Review of the Danish risk assessment methodology regarding leaching to groundwater.

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The authors wish to thank all persons for their clear presentations and the openness in the discussions about the various aspects of the methodology.

1 OVERALL RECOMMENDATIONS

The review is aware of contrasting interests. For example, preventing leaching may conflict with managing resistance of pest organisms against plant protection products. Although sometimes such conflicts are indicated, the review merely addresses the leaching aspect.

Recommendations on how to improve and streamline the assessment of the risk of leaching to groundwater.

Regulatory

A clear definition of the general protection goal and specific protection goal is the basis for a good and scientifically sound decision scheme. Without these definitions, it cannot be fully reviewed whether the decision scheme is adequate. The protection goal is safeguarding the drinking water function of the groundwater. This is not stated explicitly in documents, neither at the EU level nor at the Danish national level. Several aspects of the specific protection goal are given in various documents, but a full definition is not given. Specifying the goal in terms of limit concentration, in both space (areal aspect) and time (temporal aspect) are crucial to a good decision scheme. The temporal and spatial aspects are relevant to the assessment procedures to be followed. Setting the protection goals is the responsibility of risk managers.

The current leaching assessment procedure follows the lines of a tiered approach. For two reasons, it cannot be determined whether the approach is fully accurate to meet the specific protection goal. The first reason is the point stated above, that the specific protection goal is not fully stated in quantitative terms. The second reason is that the results of the second tier and the monitoring, including the PLAP systems, are not set into context, i.e. it is unknown how they rank in vulnerability. This vulnerability is determined by the interaction of substance properties, soil properties and climatic conditions after the application of the substance. We recommend taking the temporal aspect into account when assessing the results.

Tiered approaches ideally are set-up in a way to make the assessment procedure efficient, i.e. to decide at the lowest possible tier that a substance will meet the criteria of the protection goal. In an efficient tiered approach, each tier has sufficient 'sieving' capacity, i.e. an approval decision can be taken for a substantial part of the substances entering the tier. The point of departure, also referred to as Tier 0, is the assessment at the EU level with an assessment factor of 100. The approach in tier 1 is rather conservative. If a substance with a modern data package passes this tier, then it is highly unlikely that in practice leaching will occur above acceptable limits. Based on substance characteristics in currently available databases however, it is expected that only few substances will pass this tier. Consequently, most substances will have to be assessed in a higher tier, requiring much more effort. It would be worthwhile to investigate whether some relaxation of the procedure would still provide the high level of protection that is sought for groundwater in Denmark.

As the second tier requires results of experiments performed under conditions representative of Danish conditions, potential applicants may perform a cost benefit analysis and decide not to apply.

Denmark uses a definition for ‘relevant metabolites’ that deviates from the definition at the EU level. This definition is more strict (i.e. more metabolites are considered to be relevant).Substances that are considered mineralisation end-products are considered non-relevant. For other metabolites it is assessed whether they may occur naturally and/or, according to an ad hoc appraisal, may pose a significant risk to public health and the environment. This opens the procedure to subjectivity (what is naturally occurring, and what is significant?). It is recommended to define a clear procedure with objective end points to determine whether or not a metabolite should be considered relevant. It would still be possible to regulate non-relevant metabolites by setting threshold limits in law as for example is done in the Netherlands.

Overall, the availability of active substances onto the market is likely to be more restricted in Denmark than in other EU member states for three reasons. First, the leaching assessment is intrinsically more conservative than leaching schemes in other member states. Secondly, compounds with high Koc and thus low potential for leaching tend to have greater persistency and thus may fail the persistence criteria that exist in Denmark but not in other member states. Finally, compounds with very high degradation rates and thus low potential for leaching of the active substance may be subjected to leaching assessments on all major metabolites rather than just those that retain pesticidal and/or toxicological properties. This may result in a lower availability of substances for Danish agriculture and have negative consequences for, amongst others, resistance control.

Communication

A clearly articulated specific protection goal would help in discussions about several aspects: it may underpin the necessary actions and precautionary measures and facilitate communication about these

Management

Persons at DK-EPA may be involved in risk assessment, authorisation decisions and risk management. This has several disadvantages. A procedure in which these tasks are given to separate (legal) entities would be beneficial to the further development of the decision scheme as well as the decision taking, at least from a theoretical point of view. It should be stressed at this point that the above is from a theoretical point of view. The review did not encounter any problems in this regard and acknowledges that quality assurance measures have been taken in order to avoid the potential problems.

The leaching assessment is only one aspect of the overall authorisation procedure of plant protection products. An impact assessment of the leaching assessment on the availability of PPP to the agricultural sector (how many substances are not authorised because of (only) this assessment) could strengthen the acceptance of the procedure by stakeholders.

Recommendations for further initiatives on preventing pesticide leaching to groundwater

Currently, there are areas in Denmark, presumably vulnerable to PPP leaching, on which agriculture with intensive use of PPP occurs. For example, potato growing on sandy soils very low in organic carbon. Both the soils and the growing system make the areas vulnerable. In the current system, findings of substances in groundwater in such areas may have repercussion on the authorisation. Initiative could be taken to reduce or restrict pesticide use in these areas (e.g. via promotion of wider rotation schemes or limitations to application windows) whilst keeping the substances available for other areas.

Recommendations for further research and development

It would be beneficial to further characterise Danish agricultural soils, both sandy soils and fine-textured (heavier) soils, with respect to their vulnerability to leaching of pesticides. This would be helpful to:

- The PPP authorisation procedure and decision making
- The management of current groundwater abstraction areas and the planning of new ones.

This may be particularly challenging for the heavier soils.

