

The Water Framework Directive and Pesticides Legislation

The Influence of Environmental Quality Standards and the River Basin Approach taken in the Water Framework Directive on the Authorisation of Plant Protection Products

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*The various approaches taken in European environmental legislation are not always coordinated. For example, the effect-oriented approach for river basins taken in the Water Framework Directive differs from the risk-based approach taken in pesticide legislation. In European environmental law there is ordinarily no method for determining the hierarchy of the obligations imposed under different environmental directives. If the relevant legislation itself is silent about the hierarchy, all the obligations apply. Coordination of the various directives and their instruments is then required. This article analyses in particular the relationship between the Water Framework Directive and the Plant Protection Products Directive. Recommendations are made on how to improve the coordination of these two directives and on the integration of the Water Framework Directive's requirements into the national authorisation process for plant protection products.*²

Introduction

In this article, we examine the relationship between the Water Framework Directive³ (hereafter WFD) and the Plant Protection Products Directive⁴ (hereafter Pesticides Directive), putting special emphasis on the quality-oriented approach taken for an entire river basin in the WFD and the substance-evaluation and pesticide-authorisation approach taken in Pesticides Directive. The environmental effects of the use of a substance or product are integrated into the authorisation process primarily by setting substance-oriented and product-oriented standards.⁵ Authorisation is mainly a *generic* instrument, whereas quality requirements govern *specific* waters. In practice, the question arises whether authorised pesticide use should – if the applicable water requirements are not met – become subject to a more strict regime. If the answer is yes, it would be desirable to incorporate the WFD require-

ments into the process for authorising a plant protection product, thereby avoiding the application of overlapping rules, i.e. the authorisation process (including use requirements) and water permit issuance. To achieve this desirable objective, more clarity is needed in two areas: what are the evaluation methods on which the directives are based and how are these directives interrelated? Moreover, clarity is needed about how, under the Pesticides Directive, account can be taken of the WFD requirements.

In the Netherlands the objective is to more effectively coordinate national regulations on water protection and the authorisation of plant protection products. To ensure that the authorisation process also includes water-quality requirements, three ministries⁶ are working together on preparing a new methodology for the authorisation criterion called “risk to water organisms”. As part of this effort, we have analysed the relationship between the WFD and the Pesticides Directive and the conditions and options for integrating water quality requirements in the authorisation process for plant protection products.⁷ This article is a summary of that research project. The aim of the article is to clarify the relationship between these two directives, emphasising in particular the

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³ 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, *OJ L* 327, p. 1–73.

⁴ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, *OJ L* 230, p. 1–32.

⁵ A direct link is only made to water quality if it involves groundwater and surface waters designated as waters used for the abstraction of drinking water.

⁶ Ministry of Housing, Spatial Planning and the Environment, Ministry of Transport, Public Works and Water Management, and Ministry of Agriculture, Nature and Food Quality.

⁷ The research report prepared by the authors of this article and entitled “*De Kaderrichtlijn water en gewasbeschermingsmiddelen*” (The Water Framework Directive and Plant Protection Products), Utrecht University and University of Amsterdam, 2007, is available from the Centre for Environmental Law of Utrecht University, or can be downloaded from the Centre’s site at www.centrumvooromgevingsrecht.nl or the University of Amsterdam’s Centre for Environmental Law site at www.jur.uva.nl/cvm.

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effects the WFD has on authorisation policy. We also propose how the two directives can be better attuned.

I. The relationship between European Directives in general

It is often the case that a single environmental matter is governed by several European environmental directives that are not well (or at least not clearly) coordinated with each other. The EU regulatory system does not normally include an hierarchical order.⁸ Directives often refer to other directives using a “without prejudice to” clause. This may mean another directive *also* applies, but it does not determine any hierarchy in cases where two directives are different or incompatible. The EU regulatory system does include basic regulations on the one hand, as opposed to implementing regulations on the other. The terms “mother directives” and “daughter directives” are sometimes used. This non-legal terminology expresses a certain hierarchy, in the sense that daughter directives must be considered in the context of the more general mother directive. However, these directives must also be interpreted independently, including any references given in the directive itself.⁹ Along comparable lines, framework directives establish powers for drafting implementing directives and are the context for the implementing directives, e.g. the Framework Directives for water 76/464 (2006/11)¹⁰ and 2000/60 (WFD). The Groundwater Directive¹¹ and the proposed directive concerning priority substances implement the WFD.

Less so than in – for example – Dutch national legislation it can be said that a specific law takes priority over a more general law. The case law of the Court of Justice shows that if more than one directive applies, it is mainly the contents of the directives that determine the order in which they apply and not general criteria such as “*lex generalis – lex specialis*”.¹² In the *Geharo case*, the Court determined that, having regard to the different contents and different objectives, the standards of both directives (a substance norm and a product norm) applied. The Court did not follow the defence that a specific standard was to take priority over a more general standard.¹³ One example in which a specific rule did take priority over a more general norm is the *Spanish slurry case*.¹⁴ Here, it was not possible, the Court stated, to interpret the existing general rules for the protection of groundwater so that they replace the specific rules for slurry.¹⁵ These cases illustrate that the Court bases its rulings on the purpose and text of the relevant directives, and on the circumstances of the case. For this reason, the now following sections will describe to what extent the WFD and Pesticides Directive 91/414 determine their own mutual relationship.

II. Requirements following from the WFD with regard to plant protection products

The WFD reveals a new approach in European water policy. It represents a choice towards a fundamentally different approach to water management, an approach based on river basins focusing on the necessary coherence in water management aimed at the protection of water, not just on a certain division of powers between the various competent authorities or a choice of instruments from a certain policy area. There are objectives for each river basin in its entirety, e.g. to achieve a good water status in 2015. The Directive includes several exceptions, the minimum limit being that the status of water bodies must not deteriorate in any event. A crucial element in the river basin approach is that a transfer of pollution, for example downstream, is not allowed, which requires that the same requirements must be satisfied throughout the river basin. To this end, quality standards or requirements are introduced both at Community and Member State or river basin level.

