for certain water bodies.

The domestic regulation of Denmark, Finland and Sweden are each the focus of a report within the CHANGE project.

## References

### Legislation

#### International Legislation

Globally Harmonized System of Classification and Labelling of Chemicals (GHS), fourth revised edition 2011

The International Convention on the Control of Harmful Anti-fouling Systems in Ships, 2001

United Nations Convention on the Law of the Sea

#### European Union Treaties

The Treaty on European Union

The Treaty on the Functioning of the European Union

#### European Union Directives

Council Directive of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations

Council Directive of 21 December 1989 amending for the eighth time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations

Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market

Commission Directive 2002/62/EC of 9 July 2002 adapting to technical progress for the ninth time Annex I to Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (organostannic compounds)

Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive)

#### European Union Regulations

Regulation (EC) No 782/2003 of the European Parliament and of the Council of 14 April 2003 on the prohibition of organotin compounds on ships

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Commission implementing Regulation (EU) No 254/2013 of 20 March 2013 amending Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

## Decisions

Decision No 1600/2002/EC of the European Parliament and the Council of 22 July 2002 laying down the Sixth Community Environment Action Programme

Commission Decision (2010/477/EU) of 1 September 2010 on criteria and methodological standards on good environmental status of marine waters (notified under document C(2010) 5956)

## Cases

Case 120/78 Rewe-Zentrale AG v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon) [1979] ECR 6

Case C-300/89 *Commission v Council* (Titanium Dioxide) [1991] ECR I-2867

Case C-341/95 *Betatti v Safety Hi-Tech* [1998] ECR I-4377

Case C-178/03 *Commission v Parliament and Council* [2006] ECR I-107

Case T-182/06 *Netherlands v Commission* [2007] ECR II-2003

Case C-188/07 *Commune de Mesquer v Total* [2008] ECR I-4501

Case C-254/08 *Futura Immobiliare v Comune di Casoria* [2009] ECR I-6995

## Other documents

European Chemicals Agency [2013]; *Guidance on the application of the CLP criteria* (version 4.0)

European Commission [2001]; *Commission White Paper: Strategy for a future Chemicals Policy*; COM (2001) 27 February 2001 88 final

European Commission [2002]; *Towards a strategy to protect and conserve the marine environment*; COM(2002) 539 final Brussels 02.10.2002

European Commission [2005]; *Thematic Strategy on the Protection and Conservation of the Marine Environment*; COM(2005) 504 final Brussels 24.10.2005

European Commission [2009]; *Common Implementation Strategy for the Water Framework Directive (2000/60/EC) – Guidance Document No. 20 – Guidance Document on Exemption to the Environmental Objectives*; Technical Report 2009 - 027

European Commission [2009]; *Proposal for a regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products*; 11063/09 Brussels 16 June 2009

European Commission [2010]; *Economic and Social Analysis for the Initial Assessment for the Marine Strategy Framework Directive: a Guidance Document*; 21 December 2010

European Commission [2011]; *Common Implementation Strategy for the Water Framework Directive (2000/60/EC) – Guidance Document No. 27 - Technical Guidance For Deriving Environmental Quality Standards*; Technical Report 2011 - 055

European Commission [2012]; *Report from the Commission to the European Parliament and the Council on the Implementation of the Water Framework Directive (2000/60/EC) – River Basin Management Plans*; COM(2012) 670 Final; Brussels 14.11.2012

European Commission; *Introduction to the new EU Water Framework Directive*; European Commission's web site; URL: [http://ec.europa.eu/environment/water/water-framework/info/intro\\_en.htm](http://ec.europa.eu/environment/water/water-framework/info/intro_en.htm) (retrieved 4 August 2014)

European Commission Joint Research Centre [2003]; *Technical Guidance Document on Risk Assessment in support of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances Commission Directive 93/67/EEC on Risk Assessment for new notified substances Part II*;

EU Water Directors [2001]; *Common Implementation Strategy for the Water Framework Directive (2000/60/EC) – Strategic Document as Agreed under Swedish Presidency 2 May 2001*

Gartiser, S., Reuther, R. Reihlen, A., Luskow H., Vernon, J. & Zarogiannis, P. [2007]; *Study on Impact of the implementation of Directive 98/8/EC concerning the placing on the market of biocidal products – Final Report for DG Environment European Commission*; European Commission