Findings of PPP in groundwater in Denmark and other countries often can be ascribed to 'old uses', uses outside agriculture and disposal of package materials. It is recommended to try to identify the sources of significant positive samples, such that these are not held against agriculture when agriculture is not the source.

Validation of the assessment scheme

The extensive monitoring programmes should be used to undertake a formal validation of the registration procedure with respect to groundwater, placing all the lines of evidence into context and determining how each element inter-relates (see section 5.3 for further detail).

The current risk assessment scheme seems to be protecting groundwater because shallow (10-20 m) groundwater is increasingly free from contamination by pesticides. Given the slow rate of transfer through aquifer systems, it might be expected that there may still be an increase in detectable residues at deeper levels due to historical pesticide usage that is still working through the system. Such an increase at depth should not be taken as evidence that the regulatory system is not effective.

Design and reporting of monitoring programmes

All monitoring programmes change over time to reflect knowledge obtained and to optimise with respect to time and effort. This is certainly the case for groundwater monitoring in Denmark and we consider that the GRUMO programme is becoming more targeted at vulnerable locations over time. Vulnerability of wells within the drinking water monitoring programme will also change over time because it is risk-based and wells found to be contaminated may be closed and then will not be represented in subsequent monitoring. It is essential that the nature of any changes is communicated effectively so that the implications for results are clear to the end-user community and the general public. The performance of the PLAP programme is consistent and targeted towards confirmation of the registration procedure. To further improve the use of the PLAP programme results should be interpreted in line with the specific protection goal.

Risk management

There seems to be good potential to take a more systematic approach to pesticide management within borehole vicinity zones. This would require the mandatory definition of vicinity zones, either for all water supply boreholes or for all boreholes within areas defined as vulnerable based on knowledge of soil type and hydrogeologic context. The regulatory decision-making process to protect groundwater from contamination with pesticides could be refined to include three options: (1) authorise without any restriction as risk of leaching to groundwater is acceptable; (2) do not authorise due to unacceptable risk of leaching to groundwater; (3) authorise but with a legal requirement for changes to use under some prescribed conditions. Changes to use under the latter decision could range from complete prohibition to use under the most vulnerable conditions, to restrictions on maximum use rate or window for application timing under less vulnerable conditions. By definition, there would be some circumstances where the normal authorised use could occur without restriction (otherwise there would be no authorisation al all).

2 BACKGROUND AND TERMS OF REFERENCE (TEXT PROVIDED TO THE REVIEW)

The review was initiated in spring 2014 with the aim of evaluating the current risk assessment practice with regard to groundwater in Denmark. Furthermore, the review was tasked with giving recommendations on how to improve and streamline the assessment of the risk of leaching to groundwater and providing ideas for further initiatives on preventing pesticide leaching to groundwater.

The authors base their advice on the information provided in Annex 1 and presentations by persons responsible for / performing risk assessments or otherwise involved in the evaluation, and discussions with these persons.

2.1 Background

Regulation 1107/2009/EC (EU 2009) is the basis for the authorisation process of plant protection products (PPP) in Denmark. The Danish Environmental Protection Agency has this basis operationalised for national authorisations in the Framework for the Assessment of Plant Protection Products, which also serves as a guideline for applicants and assessors.

Among many initiatives in the Danish Government's new pesticides strategy 2013 – 2015, an important initiative is to ensure the best possible protection of groundwater in Denmark. To achieve this goal an international review of the current approval practices was launched in spring 2014.

Assessment of the risk of leaching comprises an important part of the fate and behaviour assessment of pesticides in Denmark, and the Danish approach to the risk assessment is conservative compared to the general approach in EU. The reason for this is that almost all drinking water in Denmark comes from untreated groundwater, and due to the Danish geology many soils are relatively vulnerable to leaching. The vulnerability is caused by the presence of macropores and fractures, facilitating preferential flow, in the clayey soils, and high hydraulic conductivity of the sandy soils.

The assessment of the risk to groundwater is described in the Northern Zone guidance document and in the Danish Framework for the assessment of plant protection products.

There is a close connection between the approval scheme and the three Danish groundwater monitoring programs: The National Groundwater Monitoring System, The Waterworks Well Control and The Danish Pesticide Leaching Assessment Program (PLAP).

PLAP is an integrated part of the approval scheme in the sense that it measures whether pesticides applied in accordance with current approval leach to groundwater in unacceptable concentrations. PLAP also improves the scientific foundation for decision-making in the Danish regulation of pesticides. The risk assessment of pesticide leaching to groundwater is largely based on data from modelling, laboratory and only to a minor degree (semi) field studies. However, these types of data may not adequately describe the leaching that may occur under actual field conditions as it does not include the spatial variability (at the field scale) of the soil parameters affecting pesticide leaching. This is of particular importance for silty and loamy soils, where preferential transport may influence pesticide leaching.

Under the Strategic Research Program on Pesticides a number of research projects on groundwater protection have been funded, which have increased knowledge and understanding and helped develop the framework for assessment of pesticide leaching.

In addition to the approval scheme there are a number of targeted regulations for groundwater protection in the vicinity of water supply wells that supply at least 10 households with drinking water:

Art. 21b in the Danish Environmental Protection Act lays out an obligatory 25 m protection zone around the above mentioned water supply wells. Within this zone all agricultural land use, fertilizing and use of pesticides is forbidden.

Art. 24, sct. 1, in the Danish Environmental Protection Act enables the municipality to lay down restrictions in order to protect water supplies against pollution. The municipalities can on the basis of a concrete assessment lay down protection zones around water supply wells, and regulate land uses that threaten water supply interests within these zones.