Combined approach to handle point sources and diffuse sources

The WFD is based on the idea that a combined approach to handle point sources and diffuse sources will work to attain the objectives as formulated in the directive (Art. 10 WFD). The objectives are set out in environmental quality standards. In the Netherlands, there is an ongoing debate regarding the question of whether the quality requirements only apply to designated water bodies or to all waters. This is because many pesticides are used in the vicinity of

⁸ This refers to directives and regulations by the Council or by Council and Parliament.

⁹ Also see L. Krämer, *EC Environmental Law*, London: Sweet & Maxwell 2000, p. 42.

¹⁰ Directive 2006/11 includes the consolidated text of Directive 76/464. Both numbers can be used.

¹¹ Directive 2006/118/EC of the European Parliament and Council, dated 12 December 2006 on the protection of groundwater against pollution and deterioration.

¹² E.g. the Court's findings in ECJ of 15 September 2005, C-281/03 and C-282/03 (*Cindu*).

¹³ ECJ 6 October 2005, C-9/04. This matter involved cadmium standards provided by the Substances Directive and the Toys Directive.

¹⁴ ECJ 8 September 2005, C-121/03.

¹⁵ We have some reservations as to whether it is correct for the rules concerning water to be totally sidelined if contamination by slurry is involved – the Court very generally states that in the event of contamination by fertilisers, the protection of water shall be based on the Nitrates Directive – all the more so since the Nitrates Directive includes no reference in this regard and slurry also contains contaminating substances other than nitrates.

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smaller water courses and streams that have not been designated as a water body. Our opinion is that quality standards or requirements apply to waters in general.¹⁶ It must be commented here that the text of the WFD is not particularly clear. However, the categorisation of waters into water bodies should be considered as an administrative tool to facilitate the application and implementation of the directive, and not to restrict the application of the directive to certain waters.¹⁷ The water bodies must be designated in such a way that all water satisfies the directive's requirements. Member States may determine their own policy regarding the designation of water bodies and the selection of monitoring points. This discretion does have its limits; however, in our opinion, the designation of water bodies and the selection of monitoring points must not be such that the WFD's main objective is not achieved due to a Member State's policy.¹⁸ Member States can suffice by using general surveillance monitoring if the requirements for a good water status are met. If it is suspected that the objectives are not met, additional operational or investigative monitoring must take place.¹⁹ A distinction should be made between the question of where the standards apply – which is everywhere – and the question of which location should be monitored – monitoring should take place at locations that will present an accurate reflection of the condition of the water body.²⁰

Obligations on the Commission

In tackling the pollution of European waters, it is not just the Member States that have obligations. If a Member State is confronted with problems which it cannot solve itself, it can request the Commission for assistance in the matter by reporting the issue to the Commission and any other Member State concerned and by making recommendations for a resolution of the issue.²¹

The Commission also has its own obligations. It has the duty to select and regulate priority substances, such as establishing environmental quality standards and suggesting the most suitable measures for emission control and measures for product and process control, where especially the latter are important for pesticides.²² If product control measures include an evaluation of the applicable authorisations that are granted pursuant to the Pesticides Directive or the Biocides Directive, this evaluation is conducted following the provisions of those directives. It is unclear what the legal consequences are if the Commission or other Community institutions fail to meet their obligations under the WFD, more specifically whether this affects the Member States' obligations.

Regulation of substances

The Water Framework Directive includes no specific obligations for plant protection products. Insofar as these products contain polluting substances, they are

subject to the same regime as other polluting substances. If any quality standards are in place for certain pollutants, these standards must be met.

For *priority substances*, quality standards are set at Community level, which the Member States must transpose into legal provisions. These must include the provision that it is prohibited to exceed these quality norms. For *non-priority substances*, as well as for other ecological objectives, the Member States are obligated to establish quality standards or norms at national level. The plant protection products authorised in the Netherlands often contain non-priority substances. This means that the responsibility for establishing these quality standards rests with the Dutch government – at least where it concerns the standards for surface waters. For groundwater, the standards are set at European level and are based on the new Groundwater Directive. In principle, the Member States have a certain discretion in how they comply with quality standards.

If limits are exceeded: analysis and measures based on monitoring

A Member State shall lay down the measures it wishes to use to achieve the objectives in a programme of measures, containing both obligatory basic and supplementary measures (Art. 11 WFD). These measures include measures that are directly laid down in the WFD as well as measures following from other

¹⁶ For more information, see De Gier, Groothuijse, Robbe and Van Rijswijk, The influence of environmental quality standards and safety standards on spatial planning, Water and air as examples, *Journal Of European Environmental and Planning Law*, 2007, p. 23–36; Montforts, Van Rijswijk, Udo de Haes, Legal constraints in EU product labelling to mitigate the environmental risk of veterinary medicines at use, *Regulatory Toxicology and Pharmacology*, Volume 40, Issue 3, December 2004, p. 327–335, Van Rijswijk, “De betekenis en vormgeving van waterkwaliteitseisen” (Meaning and format of water quality standards), *Milieu en Recht* 2007, pp. 394–406.

¹⁷ Guidance of 15 January 2003 “Identification of water bodies”, p. 13.

¹⁸ In this sense, a comparison can be made with the designation of projects as being subject to Environmental Impact Assessment pursuant to the Directive on Environmental Impact Assessment, also see ECJ C-72/95 (Kraaijeveldt) and C-287/98 (Linster), both rulings relating to the EIA Directive (85/337/EEC). Also see Jans, De Lange, Prechal and Widdershoven, *Europeanisation of Public Law*, Europa Law Publishing, 2007, p. 68–72, although the concept of the limits of discretion is developed within the context of direct effect of provisions in Community law.

¹⁹ Appendix V WFD, under 1.3.2.

²⁰ Appendix V WFD, under 1.3.1 states: “provide an assessment of the overall surface water status within each catchment or subcatchments within the river basin district”.

²¹ Art. 12 WFD.

²² Art. 16 WFD.

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Community regulations, such as the Pesticides Directive. The measures that Member States need to establish in order to satisfy the WFD's objectives will vary based on whether the pollution originates from point sources or from diffuse sources. Pesticides may end up in the water both from point sources and from diffuse sources.