Helsinki Commission [2010]; *Hazardous substances in the Baltic Sea – An integrated thematic assessment of hazardous substances in the Baltic Sea*; Balt. Sea Environ. Proc. No. 120B;

Jans, J., & Vedder, H. [2008]; *European Environmental Law – After Lisbon (4<sup>th</sup> edition)*; Europa Law Publishing, Groningen

Magnusson, K. & Norén, K. [2012]; *The sensitivity of the Baltic Sea ecosystems to hazardous compounds*; Swedish Chemicals Agency (KemI), Sundbyberg

## Annex I: Global and regional legislation and cooperation

The maritime environmental problem is never a matter of just national concern. To ensure continuous progress, cooperation on an international level is vital. In the following, the global and regional cooperation and legislation will be presented for a brief overview of these outside the European Union. The legislation reviewed will consist of both that specific to antifouling and more general legislation enabling measures controlling antifouling.

The United Nations Convention on the Law of the Sea (UNCLOS) defines the rights and responsibilities of states in maritime matters. The convention was initially drafted in 1982, but first came into force in 1994 a year after the 60<sup>th</sup> signature was delivered. The direct operational role in the implementation of the convention has in most provisions been delegated to a *competent international organization*, often referring to the International Maritime Organization (IMO), including the articles mentioned below.<sup>1</sup> IMO is a specialized agency of the United Nations, currently with 170 member states and three associate members. The organization's purpose is to set global standards in international shipping for safety, security and environmental performance.

The direct application of UNCLOS on antifouling, especially in connection with leisure boats, is limited. However, there are certain fundamental rights and obligations for the states, established by the Convention, that are vital for all marine environmental legislation, including the competence and obligation of nations to legislate and enforce treaty-based or customary rules of law.

In Article 3, UNCLOS establishes the territorial waters of each coastal state as up to 12 nautical miles from the baseline<sup>2</sup>. The territorial waters are regarded as sovereign territory of the state,<sup>3</sup> with full control of the waters from the coastal state with the exception of the right of innocent passage.<sup>4</sup> The convention also defines the Contiguous Zone and the Exclusive Economic Zone of each coastal state.<sup>5</sup>

Part XII of the Convention concerns the protection and preservation of the marine environment, containing, inter alia, provisions demanding global and regional cooperation to combat pollution as well as recognized pollution issues and methods of enforcement. Article 211 concerns pollution from vessels. The pollution is not defined further than the states' obligation to *prevent, reduce and control* it. Port states and coastal states are given the right to adopt laws and

---

<sup>1</sup> Division for Ocean Affairs and the Law of the Sea [1996]; *Law of the Sea Bulletin No. 31*; United Nations; p. 87-89

<sup>2</sup> For the calculation of the baseline, see articles 5, 7 and 14 of the convention

<sup>3</sup> Article 2.1

<sup>4</sup> Article 17

<sup>5</sup> See articles 33 (Contiguous Zone) and 55-57 (Exclusive Economic Zone)

regulations to achieve this without prejudice to the right of innocent passage.<sup>6</sup> This also extends to the exclusive economic zone of a state, to the extent that the laws and regulations must conform to *generally accepted international rules and standards* established through the IMO, unless special circumstances allow for unique laws and regulations to be adopted within a clearly defined area.<sup>7</sup>

The states are also obliged to cooperate on both a global and regional level in *formulating and elaborating international rules, standards and recommended practices and procedures*, to protect and preserve the marine environment. For the protection and preservation of the Baltic Sea marine environment, HELCOM<sup>8</sup> is the most prominent regional organization. The contracting parties include all states surrounding the Baltic Sea<sup>9</sup> as well as the European Union. Of note is that both Russia and the European Union are contracting parties, as the commission offers the two a forum for cooperation that otherwise might not have existed.

HELCOM works to coordinate and harmonize the legislation, monitoring and actions taken in several aspects regarding the Baltic Sea, including hazardous substances. In their 2007 Baltic Sea Action Plan (BSAP), HELCOM aims to achieve a Baltic Sea *undisturbed* by hazardous substances with concentration close to natural levels by the year 2021. Among the substances chosen as indicators and primary targets for prevention tributyltin (TBT) is included, a substance almost solely introduced to the marine environment through its use in antifouling. Also other substances, not chosen as indicators or primary targets in BSAP, are monitored, such as copper.<sup>10</sup>

Besides joint actions, that for antifouling related hazards mainly consists of monitoring substance levels, each state has to formulate a National Implementation Programme to achieve the goals set in the BSAP.<sup>11</sup> The programmes contain past, present and future measures taken and for harmful antifouling the measures were mostly connected to the AFS Convention (detailed below). The plans and progress are followed up during ministerial meetings, last held in Copenhagen on 3 October 2013.