With the aim to further support the municipalities' use of protection zones around water supply wells, there has been an allotment of 40 mill. DKK in 2012 and 2013. The Ministry of the Environment established a task force that counselled and assisted the municipalities on the administration of the laws on protection of groundwater and drinking water. Furthermore, the 40 mill. DKK financed the delineation of protection zones around approximately half the water supply wells to public waterworks on agricultural land, and also financed an analysis of the need for restrictions on land use within these protection zones.

Art. 26a in the Danish Environmental Protection Act empowers the municipalities to put in place special measures and regulations to safeguard drinking water interests, where a special plan for the area has been enacted. To prevent future pollution from the filling and washing of equipment used for spraying pesticides, a national order was put in place in the spring of 2010 (no. 268 of 31st March 2009) on filling and washing etc. of spraying equipment for substances used for plant protection (the order on washing sites). This national order is superseded in December 2012 with Regulation BEK no 1355.

2.2 Terms of reference and process

The review concerns the Danish assessment of the risk of leaching of pesticides to groundwater as performed by the Danish Environmental Protection Agency when assessing pesticides in the approval process.

The expert group was asked to give their evaluation in the form of a report written in English. The deadline for finishing the report is October 2014.

The primary question was whether the Danish approval scheme gives the necessary protection of the groundwater in order to ensure that the limit value of 0.1 µg/L expressed as an annual arithmetic mean concentration in a groundwater body is not exceeded[1]. The question should be seen in relation to the Danish geology, water supply structure and policy of limited water treatment, and lastly also the precondition, that 90 - 95 % of the Danish territory is represented in the supplementary documentation of the approval system by way of The Danish Pesticide Leaching Assessment Program.

In addition to agriculture, horticulture and forestry the approval procedure also concerns the use on public and paved areas and recreational areas (including golf courses).

[1] Directive 2006/118/EC on the protection of groundwater against pollution and deterioration.

In the review the following points were requested to be considered:

- An overall evaluation of the Danish approach to assess the risk of leaching of pesticides and their metabolites[2] to groundwater as part of the Danish approval system with emphasis on considering if the risk assessment ensures the necessary protection of the groundwater[3] resources in Denmark. This should include an evaluation of the Danish approach for assessing metabolites.
- Compare the Danish risk assessment to the approach applied when approving pesticides in the EU and compare to the approaches in the other countries in the Northern Zone/EU.
- Does the Danish risk assessment scheme take the vulnerable geology in Denmark sufficiently into consideration?
- Are results from the Pesticide Leaching Assessment Program and the other groundwater monitoring programs used to their full extent in the approval scheme?
- Do the three above mentioned Danish monitoring programs give a reliable description of the leaching of individual pesticides used according to the approval conditions and the general status for the groundwater, respectively?
- To which degree of certainty do the current and the planned procedures prevent leaching exceeding targeted limits a) by means of a strict risk assessment and b) by means of designated protection zones?
- Can the risk assessment for groundwater be done in a more simple way without compromising the protection of the groundwater?

The report should as a minimum include conclusions and recommendations concerning:

- An overall assessment of the Danish approach to assessing the risk of leaching of pesticides under the approval scheme seen in connection with other initiatives to protect groundwater.
- Recommendations on how to strengthen the assessment of the risk of leaching to groundwater – if necessary.
- Recommendations on how to improve the groundwater monitoring systems – if necessary.
- Provide ideas for further initiatives on preventing pesticide leaching to groundwater.
- Provide a perspective on the comparison with the approach in EU/other Nordic Zone countries.
- Provide recommendations for further research areas under the Strategic research program on pesticides.

2.3 Limitations

The leaching assessment of PPP is part of the total framework for the authorisation of plant protection products in Denmark. Some observations in this review may be relevant for other parts of the Framework as well. This review does not identify these cross-links nor the possible consequences for those other parts.

Risk assessment for surface water and leaching to groundwater are two areas of the overall authorisation procedure that cannot be seen as independent areas. For example, the procedures may share instruments that are used (e.g. leaching models may be used to quantify drainage and the same input data may be used) and results of one area may affect results for the other area. In general such interaction is ignored in risk assessment procedures. It is also ignored here.

Results of assessments in other areas of the authorisation procedure may affect decisions taken in the assessment of leaching. For example, exceeding a trigger on persistence in soil may lead to the decision not to perform a leaching assessment for the substance as it would not be eligible for authorisation because of the persistence criterion. This type of interaction has not been reviewed.

[2] The Danish EPA is more stringent than the recommendations in the Guidance Document on relevant Metabolites and carries out *ad hoc* appraisals of the extent to which metabolites are significant with respect to health and the environment.

[3] The evaluation should deal with groundwater as defined by the Water Framework Directive.

3 CONTEXT FOR THE LEACHING RISK ASSESSMENT PROCEDURE

3.1 Definitions and starting points

General and specific protection goals

Following EFSA (2010) a risk assessment procedure should be in line with the protection goal set for or agreed upon. This applies to each area of risk assessment. In the documentation provided for the review (see Appendix), the general protection goal of the leaching assessment is not stated, but from that information it may be taken that the general protection goal is 'safeguarding the groundwater from being contaminated with active substances contained in plant protection products (PPP) and their metabolites in view of the drinking water function of the groundwater'.

A specific protection goal translates the general protection goal into terms that are directly usable in the risk assessment procedure. The specific protection goal usually is stated in quantifiable terms, i.e. in terms of both level and extent. Elements of the specific protection goal for groundwater may include:

1. Concentration levels that are acceptable
2. The depth level at which those concentration levels should not be exceeded
3. The basic unit for which the concentrations are estimated
4. The time over which the concentrations are averaged
5. The quantitative target (in terms of space and time).

For example, the specific protection goal may state that the median of the annual average leaching concentrations from a field should not exceed 0.1 µg/L at 1 m depth below the soil surface in 90% of the area of the (potential) use of the PPP.