If objectives are not met, or if it seems that way, an analysis must take place on the basis of monitoring data to find the cause. If it becomes clear that the transgression is caused by the use of plant protection products, suitable measures must be taken to ensure that the objectives and standards will be met. If it concerns transgressions caused by non-legal use (use of unauthorised products or use in contravention of the use requirements), enforcement must be intensified. If it concerns legal use (an authorised product used in accordance with the requirements) resulting in a transgression of the water quality standards, measures shall be based on pesticides regulations or on regulations in the field of water protection. Protecting water quality from pollution by pesticides both requires measures regulating point sources and measures regulating pollution from diffuse sources. For *point sources* primary use should be made of instruments as provided by the WFD such as taking emission control measures, e.g. issuing or tightening permits or general rules. For *diffuse sources*, the WFD lists several types of control measures based on prevention (prior regulation, such as prohibition against introducing a substance into the water, prior approval or registration), in addition to the instruments based on Community legislation, such as authorisation.

It is unclear, however, how the meaning of terms such as "discharge" and "diffuse sources" as determined by the Court of Justice based on Directive 76/464/EC²³ relates to the terms "point sources" and "diffuse sources" in the WFD.²⁴ Specifically, the question arises whether under the WFD the term "discharge" is limited to pollution from point sources and whether the other discharges (the "non-point discharges" such as the leaching of creosote and atmospheric deposition) will be equated with diffuse sources.

The Court of Justice's *Nederhoff* ruling shows that environmental quality standards may result in the restriction or prohibition of the use of a product. It would be logical to assume that this would also apply to situations under the Pesticides Directive, all the more so after Directive 76/464 has been replaced by the WFD; this is ultimately decided, however, by the Court of Justice. The situation as proposed by the Commission, with a directive for the sustainable use of plant protection products based on Art. 175 EC (see Section 8), will also include options to take additional measures pursuant to the WFD because it basically allows Member States to take more stringent measures. The directives do not determine the procedures

to be followed when taking stricter emission control measures.

Exceptions and stricter requirements

The WFD and the proposed Directive concerning priority substances include the option for Member States to invoke certain exceptional circumstances that relate to all substances (Art. 4 WFD), or the option to designate transitional areas where the norms for priority substances need not be satisfied if this exceedance is caused by pollution from point sources (Article 3 proposed Directive concerning priority substances). The WFD itself contains no explicit rules for the designation of transitional areas for non-priority substances, which is significant since pesticides often do not contain priority substances. It is unclear whether Member States themselves can designate transitional areas under the same conditions that apply to priority substances. In view of the WFD's underlying objective, however, we can imagine that designating transitional areas for pollution from diffuse sources may encounter some difficulties.

In practice, the question arises whether the WFD allows any space to accept a temporary deterioration in the condition of the water body, so that the recovery of the water quality can be taken as the starting point after the use of plant protection products in smaller waters resulting in a transgression of the norms, while these norms will be satisfied at the time that the water flows into a larger designated water body. This is also referred to as "differentiation of location" or "level" to which the standards apply. For the WFD, the question of whether it will be possible to introduce such differentiation is difficult to answer. On the one hand, we have noted above that in principle the norms apply to all surface waters, unless one of the aforementioned exceptions occurs. On the other hand, WFD terminology is not unequivocal and clear. With regard to objectives, norms, designation of areas, exceptional provisions and monitoring obligations, mention is made of "river basins, waters, surface waters, groundwater and water bodies". The Court of Justice adds "water masses" to the list,²⁵ whereas pesticide regulations add the term "water courses". Our conclusion is that the WFD includes no general option to differentiate norms as to location or level. This would only be different insofar as the directives included specific exceptions, and also for areas that need additional protection. The WFD and accompanying daughter directives leave no room for the

²³ ECJ 29 September 1999, C-231/97 (Van Rooij), *Jur.* 1999, p. I-6355 and ECJ 29 September 1999, C-232/97 (Nederhoff en Zn), *Jur.* 1999, p. I-6385.

²⁴ See Van Rijswijk, EC Water Law in Transition: the Challenge of Integration, Yearbook of European Environmental Law, Oxford University Press, 2003, p. 249–304.

²⁵ ECJ case C-32/05, Commission vs Luxembourg.

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transgression of norms, unless they fall within the frameworks outlined in the directive(s), such as the exceptions in Art. 4 WFD, or if they are part of the guaranteed annual average and remain under the MAC norm²⁶ (see Section 5). The WFD has no provisions clearly revealing any options to take a recovery of water quality into account.

III. The system and requirements of the Pesticides Directive

In the Pesticides Directive the protection of the water quality is part of the protection of the environment²⁷ and as such is one of the Directive's objectives. According to the recitals of the Directive its objectives are: protecting plant production, improving the free movement of products between Member States and the protection of humans, animals and the environment against side-effects of use.²⁸ The protection of human and animal health, and the health of the environment, must take priority over the improvement of plant production.²⁹ These objectives form the basis for authorisation criteria and so called "Uniform Principles" for evaluation and decision making.³⁰ The Uniform Principles aim to ensure that Member States apply the Directive's requirements in a uniform manner and at the high level of protection of human and animal health and the environment sought by the Directive.

The Pesticides Directive covers the authorisation, placing on the market, use and control of plant protection products in the EU. It also covers the marketing and control of the active ingredients (substances) in these products. In spite of its scope being rather wide, the Directive does not include a comprehensive coverage of the use phase of the products. Apart from some general use provisions, use requirements are lacking.³¹ There are, for example, no provisions on matters such as professional skills, use in vulnerable areas, monitoring or information to the general public.³² In general, Directive 91/414 lacks clarity regarding the way it relates to other directives. It fails to include, for example, a provision such as Article 5, paragraph 4, in the Biocides Directive, stipulating that the competent authority shall take into account other relevant Community provisions when issuing an authorisation and, where necessary shall issue the authorisation subject to those requirements. The Uniform Principles however do provide some clarity on the relationship with the water directives (see Section 6).