Another regional organization of interest for the Baltic Sea is the OSPAR Commission<sup>12</sup>, regulating international cooperation and environmental

---

<sup>6</sup> Article 211.3-4

<sup>7</sup> Article 211.5-6

<sup>8</sup> Baltic Marine Environment Protection Commission, also known as the Helsinki Commission

<sup>9</sup> Denmark, Estonia, Finland, Germany, Latvia, Lithuania, Poland, Russia and Sweden

<sup>10</sup> See Helsinki Commission [2010]; *Hazardous substances in the Baltic Sea – An integrated thematic assessment of hazardous substances in the Baltic Sea*; Balt. Sea Environ. Proc. No. 120B; p. 13

<sup>11</sup> All National Implementation Programmes are available at: <http://helcom.fi/baltic-sea-action-plan/national-follow-up/>

<sup>12</sup> The Convention for the Protection of the Marine Environment of the North-East Atlantic

protection of the North-East Atlantic. The OSPAR definition of Greater North Sea overlaps slightly with HELCOM's definition of the Baltic Sea, but they mainly influence each other through sharing some of the contracting parties and the continuous cooperation between the two organizations. OSPAR also contributed to a large extent to the work of the European Union's maritime chemicals policy.<sup>13</sup>

The IMO has also issued legislation more specific to antifouling, namely the 2001 International Convention on the Control of Harmful Anti-Fouling Systems on Ships (the AFS Convention). The convention entered into force on 17 September 2008 and as of August 2016 has been ratified by 73 states representing more than 93 per cent of the world tonnage. While the convention is intended to mainly regulate ships, not pleasure craft, it applies to vessels *of any type whatsoever operating in the marine environment*.<sup>14</sup> All ships (with inor exemptions) entitled to fly the flag or under the authority of a state party and secondly, to ships that enter a port, shipyard, or an offshore terminal shall not bear organotin compounds on the hull or external parts or surfaces of ships unless there is a barrier to such compounds from an underlying non-compliant antifouling system. This last prohibition is applicable to all ships with the exception of the following.. The convention prohibits the use of TBT and other organotin compounds, but it is also constructed to be expandable adding restrictions to additional hazardous antifouling substances in the future. All ships longer than 24 metres but less than 400 gross tonnage, that fly a flag of a party or entering a port of a party, need to carry a declaration signed by the ships' owner or an authorised agent stating that no prohibited antifouling system was used. Ships of more than 400 gross tonnages are to carry an Antifouling System Certificate and shall be inspected. All parties are required to take appropriate measures to collect, handle, treat, and dispose residues in a safe and environmentally sound manner, although no precise requirements on waste management are set down. Sanctions shall be established under the law of the flag state. The Convention further provides that the parties shall ensure that violation of the Convention shall be prohibited. Adequate sanctions were established in order to ensure compliance with the Convention rules. If violation takes place within a states' jurisdiction and the flag state is a non-party flag, the state can start proceedings in accordance with its national law. The effect of the AFS convention on pleasure crafts in the Baltic Sea is, however, limited as the national legislation is already effective. and the measures introduced by the Convention, such as increased port state control, mostly aim to target ships flying the flag of an open registry.

International law, outside the realms of the European Union, contains little specific legislation regarding antifouling and its use on pleasure crafts. The international cooperation is, however, vital and as such, HELCOM bridges Russia and the European Union to create a forum for cooperation. Outside of that, the European Union carries a big responsibility, becoming the most important

---

<sup>13</sup> European Commission [2001]; *Commission White Paper: Strategy for a future Chemicals Policy*; COM (2001) 27 February 2001 88 final, p. 9-10

<sup>14</sup> Article 2(9)

regional cooperation for the Baltic Sea, but it has also been given the competency to act accordingly by international law. The impact of other international legislation, including legislation of specific neither environmental nor maritime character, must also be considered. An example is the possible impact of the World Trade Organization and its Agreement on Technical Barriers to Trade and the compatibility of the REACH regulation to this international agreement.