In a tiered assessment approach, the highest tier should exactly address the specific protection goal. In earlier tiers conservative approaches and assessment factors can be used.

Several elements of the specific protection goal are given in the relevant documents (see references). Based on the assessment procedures in use at the moment, the level with which concentrations should comply is set at 0.1 µg/L for the annual average concentration in water (leachate) reaching the groundwater and the basic unit is the field (with a size of approximately 1 ha). The specific protection goal is not consistently further specified in terms of space (fraction of area that should comply and time (fraction of years in a sequence of years that should comply), so essentially the fifth element is lacking. Therefore it cannot be fully assessed whether procedures are fit for purpose.

A definition of the specific protection goal and a description of the scientific (conceptual) approach taken in the assessment procedures would be beneficial to:

- The assessment of the correct functioning of the procedure (the tiered approach as a whole and the method(s) within each tier);
- The communication with stakeholders, including the general public.

Relevant metabolites

Metabolites are defined as all degradation, reaction and transformation products of pesticides that differ from the ultimate mineralisation products, i.e. CO_2, H_2O and mineral salts. Under anaerobic conditions other ultimate mineralisation products may be formed, but that is not considered in the Framework.

According to the Framework, all metabolites formed in amounts above 10% of applied and in addition those formed in lower amounts but that are suspected to have potential for transport to groundwater are to be assessed, unless they occur commonly in the environment. A few examples of these commonly occurring metabolites are given, but criteria and/or an extensive listing of these substances are missing. DK does not accept the European Guidance Document on non-relevant metabolites (EC 2003). Industry may decide not to apply for an authorisation because of the additional costs to provide data. This potentially leads to a data gap as substance properties may be missing. As such this may violate the principle of the 'level playing field[4]', although it is recognised that some other countries, for example Germany and the Netherlands, do not follow entirely the EU Guidance Document on non-relevant metabolites and have limit values different from those in the guidance in their law. For Denmark, this may have the consequence of a lower availability of PPP.

3.2 Responsibilities

Setting the general and specific protection goals (see under definitions) is the responsibility of politicians and risk managers. In Denmark, the Minister of Environment is responsible (ultimately the Parliament) for the policy concerning the authorisations of PPP. The Danish EPA is the competent authority, i.e. DEPA is responsible for (making) decisions on individual PPP. The further detailing of the procedure on how to assess whether the specific protection goal is met is in the scientific domain.

In daily practice however, employees of the Danish EPA may have preparation of policies, preparation of risk assessment methodology, risk assessment and authorisation decisions as part of their regular job. This is not an ideal situation as:

- Practical, day to day risk assessment issues may have rather large influence on the development of risk assessment methodology. Taking account of particular or specific situations may become the rule rather than the exception in the ERA.
- Personal (political) interest may interfere with authorisation decisions.
- At the political level, considerations other than environmental aspects may steer policy development and, in exceptional cases, overrule the decision on approval / authorisation.

These aspects may interfere with the development of sound ERA methodology and it is recommended to separate responsibilities, where possible.

It should be stressed at this point that the above is from a theoretical point of view. The review did not encounter any problems in this regard and acknowledges that quality assurance measures have been taken in order to avoid the potential problems.

3.3 Procedures

In the European Community, it has become quite common that risk assessment in view of authorisation of plant protection products is according to decision schemes that follow tiered approaches. This is at the European and zonal levels as well as at the national level, although the aim at the European level is to find out whether there are safe uses and at the zonal and national level whether there is compliance with the protection goal(s). Because of the different aims, the decision at the European level, i.e. approval of the active substance, is a boundary condition and should not be seen as a part of the decision scheme at the national level. The national protection goal(s) should not be less protective for the environment than the protection goal set at the European level. Although this requirement has not been assessed explicitly, the approach taken in Denmark regarding groundwater protection is in compliance and there is no indication that the methodologies used violate this requirement.

For each decision scheme, it is essential that it addresses the specific protection goal(s) adequately, i.e. following the decision scheme leads to a negligibly small number of false decisions, in either a positive or negative sense. So the decision scheme has to be effective. In addition, efficiency of the scheme is an important aspect. Efficiency is achieved when decisions are taken with the least effort possible (and acceptable). To this end, in many countries and at the European level, tiered approaches have been introduced in the risk assessment schemes. Major features of a tiered approach are:

- Each tier addresses the same specific protection goal.

[4] 'level playing field' is a concept of fairness, i.e. the same set of rules for agricultural in different countries of the EU; lack of harmonisation may result if the principle is not followed.

- An approval decision at a lower tier is not followed with a non-approval decision at a higher tier (if that higher tier assessment would be performed). As a consequence of this and the first feature, it is always acceptable to skip over tiers (although this may reduce efficiency).
- Lower tiers are simple and conservative, while higher tiers are more realistic but will usually require more effort.
- Each tier, except the highest tier, has sufficient sieving function, i.e. a final decision can be taken for a sufficiently high percentage of substances and only an acceptably low percentage of substances is taken to the next higher tier.

In general, methodologies for establishing input parameters (endpoints) for higher tiers are more complex but also more realistic than those for lower tiers (see for example FOCUS 2009). This is not a feature of tiered approaches, although it can be expected because of introduction of more realism in higher tiers.

The current approach taken in Denmark is a tiered approach towards the assessment of leaching to groundwater; although it is not formally depicted in that way, it is used in that way. As an overview, the following tiers could be distinguished:

Tier 0	Use of results from the EU leaching assessment with the FOCUS Hamburg scenario, with an assessment factor.
Tier 1	Calculations with selected FOCUS scenarios and models or specific Danish scenarios in combination with the MACRO model
Tier 2	Dedicated field tests (or equivalent), representative of Danish conditions

In addition there is post authorisation monitoring. Results from the PLAP (VAP) monitoring may have direct consequences for the authorisation if substances fail to meet the authorisation criterion.