The authorisation process: inclusion of substances and authorisation of products

The Pesticides Directive distinguishes two levels of decision-making and evaluation: one is the Community level, concerning the inclusion (approval) of an active

substance, and the other is the national level, concerning the authorisation of a plant protection product. Decisions regarding the inclusion of a substance – in Annex I of Directive 91/414 (the "positive list") – are taken by the Commission.³³ A positive decision on inclusion forms the starting point for decision-making on authorisation by Member States. For new substances and products inclusion and authorisation are a form of preventative testing, before the product is marketed. For products already on the market reviews are conducted, for which the Directive contains transitional measures.³⁴ A non-inclusion decision means the end of an authorisation procedure and, if a product is already on the market, the cancellation by a Member State of existing authorisations. For both the inclusion of the substance and the authorisation of the product, the applicant is to supply a technical dossier containing research results. Annexes II and III of the Pesticides Directive lay down the requirements for these dossiers. The scientific assessments for the evaluation of substances are conducted by the European Food Safety Authority.³⁵ Product evaluations are conducted by the Member State authorities.³⁶

An authorisation decision must include use requirements for types of cultivation in which the product may be applied.³⁷ Requirements regarding e.g. types of soil can be included. This implies that use requirements can focus an authorisation on certain areas. An authorisation can also be restricted to part of a

²⁶ MAC = Maximum Admissible Concentration.

²⁷ See the definition of "environment" (Art. 2 par. 1 under 12) and the authorisation criteria (Art. 4).

²⁸ Directive 91/414 is legally based on Art. 43 EEC (now Art. 37 EC) (Common agricultural policy).

²⁹ Recital 9 in Directive 91/414.

³⁰ The Uniform Principles for the evaluation and authorisation of plant protection products were added as Annex VI to Directive 91/414 by separate directive (97/57/EC, OJEC 1997 L 265, later amended).

³¹ Article 3, paragraph 3 does include a general provision on use, stipulating that Member States must determine that plant protection products must be used properly. Article 4, paragraph 2 provides that the authorisation must stipulate the requirements regarding the use of the product.

³² The Uniform Principles do include some provisions regarding use, such as Principles B 2.5.1.4 and C 2.4.1.3.

³³ Art. 5 and 6 Directive 91/414.

³⁴ Art. 8, paragraphs 2 and 3. For some 800 existing active substances at the time the Directive was adopted, Commission regulations contain special work programmes. E.g. Commission regulation 1095/2007 (OJEC 2007 L 246) implementing the third and fourth phase of the work programme of Directive 91/414.

³⁵ www.efsa.eu.int (PPR Panel and PRAPeR).

³⁶ In the Netherlands the Board for the Authorisation of Plant Protection Products and Biocides (*Ctgb*) is the competent authority, www.Ctgb.nl (part of the website in English).

³⁷ Art. 4, paragraph 2.

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Member State's territory.³⁸ An authorisation must be amended if new knowledge indicates that the use requirements can be changed and must be cancelled if the authorisation requirements are no longer satisfied or if information provided regarding authorisation data was incorrect.³⁹

The authorisation criteria

The authorisation criteria laid down in Article 4 require, amongst other things, that the product must have no *harmful* effect on human or animal health, directly or indirectly (e.g. through drinking water) or on groundwater. It also must have no *unacceptable* influence on the environment, having particular regard to the pollution of water, including drinking water and groundwater. With regard to the effects on water, Article 4 shows that consequences for groundwater and drinking water are both part of the harmful effects on health and of unacceptable effects on the environment. The pollution of water in general and the impact on non-target species (e.g. water organisms) are part of the unacceptable influence on the environment. One of the other authorisation criteria requires that residues that result from authorised uses and which are of toxicological or environmental significance can be appropriately determined.⁴⁰

The authorisation criteria refer to the Uniform Principles, which contain general and specific provisions for evaluation (part B) and decision-making (part C). Regarding leaching into groundwater, concentration limit values have to be estimated, using a suitable and validated calculation model.⁴¹ Amongst other information relevant monitoring data must be considered regarding the presence of substances in groundwater as a result of previous use of plant protection products.⁴² The evaluation of effects on surface water will consider the possible routes of exposure: spray drift, run-off, "overspray", discharge via drains, leaching, and atmospheric deposition.⁴³ The decision-making requirements regarding the influence on the environment include figures regarding fate and distribution in e.g. groundwater and surface water, and the impact on non-target species.⁴⁴

Exemptions

It is important to note that Directive 91/414 includes various exemptions and other deviations, due to which the authorisation requirements do not always fully apply. For example, there is a temporary arrangement for unforeseen agricultural emergencies and an exemption for product research and development. There are also "essential use" arrangements, which under conditions allow designated Member States to maintain an authorisation during a certain period for certain substances and applications, although the product does not satisfy the authorisation criteria.⁴⁵ Next to these exemptions, it is also due to the long transitional regime for products containing existing substances,⁴⁶

that the standard authorisation procedure is not always fully applied.

Discretionary power for Member States

Considering its legal basis, purposes and contents, the Pesticides Directive must be regarded as a comprehensive regime for *the placing on the market* of plant protection products. A Member State will only have discretionary powers insofar as the Directive allows this.⁴⁷ Within the authorisation process the Directive does allow some discretion to Member States in taking into account their specific circumstances.⁴⁸ For *the use* of plant protection products, the Directive's regime is not comprehensive. As described above, there are aspects of use which are not covered by the Directive. This limitation of the Directive's scope means that Member States may develop their own policy, within the limits of the EC Treaty and other EC regulations, if any. Our conclusion is that, within these limits, the Pesticides Directive leaves discretion to Member States to develop their own water protection policy for the use phase of plant protection products, either through authorisation requirements or, when appropriate, through other instruments. A Commission proposal for a framework Directive aiming at a more sustainable use of pesticides is discussed in Section 7 below.

The authorisation process must take place "in the light of current scientific and technical knowledge", having regard to "all normal conditions under which it may be used".⁴⁹ At the same time a "proper use" of the product is supposed, which implies:

- compliance with authorisation conditions, specified on the labelling, and

³⁸ This follows from the phrase "...authorizes the placing on the market of a plant protection product in its territory or in a part thereof." (Art. 2, under 11).

³⁹ Art. 4, paragraph 6.

⁴⁰ Art. 4 paragraph 1 sub d.