All tiers address the same (specific) protection goal, although that specific protection goal is not given exactly. The first tier (Tier 1) is clearly more conservative than the second tier, although the extent of additional conservatism cannot be quantified. In an effective tiered approach, each tier has sufficient ‘sieving action’, i.e. there is a certain balance in positive and negative decisions, with this sieving action related to the effort necessary to reach a decision. A tier in which almost all substances get a negative decision, while the majority gets a positive decision at the next higher tier, does not contribute to the effectiveness. It would be better to revise such a tier or combine it with another tier.

Tier 0 is the point of departure. Results from the EU assessment, with an assessment factor, are used to determine whether a further assessment, specific for Denmark, is necessary. Results of PECgw calculations for FOCUS Hamburg are used in combination with an assessment factor of 100. Because of the approach taken in tier 1, it cannot be excluded that substances fulfilling the criterion do not pass tier 1 when assessed according to the methods pertaining to this tier.

Tier 1 consists of a modelling exercise in the same way as the approach taken at the EU level, with prescribed scenarios and models. Major differences are:

1. Inputs to the model are the 80^{th} percentile DegT50, the 20^{th} percentile Koc and the 80^{th} percentile of the Freundlich exponent (no default value given in the documentation). In the EU assessment, geomean values for DegT50 and Koc are taken and the normal mean for the Freundlich exponent (with default values of 0.9 and 1.0 for parent substances and metabolites, respectively.
2. If more than one of the calculated annual average concentrations is above the limit, registration is denied. At the EU-level the 80^{th} percentile concentration is used for the decision, which in practice means that four out of 20 annual averages may fail the criterion. For biennial and triennial application schemes annual averages are calculated, instead of the periodical averages at the EU-level. In these calculations, the substance fails if more than two resp. three of the annual averages are above the criterion. At the EU-level, the 80^{th} percentile from periodical averages is used for the decision.

Both of these points add conservatism to the approach as compared to the approach taken at the EU level and in several member states. Wash-off is not included in the procedure, which is the same approach as currently taken at the EU level. This is not conservative. The overall added conservatism may amount to a factor of 100[5] or even above. Whether or not this factor is too high can only be assessed fully when the specific protection goal is defined. Based on experience in the Netherlands, where a number of hypothetical substances were run through both tier 1 and tier 2 of the Dutch decision scheme, there seems room for relaxation while still preventing false positive decisions. The Netherlands use the FOCUS Kremsmünster scenario in the first tier and run this with PEARL using central values for DegT50, Koc and 1/n, with 0.1 µg/L as the limit value. Results of these calculations are higher than 90th percentile results of the spatially distributed GeoPEARL model. Differences are often less than an order of magnitude.

In the second tier, dedicated field or lysimeter experiments may prove that a substance does not constitute the potential leaching risk that was identified in tier 1. A number of criteria are defined to check whether the experiments are representative of Danish conditions, although some requirements will not be possible in practice. For example, it will generally not be possible to determine influence of soil characteristics on degradation; hence, it will not be possible to select a realistic worst case with respect to this.

The relevant endpoint of the field or lysimeter experiment is clearly defined: the annual average concentration in the groundwater (or leachate) over the field / lysimeter (i.e. the areic leaching concentration). Furthermore, the concentration is not used as such but after appraisal of the conditions during the experiment. As it is impossible to fully standardise field and lysimeter experiments, this is a strong point in the Danish procedure. However, the appraisal procedure could be made more transparent on how to put the experiments into context (i.e. assessing the experimental conditions in view of the specific protection goal, ranking the experiment in the cumulative vulnerability frequency distribution with respect to both space and time). With respect to decision making, it is not clear how many field/lysimeter experiments are required or how frequently this tier is deployed.

Post authorisation

The PLAP system is a post-authorisation system in which leaching of substances is determined in the field under controlled crop management conditions on behalf of the Danish authorities. Leaching is studied in fields that are thoroughly characterised, with carefully designed and installed monitoring equipment. This is rather unique, but requires quite some effort and resources. The results of the 2 – 3 year experiments have direct effect on the authorisation as results above the threshold limit may lead to withdrawal of approved substances from the market.

With respect to the functioning of PLAP in the decision scheme three observations have to be made: 1) the selection of the monitoring locations is not (yet) related to the specific protection goal, 2) environmental conditions during the experiments are normally not considered in the decision making, and 3) the relative vulnerability as compared to tier 2 is not defined. As this is an important feedback into product authorisation, results of the experiments should be analysed and related to the specific protection goal. In other words, results should be put into the context of the authorisation process. First steps have been set in this direction by establishing the relative vulnerability of some test locations for specific substances. The procedure is however not yet formalised.

Based on the first results of the vulnerability estimation, it seems that the PLAP locations that are tested are relatively vulnerable, not far from a 90th percentile which is frequently used in risk

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[5] The factor of 100 is an indication and dependent on the substance. The overall factor is the result of the selection of properties (a factor of 2 in DT50 may result in a factor of 10 in the concentration, idem for the Koc, going from a 1/n value of 0.9 to 1 may lead to a factor of 10 increase in the concentration. Finally the endpoint of the leaching calculation, effectively the 19th value out of the sorted 20 annual average concentration instead of the 80th percentile adds to the conservatism. Multiplying all these factors would however exaggerate.

assessment. If this percentile would be chosen, the locations might be well suited for such monitoring. When not taking environmental conditions during the experiment into consideration, there is a chance that false positive decisions are taken due to for example lower rain or higher temperature but also that false negative decisions are taken due to extreme weather conditions shortly after application. The review therefore recommends examining PLAP results in line with the specific protection goal.