⁴¹ In the absence of a validated Community model the evaluation shall be based on certain studies required by the Annexes II and III of Directive 91/414 (Principle B 2.5.1.2).

⁴² Principle B 2.5.1.2.

⁴³ Principle B 2.5.1.3.

⁴⁴ Principle C 2.5.

⁴⁵ Commission regulation 2076/2002, OJEC 2002 L 319/3, Art. 2, paragraph 3 and Annex II (Third work programme).

⁴⁶ The twelve-year transitional period for these products (Art. 8 Directive 91/414) has been extended to 2008.

⁴⁷ Art. 95 EC Treaty, regarding the maintaining or introducing of national provisions that are stricter than those of a Directive, does not refer to Directive 91/414, in view of its legal basis.

⁴⁸ As part of the "mutual recognition" of authorisations of other Member States, agricultural, plant health and ecological circumstances play a role (Art. 10, paragraph 1, Directive 91/414).

⁴⁹ Art. 4, paragraph 1(b) in conjunction with Art. 3, paragraph 3.

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- application of principles of good plant protection practice and, whenever possible,
- application of the principle of integrated control.

For the principle of integrated control a definition is given (Art. 2, sub 13). Neither of these principles however is fleshed out in the Uniform Principles. Taking “proper use” as a starting point indicates that assessments and evaluations do not primarily focus on the actual situation (such as the water quality) but on situations where compliance with certain conditions and principles is presupposed. In Section 4 we will further analyse the ways in which the “authorisation approach” differs from the “water quality approach”.

IV. The evaluation methods and the role of monitoring based on the Pesticides Directive and the WFD

Regarding the authorisation process for plant protection products, the Pesticides Directive requires that, using the current state of scientific and technical knowledge and based on the evaluation of the dossier, it is established that a product, when used under certain conditions, satisfies the authorisation criteria. As described in section 3 the authorisation criteria in Art. 4 are relatively vague, such as “no harmful effect” or “no unacceptable influence”, but they are fleshed out in the Uniform Principles.⁵⁰ These Principles include, amongst other standards, concentration standards for groundwater and for surface water which is intended for the abstraction of drinking water. For the impact on water organisms a tiered approach is set out. In this approach the first step, which is limited to certain coefficients and a bioconcentration factor, does not include a general standard for what is “unacceptable influence”. In this step a requirement to satisfy the WFD’s quality standards would be an additional requirement. The following steps do include an evaluation of unacceptable effects, in the form of so-called “unless-provisions”. These provisions allow that, even if the first step is not complied with, authorisation is still granted if risk assessment scientifically demonstrates that under field conditions there is no “unacceptable impact”. However, the term “unacceptable” used here still needs further definition. As yet it seems this could include WFD quality standards.⁵¹

The provisions on evaluation and decision-making provisions are further worked out in dossier requirements (Annexes II and III to Directive 91/414), in technical, scientific and policy documents, such as a Guidance Document⁵² and in national documents.⁵³ In the authorisation process the assessments applied are mainly risk assessments, focusing on the application of a plant protection product and on exposure and risk related to this application. Models play a central role in evaluations and decision-making. The choices to be

made for using a model, will determine the results. This may concern, for example, including or excluding emission routes, or the location and duration of exposure.

The WFD requirements with regard to chemical aspects pertain to substances and are expressed in a certain maximum concentration of substances that are allowed in the water. This means that the WFD also sets norms for substances in plant protection products, in the form of a maximum accepted concentration of substances. In the determination of norms for the maximum concentration of priority substances, the WFD uses both an annual average of the pollution substances and a maximum for the admissible peak concentration.

On many of these points, the evaluation system of the Pesticides Directive, which centres on the application of a product, is different from the WFD, which focuses on the quality of the water and the status of the water body. A significant difference is that the Pesticides Directive focuses on the application of a separate product and the ensuing exposure and risk. In principle, effects of combinations of products or cumulative effects are not considered in the product evaluation. Moreover, it is assumed that the product is used in accordance with use requirements or under normal conditions of use. The evaluation by the WFD focuses on the chemical and ecological quality of the water in river basins. Monitoring data are crucial in the WFD system, because a differentiated monitoring system is used to determine which measures must be taken to attain the environmental objectives and comply with the environmental quality standards in time.⁵⁴ As opposed to the WFD, the Pesticides Directive does not mention monitoring data.⁵⁵ The decision-making in the authorisation process is based on use in accordance with use requirements, not on effects that occur in practice. Following authorisation, no structural feedback or communication takes place to link up with the results of monitoring. Nor do the

⁵⁰ Uniform Principles C.2.5.1.2 and C.2.5.2.2.

⁵¹ In The Netherlands a maximum admissible risk standard, laid down in a ministerial regulation, is applied in the authorisation process.

⁵² Guidance Document on Aquatic Ecotoxicology, SAN-CO/3268/2001 Rev. 4 (final), 2002. The status of Guidance Documents is sometimes unclear and they are not legally binding.

⁵³ At the Dutch national level, this issue is governed by a ministerial regulation and an authorisation manual of the national competent authority. See the website: www.ctgb.nl.

⁵⁴ See the Guidance Document of the Water Framework Directive Common Implementation Strategy, Working Group 2.7. Monitoring, Guidance on Monitoring for the Water Framework Directive. Final version, 23 January 2003.

⁵⁵ This concerns the monitoring of distribution in the environment, not residues in foodstuffs.

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Uniform Principles clearly include any monitoring. The fact that the authorisation system focuses on use in accordance with the requirements and on an evaluation using data from dossiers, based on models, hinders the impact of monitoring data in the authorisation decisions.

Under the WFD, if the norms are transgressed, an investigation will first have to take place. The extent of this procedure depends on how strong the argument supporting the clues is and on the gravity of the transgression. The WFD does require plausibility but not certainty of a causal connection between the use of a substance and the contamination, before measures must be taken. After all, measures must be taken for sources that *may* cause pollution. There will have to be some evidence indicating the connection, however, in view of the required proportionality of measures to be taken. This means that monitoring data will have to satisfy certain standards. There is no clear regime for the impact of WFD monitoring data on the authorisation decisions as part of the Pesticides Directive.