4 REGULATION AND RISK ASSESSMENT

4.1 Effectiveness of the scheme in protecting groundwater

The risk assessment scheme for leaching to groundwater has a set-up that is similar to set-ups in several other countries in the EU. It is also similar to the scheme provided by FOCUS (2009), but should not be compared to that because of the totally different goals of the schemes.

As discussed earlier, the most important aspect of an assessment scheme is that it is effective, i.e. that decisions are taken in agreement with the overall and specific protection goals. Currently often a tiered approach is followed, aiming at adding efficiency to the decision process. It is important to realise that in a tiered approach each tier addresses the protection goal, but that the consequences for the availability of PPP ultimately are determined in the highest tier (provided that this tier is feasible from an economic point of view). In a tiered approach, the number of tiers is not important, but overall the approach has to be efficient. This means that there has to be an acceptable balance between the effort and the decision taken at that tier, i.e. the ratio fail/success has to be acceptable. There has to be an acceptable balance between the tiers as well, i.e. a tier with hardly any discriminating function has no sense.

The current authorisation approach in Denmark has two tiers, with an additional post-authorisation check. The two pre-authorisation tiers clearly follow a tiered approach. This conclusion is based on comparison of the approaches taken in both tiers.

The first tier is considered not very efficient as, based on currently available databases and expert judgement, many substances probably will fail this tier and will be taken to the next tier. The effort investment necessary to reach a conclusion at this tier is rather low, but the success/fail ratio is probably low as well. As the next tier requires experiments representative for Danish conditions and quite some effort from both applicants and risk assessor, it may be worthwhile to introduce intermediate assessments, with lower requirements while still keeping sufficient margin of conservatism. Such intermediate assessments could, for example, use scenarios closer to the specific protection goal and/or more central values for substance properties.

For the second tier, a clear relationship with the SPG is missing. Both the soil and the climatic conditions should be representative of realistic worst-case conditions, but the overall situation is not quantified in terms of time and space. This would be expected as it is stated that an appraisal of the results and the circumstances under which they were achieved is necessary, as "field and lysimeter studies do not yield incontrovertible results". The post registration monitoring has a kind of control function for authorisation decisions. Monitoring results are in general not used to demonstrate that leaching does not occur in practice despite a suspicion of leaching in the first or second tier, although in some cases such a conclusion was reached. Preferably the results of monitoring should be related to the SPG in order to establish a (solid) basis for withdrawal decisions.

4.2 Impact of the scheme on availability of pesticides

Whether or not authorisation of a PPP is possible is not only determined by the leaching assessment scheme. Other assessment elements may lead to non-approval (e.g. risk to aquatic organisms). There may also be consequences of general decisions and interactions between schemes. This is not considered here.

Within the area of environmental risk assessment two issues are important: 1) the definition of non-relevant metabolites and 2) the persistence criterion. The definition of non-relevancy used in Denmark is more strict than the definition used in many other countries, which means that more metabolites will be subject to the leaching decision scheme. Consequently, it is probable that more substances will not be authorised because of failure of metabolites to meet the leaching criterion. Not meeting the persistence criterion (by these metabolites) would lead to a negative decision, whether or not leaching is assessed.

Denmark uses the same leaching criterion as other countries in the EU, i.e. a concentration of 0.1 μg/l (annual average) in groundwater should not be exceeded. If this is assessed for the agreed specific protection goal, with similar assessment methods and this SPG is in line with that in other countries, then there would be a level playing field. By definition, the highest tier in the decision scheme ultimately determines whether a PPP can be authorised or not. This is true for substances for which authorisation is applied for. Risk/benefit or costs/benefit analyses may however influence the decision whether or not to apply for authorisation. A procedure that asks for much country-specific information may lead to decisions by the potential applicant not to apply.
A relatively small number of available PPP may have side-effects:

- The available PPP will be used more intensively and this may exacerbate the likelihood of exceeding the threshold level by these substances.
- A limited availability of alternatives may have consequences for the development of resistance of pest organisms against PPP. A sufficiently broad availability of substances is crucial in controlling resistance.
- Leaching problems may become worse when higher doses are required to obtain the required results because of adaptation.
- There may be pressure on farmers to use a substance outside label instructions or even to use non-authorised PPP. Eventually this may have consequences for the export position of Danish agriculture when residues are found on products exceeding the MRL.

4.3 Assessment endpoints and criteria

The review heard that there are several assessment endpoints that have a bearing on the environmental fate of pesticides and thus on the protection of groundwater. Risk of parent compounds and relevant[6] metabolites leaching to groundwater is assessed against likelihood that concentration in soil water at the base of the soil layer (1-m depth) will exceed 0.1 μg/L. This is consistent with European regulatory procedure (FOCUS 2000, 2009). However, the modelling undertaken to assess risk of leaching appears to be significantly more conservative than standard European practice (FOCUS 2009); see Section 4.4).

An additional endpoint is included for parent compounds and relevant metabolites, whereby the review heard that an annual average concentration of an active substance or metabolite above 0.1 μg/L in a single experiment in the Pesticide Leaching Assessment Program (PLAP) can initiate regulatory action to take the respective active substance off the market for Denmark. The relative vulnerability of the soils (sandy PLAP sites) was stated to rank approximately at the 90th percentile of Danish sandy agricultural soils; work is in progress for the loamy / clayey soils and the vulnerability of these sites is as yet undefined. Climatic conditions occurring during the experiments should be taken into account when establishing the overall vulnerability of the experiment (see Section 4.5) and application of the 0.1 μg/L criterion to a single detection at any site in PLAP is not-consistent with the assessment target in groundwater modelling for Denmark

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[6] In the context of groundwater, the term "relevant metabolite" is used in a unique legislative context determined according to Sanco/221/2000-rev. 10 (25 February 2003) and refers to metabolites for which there is reason to assume that it has comparable biological activity as the parent substance or meets certain toxicological properties.

(stated to be comparison against the 19th out of 20 *annual average* concentrations taken from the modelling study, related to the field scale).

The Danish assessment scheme includes two additional endpoints relative to practice in other European member states. First, the assessment scheme includes a persistence criterion that is absent in European regulation. This criterion establishes that DT50 must be <6 months for an approval to be granted. The review heard that the persistence endpoint is included partially because of concerns about accumulation in soil, but also because of concerns about basing a long-term risk assessment on data from relatively short-term experiments.

A second difference from standard European practice is that metabolites for inclusion in the environmental risk assessment are mostly solely defined on criteria for presence in regulatory fate studies (concentrations reach >10% of applied radioactivity in soil studies or accumulate over the course of the fate studies). Sometimes an ad hoc non-relevancy assessment is performed, but mostly such metabolites are then assessed against the 0.1 µg/L criterion for concentration in soil water, against detection at >0.1 µg/L in PLAP and against the persistence criterion. In contrast, European regulatory practice is to assess major metabolites for relevance based on whether they exhibit toxicity and/or pesticidal activity. Non-relevant metabolites for European procedures are assessed against a different concentration threshold in the groundwater assessment, i.e. a calculated concentration of 10 µg/L (0.75 µg/L when toxicological information is lacking).

Thus the Danish assessment scheme deviates quite markedly from regulatory practice in the rest of the EU. It is worth noting that the assessment endpoints are not necessarily complementary. As soil persistence is frequently correlated with strength of sorption to soil (high DT50 tends to correlate with high Koc), the persistence endpoint is likely to exclude some compounds that may pass the groundwater assessment and vice versa. The assessment of all major metabolites as for parent compounds is likely to prohibit registration of some compounds that break down rapidly in soil to daughter products of little or no toxicological concern. Coupled with a very precautionary approach to assessing leaching to groundwater, the combined effect may be that there is only a very small number of active substances that can pass the groundwater assessment and persistence assessment for both parent compound and all major metabolites independent of toxicological concern.

4.4 Groundwater modelling assessment in Denmark

Danish modelling for the groundwater leaching assessment is based on PELMO 4.4.3 with the Hamburg scenario or MACRO with Karup and Langvad scenarios. The modelling protocol differs from the standard FOCUS GW scenarios approach as well as the methodology used in national registration procedures in other EU Member States. All of the differences render the Danish modelling assessment more precautionary than it would otherwise be. The differences are briefly detailed below:

a) FOCUS modelling and that in most Member State schemes is based on the geometric mean for pesticide DegT50 and Koc and the arithmetic mean for the Freundlich coefficient, nf. In contrast, the Danish protocol requires the 80th percentile value for DegT50 and nf and the 20th percentile value for Koc. All three parameters are very sensitive in both models, but particularly in PELMO (Dubus, Brown et al. 2003). It is likely that for some compounds this difference in input parameters could yield a difference of several orders of magnitude in predicted concentrations at 1-m depth.
b) FOCUS groundwater modelling ranks predicted annual concentrations at 1-m depth and uses the 80th percentile value for comparison against the 0.1 µg/L threshold. The Danish protocol uses the 19th value out of 20, so only 1 year out of 20 may exceed 0.1 µg/L.
c) The assessment against 0.1 µg/L applies to most metabolites (except ultimate mineralisation products, i.e. CO_2, H_2O and mineral salts, and common naturally occurring substances), rather than to just those metabolites of toxicological and/or pesticidal concern (see also section 4.3).

The review heard that refinements to modelling assumptions allowed within the Danish protocol include using field-derived degradation rate, generating new sorption or degradation data, and excluding specific behaviours (e.g. slower degradation) in alkaline soils because the soil pH range in Denmark is predominantly <pH 7.

Incorporation of time-dependent sorption is allowable in some other EU Member States, but is not permitted within modelling for the Danish assessment. Time-dependent sorption currently is being reviewed by EFSA; the review wishes not to advise on this point at this moment.

The overall conservatism of the Danish leaching assessment is confirmed by a study that compared Northern Zone groundwater modelling for hypothetical pesticides with a wide range in Koc, DegT50 and application timing (Stenemo and Alvin 2013). Multiplication factors derived from analysis of pesticide databases were used to convert between mean pesticide properties and those based on 80^{th} (Koc, nf) or 20^{th} (DegT50) percentiles. Of the combinations of Koc, DegT50 and application timing assessed, one of the three Danish modelling scenarios was the most vulnerable for all but one; the Norwegian Heia scenario was most vulnerable for a moderately sorbing pesticide (Koc = 100 mL/g) with very rapid degradation (DegT50 = 1 day). The Stenemo and Alvin (2013) report also compared the PELMO Hamburg scenario for simulations with FOCUS modelling inputs (means for DegT50, Koc and nf) and with Danish modelling inputs. Differences were relatively small (factors of ca. 1.5-5) for compound properties yielding very large PECgw's (10s to 100s of µg/L) though in practice such compounds would never be considered for registration. The report confirms that selection of 80^{th} percentile DT50 and nf and 20^{th} percentile Koc yielded PEC values that were several orders of magnitude larger than those based on mean pesticide properties for PECgw values that were closer to the 0.1 µg/L threshold. For example, runID 64 (DegT50 10 d, Koc 100 mL/g, nf 0.9) gave 0.004 µg/L for standard Hamburg PELMO and 2.472 µg/L for Danish Hamburg PELMO.