In view of the proportionality of measures, when investigating causes of transgression of norms, other applications of a substance will also have to be considered. The WFD does not require the degrees of contributions to the pollution to be exactly established. For substances that are also used for other applications than solely as a plant protection product, measures must also be included in the programme of measures required by the WFD. For other applications of a substance, the WFD usually requires the same type of measure as for plant protection products, i.e. control measures, emission control and prevention. The WFD does not prioritise measures. Measures for substances in plant protection products and for nitrates might have a certain priority, because these regulation frameworks are mentioned in Annex VI part A and must therefore be included in the programme of measures. For these substances, the quality standards for groundwater are set at European level. Moreover, plant protection products are included as a product group in the indicative list of the main polluting substances.

V. How the WFD and the Pesticides Directive relate

Considering the system of EC legislation and the reference clauses in the Pesticides Directive and the WFD, it cannot be concluded that either of the directives prevails, in the sense that it would preferably or definitely take priority. The text of the Pesticides Directive lacks clarity on the relation to the water directives. However, recital seven of the Uniform Principles is more clear, stating that:

“Whereas the provisions of this Directive concerning the protection of water, including provisions

related to monitoring, are without prejudice to Member States’ obligations under the Directives concerned, and in particular Directives 75/440, 80/68 and 80/778”.⁵⁶

The standards of directives listed in this recital⁵⁷ have been integrated in, and are applied in, the Uniform Principles. Water directive 76/464/EEC is not mentioned. Therefore it does not expressly follow from these Principles that directive 76/464 influences the authorisation process. It can be concluded, however, that the Principles do leave room for that, by using the word “particularly” in the recital mentioned above. This wording indicates that it also does not mean to detract from other relevant water directives. This has, however, not been expanded on in the Principles. The purpose of the Principles – to reach a high level of protection⁵⁸ by uniform application – would indicate that they do not intend to exclude other relevant standards when evaluating “unacceptable effects”. Since two out of three of the water directives listed in the Uniform Principles are now being replaced by the WFD, it can be assumed that an integration of the WFD requirements is intended.

The WFD assumes that the environmental quality standards will influence the measures to be taken, this in view of e.g. the WFD’s Art. 10, paragraph 2. Measures that are based on the Pesticides Directive are part of the WFD’s measures programmes as laid down in Annex VI. If a quality objective or standard requires more stringent conditions for emission control measures than those that follow from the combined approach, this should result in stricter measures, including the review and update of the prescribed controls.⁵⁹

Non-inclusion measures (concerning Annex 1 of the Pesticides Directive) taken by the Commission, are considered by the Commission as product control measures in the sense of the WFD. This is in accordance with Art. 16, paragraph 6 WFD. The Communication from the Commission to the European Parliament and the Council “Towards Sustainable Water Management in the European Union”⁶⁰ shows that the Commission gives Member States ample space to take their own measures, both for

⁵⁶ The Dutch version of this Directive is more clear, using the expression “geen afbreuk doen aan”, which means “do not harm” or “do not spoil”.

⁵⁷ Directives concerning surface water for the abstraction of drinking water, groundwater protection and water intended for human consumption.

⁵⁸ Recital 2 and Uniform Principle A1.

⁵⁹ Art. 10, paragraph 2 and 3 in conjunction with Art. 11, paragraph 3 under h, WFD.

⁶⁰ Communication from the Commission to the European Parliament and the Council “Towards Sustainable Water Management in the European Union, First Stage in the Implementation of the Water Framework Directive 2000/60/EC, COM 2007, 128 final, SEC 2007, 363.

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priority substances and for other polluting substances. It does not become clear what the Commission's view is on the relationship between national and Community measures. The Commission Communication does include that a procedure should be established for Member States to exchange information as a basis for Community action, but this is not part of the Commission proposal itself.

Due to the differences between the WFD and the Pesticides Directive as to their objectives and evaluation systems, it can be concluded – in view of the case law of the Court of Justice – that for plant protection products standards of both directives must be applied.⁶¹ An environmental quality standard for a polluting substance will thus, *in addition to* the norms under the Pesticides Directive, have to be applied when taking authorisation decisions. The WFD fails to indicate, however, how this should be effected. It is clear, however, that if an environmental quality standard is less strict than a norm under the Pesticides Directive, the strictest quality standard must govern the determination of emission control measures to be taken. Therefore, environmental quality standards cannot serve to replace the standards of the Pesticides Directive.

VI. Remaining questions about how the WFD and Directive 91/414 relate

There is a lack of clarity and some uncertainty regarding the way that the quality norms under the WFD will affect the authorisation process for plant protection products. We would highly recommend counteracting this lack of clarity. For certain aspects, this will require consultation at a European level. Most of this does not concern technical issues, since the Pesticides Directive also indicates that it does not intend to exclude water quality standards from the authorisation process. What is lacking, however, are procedural arrangements, especially governing the role of the WFD monitoring data in the Pesticides Directive. Nor have arrangements been made for the exchange of information between Member States and Commission, as a basis for Community action. This is caused by the fact that the scope of the obligations that the Community institutions have under the WFD is unclear and it is also unclear what the consequences will be for the Member States' obligations (concerning results), should the Community obligations not be satisfied.

Some questions require further research. We have identified the following issues as unclear.

The WFD terms of water, water bodies, and water mass, contamination, point sources, diffuse sources, discharge and point discharge are not sufficiently explained, at least where it concerns their meaning related to the environmental objectives and quality

standards. These terms should be absolutely clear to allow good understanding of the scope of the WFD and of the relationship between the WFD and the Pesticides Directive. For non-priority substances – that include many substances of plant protection products – it is unclear whether Member States have the power to make arrangements that are similar to the “transitional areas” that can be designated for point discharges of priority substances based on the proposed daughter directive concerning priority substances. This proposal also fails to include concrete procedures for establishing stricter emission control measures. Finally, it should be noted that some questions will only receive a definite answer once a Court (national or European) has ruled on the subject.

In Art. 10 Pesticides Directive the term “environmental conditions” as part of the system of mutual recognition of authorisations of other Member States, needs clarification. For the integration of the WFD requirements in the authorisation process it is important that these “environmental conditions” also include the Member State's specific environmental quality standards under the WFD.

VII. New EC legislation for plant protection products

In 2006 the Commission submitted two proposals for new pesticide legislation. A proposal for a Directive on sustainable use of pesticides⁶² (hereafter: use proposal) and for a Regulation on marketing of plant protection products⁶³ (hereafter: authorisation proposal) went through the first part of the legislative process in 2007. Parliament amended both proposals⁶⁴ and the Council reached a political agreement on the use proposal.⁶⁵ The Council, Commission and Parliament will further negotiate these texts in 2008. Both measures follow from the “Thematic Strategy on the sustainable use of pesticides”⁶⁶ Some elements relevant to the aquatic environment are the following.

⁶¹ See the *Geharo* ruling described in Section 2.

⁶² Proposal for a Directive of the European Parliament and Council to adopt a framework for Community action towards sustainable use of pesticides, COM(2006) 373.

⁶³ Proposal for a Regulation of the European Parliament and Council concerning the placing on the market of plant protection products, COM(2006) 388.

⁶⁴ First reading, 24 October 2007, amended texts P6_TA(2007)0444 and 04445, <ec.europa.eu/prelex> (2006/0132(COD) and 2006/0136(COD)).

⁶⁵ 13 December 2007, 16451/07 ADD 1.

⁶⁶ Communication regarding a Thematic strategy for sustainable use of pesticides, COM(2006) 372 def.

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The Strategy

According to the Commission one of the shortcomings of the existing legal framework is that the actual pesticide use phase is barely addressed. This phase is a key element for the determination of the overall risks pesticides pose.⁶⁷ As the use phase is affected by other policy areas, such as water policy, the Strategy will allow the development of a horizontal and cross-policy approach beyond the scope of the specific legal instruments.⁶⁸ Environmental monitoring is one of the proposed measures. This is a means to verify model calculations and predictions during risk assessment and compliance of users with restrictions and label instructions. For the monitoring of pesticides in water the Commission refers to the WFD. In a resolution about this Strategy Parliament made the following statement about the protection of the aquatic environment:

“Believes that designation of zones, including drinking water catchment protection areas, with reduced or zero pesticide use and enhanced protection of the aquatic environment from pollution by pesticides are necessary in order to avoid unwanted exposure; considers that “buffer zones” of appropriate width taking account of the different agricultural, geographical and weather conditions should be established; . . .”⁶⁹

To gain effect this statement will need translation into a provision of the Directive.

A directive on sustainable use of pesticides

The proposal for a directive on sustainable use pertains to the distribution and use of plant protection products.⁷⁰ This proposal, based on art. 175 EC,⁷¹ requires, amongst other things, national action plans for reducing risks and dependence on pesticides, training programs, specific practices, such as Integrated Pest Management, and specific measures. Measures for the protection of the aquatic environment are laid down in art. 10. This article requires that preference is given to certain products and application techniques in the vicinity of water bodies. It also requires that pesticide free buffer zones are established on fields adjacent to water courses. These measures were more or less endorsed by Parliament⁷² but watered down by the Council in the first reading.⁷³ For specific areas art. 11 requires specific measures to be taken. Here Parliament added the protected areas as defined in the WFD. The Council watered this article down by adding risk reduction as alternative to the prohibition or restriction of the use of pesticides in these areas.

A regulation on placing plant protection products on the market

In the proposal for a regulation concerning marketing of plant protection products – this regulation will replace Directive 91/414 – the Commission introduces the element of zonal licensing. Parliament,

however, rejected this element in the first reading. It is remarkable that the proposal makes no reference to the WFD whatsoever. Parliament added a general reference to the WFD in the recitals.⁷⁴ Several amendments by Parliament seem important for the protection of the aquatic environment, such as the addition of the purpose of the directive (ensuring a high level of protection) and of the precautionary principle (Art. 2), the extension of the definition of “substances of concern” (Art. 3), the priority for non-chemical measures as part of “integrated pest management” and the tightening of approval criteria, amongst others by adding surface water to the “harmful effects” (Art. 4). Parliament also amended the dual legal basis of the proposal (environment instead of agriculture) due to the purpose of the regulation.⁷⁵

New pesticide legislation and the WFD

It seems a missed opportunity that the texts for the Directive and the Regulation until now have not been very clear about the relation to the WFD and about the integration of WFD quality requirements in the authorisation process. A concrete link to WFD requirements is still missing, especially within the approval criteria.⁷⁶ The texts however do seem to offer possibilities to fulfil WFD requirements. The amendments indicate a stronger link to the general purposes and measures of the WFD. Preventive and substitution measures based on the new regulation can be important tools, also for water quality, within the

⁶⁷ Communication Thematic strategy, par. 1.

⁶⁸ Communication Thematic strategy, par. 3.

⁶⁹ European Parliament Resolution, 24 October 2007 (P6_TA-PROV(2007)0467).

⁷⁰ Although the term “pesticides” is used, the application field only covers plant protection products (art. 2). Here “use” includes all operations carried out with a pesticide, such as storage, handling, dilution, mixing and application (art. 3 sub b).

⁷¹ In the first reading Parliament added art. 152(4) EC as a legal basis, which was deleted by the Council.

⁷² With several amendments (Legislative resolution 23 October 2007, P6_TA-PROV(2007)0444, amendments 68–72, 74, 135 and 143.

⁷³ For example by adding “when necessary” to the buffer zone requirement in art. 10, par. 2 sub c (Political agreement 13 December 2007; 16451/07).

⁷⁴ The measures apply “without prejudice to existing Community legislation, in particular” (amongst others) the WFD.

⁷⁵ Art. 37 and art. 152(4) EC were replaced by art. 175 and art. 152(4) EC (Amendments after first reading, 24 October 2007).

⁷⁶ Art. 4 or art. 29 of the authorisation proposal. Compare for example REACH (regulation 1907/2006) where compliance with the WFD’s objectives is required within the re-evaluation (Art. 61, par. 5).

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authorisation process.⁷⁷ Moreover art. 10 of the use proposal does make clear that measures shall support and be compatible with relevant WFD provisions.⁷⁸ In both texts the various terms for water (water body, water courses, waters, surface water and groundwater in general) strengthen the need to explain these terms as they relate to the applicable requirements.

VIII. Recommendations concerning WFD requirements and the authorisation process

Our research into the relationship between the WFD and the Pesticides Directive, and the impact of WFD requirements for the authorisation of plant protection products, has resulted in several recommendations. They include recommendations at the national and the Community level. In view of the budding new pesticide legislation our recommendations for the Community level will focus on the proposals for the new pesticide legislation.

Recommendations at the national level

The WFD objectives and relevant water quality requirements must be satisfied in time. Special attention should be given to how the various measures to be taken to this end are related. We recommend that when taking product control measures, authorisation approvals be related to the quality standards set by the WFD, in order to improve the way in which the regimes of the WFD and the Pesticides Directive are connected. Attuning these two regimes would fit in the WFD's so-called "combined approach".⁷⁹

The WFD's quality standards should be clearly defined as to their status in the authorisation process. They should be integrated in the evaluation methods, allowing the national authorisation policy to focus on control of pollution at source and on measures to prevent or control the input of pollutants, as the WFD requires.⁸⁰ At the level of objectives and criteria it is clear that WFD quality standards should and can play a role in the authorisation process. However, at the Dutch national level practical and procedural provisions, e.g. for timescales for submission of data regarding specific waterquality aspects, are lacking.

We recommend laying down basic assumptions and arrangements regarding the integration of WFD monitoring data in the authorisation procedure, and doing so in a national legislative or policy document in which powers, procedures, terms and measures with respect to monitoring data and their status in the authorisation process, especially in the review process, are clearly defined.

Recommendations at the European level

At the Community level more clarity is required on terms such as "waters", "water bodies", "water

masses" and "water courses" especially, in connection with the relevant obligations.

It should also be made clear that a Member State's environmental quality standards under the WFD are part of the specific national environmental or ecological circumstances, forming a ground for specific national authorisation measures in any system of mutual recognition of authorisations. This issue can be clarified in the pending proposal for a Regulation on Plant Protection Products.

We also recommend that in this proposal the definition of the term "authorisation" will be clarified. Different from the current Pesticides Directive, the definition does not specify that an authorisation can be restricted to a part of a Member State's territory. In the light of the river basin management approach to specific measures to meet WFD requirements, authorisation decisions might need to be more restricted to certain areas within a Member State or within a river basin.

Neither of the present directives clearly addresses the question which evaluation and decision-making procedures should be followed in the event of (impending) failure to achieve water quality standards, neither does the proposal for a new regulation on plant protection products. For the sake of clarity and in view of legal certainty and legislative unity, we recommend the following issues be introduced in the proposal for a Regulation on Plant Protection Products:

- a general provision or recital that the Regulation applies without prejudice to other community legislation, in particular the WFD;⁸¹
- a provision that the competent authority take into account relevant requirements pursuant to other Community provisions, e.g. the WFD; where necessary the authorisation shall be granted subject to these other requirements;⁸²
- a provision that the competent authority shall take into account all discharges, emissions and losses, including risks of diffuse or widespread use, known at the time of decision;⁸³

⁷⁷ Such as giving priority or preference to certain substances or techniques and reducing or eliminating certain applications with a high risk of run-off (art. 10 use proposal) and the preference for non-chemical methods as a principle of Integrated pest management (Annex III use proposal). The comparative assessment and use requirements in the authorisation proposal (art. 48)

⁷⁸ Art. 10 par. 1 and 2 Sustainable use directive proposal (Political agreement 13 December 2007).

⁷⁹ WFD Art. 10.

⁸⁰ WFD Art. 11, paragraph 3(h) and recital 40.

⁸¹ Cf. recital 39 as amended by Parliament in the first reading.

⁸² Cf. Art. 5, paragraph 4 of Directive 98/8/EC (Biocides Directive).

⁸³ Cf. Art. 60 paragraph 2 Regulation 1907/2006 (REACH).

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- a provision that exceeding water quality standards be a ground for authorisation restriction measures, for reviewing a substance approval (Commission decision) and for reviewing a plant protection product's authorisation (Member States decision);⁸⁴
- a provision assuring that WFD-monitoring results are integrated in the review, renewal and withdrawal procedures for authorisations.⁸⁵ Therefore implementing measures should contain procedures for the submittance of monitoring results and the evaluation of these results in the authorisation process.

In view of the differences in evaluation methods of the WFD and the pesticides legislation, we recommend that, in annexes, uniform principles and guidance documents to the pesticides legislation arrangements be made regarding the way WFD requirements affect the authorisation process, including e.g. with regard to research data, basic assumptions or choices of methods for assessments and evaluations.

A first example are the dossier requirements. Although the evaluation of WFD quality standards may not require any additional dossier data, we would recommend for clarity's sake that these WFD requirements are integrated in the dossier requirements for the authorisation process.

A second example is the integration of WFD monitoring data in the authorisation process. Either in an Annex to the pesticides legislation or in a technical guidance document the role of monitoring data in assessments and evaluations for reviews of authorisations should be made clear. Interested parties

should, e.g., have a possibility to submit their monitoring data.

A third example is the integration of the water quality requirement in the principles for evaluation and decision-making. We recommend that it be made clear that the term "unacceptable" also refers to not fulfilling water quality standards.

In this article we have concluded that the relationship between the environmental quality standards and the river basin management approach of the WFD on the one hand and the authorisation process of the pesticides legislation on the other hand is not very clear and hinder the compliance with the WFD obligations. Our opinion is that the above mentioned recommendations will strengthen the coherence between the WFD and pesticides legislation. They will improve the coordination of these directives and the integration of the WFD requirements into the national authorisation process for plant protection products. The pending new pesticides legislation offers an excellent opportunity to achieve these improvements.

⁸⁴ Cf. Art. 61, paragraph 5 of Regulation 1907/2006 (REACH).

⁸⁵ Cf. recital 72, last sentence, Regulation 1907/2006 REACH, stating that an authorisation (of a substance) should in general be subject to monitoring conditions (of an authorisation).