The Danish modelling protocol has recently adopted use of PELMO 4 (version 4.4.3) in place of PELMO-3. This version has been shown to be more conservative than PELMO-3 (FOCUS 2009).

Overall, the review felt that the groundwater modelling assessment for Denmark is very conservative relative to other protocols operating across Europe. The selection of input values for pesticide properties is a large part of this conservatism and can result in some very large differences (several orders of magnitude) in predicted leaching relative to other protocols. It will be particularly important to be confident that the combination of 80^{th} percentile DT50, 20^{th} percentile Koc, and 80^{th} percentile nf is a plausible combination that could actually occur in practice.

Given the conservatism of the groundwater modelling assessment, the reviewers sought information on how model predictions compared with observations made in PLAP. It was stated that there are a few examples of false negatives (compounds passed the leaching assessment but were detected above 0.1 µg/L in PLAP); this situation was associated with very old compounds where property datasets were not up to modern standards. There are also examples of false positives (compounds failed the leaching assessment but were not detected above 0.1 µg/L in PLAP); fluroxypyr, clomazone and bentazone were stated to fall into this category.

The review noted that compounds that narrowly pass the modelling assessment will normally be identified for monitoring within PLAP, but that this possibility does not operate for compounds that narrowly fail the modelling assessment.

4.5 Design of PLAP and its role in risk assessment

PLAP was established by the Danish Parliament in 1998 for two reasons: 1) to function as an early-warning system, and 2) to provide confirmation that the registration procedures are working properly. PLAP has now evolved into a fully-integrated part of the regulatory process It is applied post-authorisation, but assessors are aware that they can refer borderline substances for inclusion within PLAP; assessors can also refer substances with very heavy usage. Results of the measurements from monitoring wells at these sites are directly fed back into the authorisation procedure and may lead to withdrawal of substances.

The PLAP system consists of five sites, which are run under good agricultural practice. The relative vulnerability of the leaching results (above and below the threshold limit) is however not exactly known. This relative vulnerability should be made more clear in order to avoid false decisions (see also earlier section). The role in the risk assessment should be more clearly related to the pre-authorisation tiers, including the relative vulnerabilities as compared to the decisions taken. In addition, circumstances before, during and after application have to be taken into account.

Whether or not a substance will be included in the PLAP programme is not clearly defined. There is no single criterion for taking a substance to a PLAP experiment. Such decision seems to be somewhat subjective. The number of substances taken to PLAP could be related to the 'margin of safety', i.e. substances within a specific factor of the threshold criterion. Risk managers could also decide to refer substances that narrowly fail the authorisation criterion to the PLAP system, though this does not happen at present.

At the moment it is rather unclear how results of PLAP are used. The results should be interpreted in line with the specific protection goal. As part of this, the results have to clearly distinguish between those findings originating from drainage water and those from groundwater monitoring screens, as well as to answer the question whether or not the annual average concentration in the groundwater exceeded the threshold value. Direct use of individual sampling values to inform authorisation decisions (as done in Table 8.3 in the PLAP report) is not consistent with the protection goal.

The ensemble of PLAP results could be used to provide an overall assessment of the functioning of the authorisation procedure, by comparing results with both the second tier of the risk assessment and with groundwater monitoring results. A first assessment in this sense suggested 18 non-leachers, 24 in-between and 18 leachers, but further analysis is necessary.

5 GROUNDWATER MONITORING

5.1 Overview of groundwater monitoring programme

There are basically two kinds of pesticide monitoring data generated in Denmark. One is the general pesticide monitoring program in Denmark (Grundvandsovervågning, GVO) with data covering the period 1989-2012 (Thorling, Brüsch et al. 2013) and the other is the Danish Pesticide Leaching Assessment Programme (PLAP) with data covering 1999-2012 (Brüsch, Rosenboom et al. 2013).

The GVO data originate from different sources such as The Groundwater Monitoring Programme (GRUMO), the Waterworks' Well Monitoring Programme (WWMP) and from the Danish regions in connection to separate investigations ("Other wells", including data from e.g. closed down drinking water wells and also some wells exposed to, point source contamination). The data are stored in a publically available database JUPITER, which forms the basis for annual reports on the groundwater status in Denmark. Until now there is no single national overview of all active waterworks and abstraction wells in Denmark. This causes a range of problems related to data handling and reporting, and it limits the answers WWMP monitoring can provide concerning the quality of groundwater used for drinking water supply.

Within the GRUMO program there is a bias in the sampling strategy (Thorling, Brüsch et al. 2013, p. 97), which gives substantial problems in giving meaningful long-term time series. Boreholes with no previous findings of pesticides are only sampled every third year (2007-2010) or two times per five years (2011-2015), as compared to boreholes with previous pesticide detections that are sampled every year.

Interpretation of data generated within GVO would benefit if the figures in the report could be more transparent when it comes to showing the long-term trends of those compounds that have been analysed over the entire period. Presently it is difficult to evaluate the overall trend and to elucidate the contribution of different factors such as *i*) increased number of active substances and degradation compounds included in the analytical program over the years, *ii)* a shift towards more shallow and impacted groundwater being monitored during later years, and *iii*) distribution between banned pesticides versus those still on the market.

Interpretation of data presented in the report would benefit by e.g. subdividing the dataset into 5-year periods and separating the pesticides included in the graphs/tables. It would also be interesting if there were some information on the selection procedure of new pesticides that have been included in the monitoring program, as well as the procedure on the selection of pesticides to be excluded from the program.

In the introduction to the pesticide section in the latest GVO report the general goal of the report is given as "to describe how pesticides behave in groundwater", with the addition of two specific goals, *i*) to demonstrate the present situation during 2012 and *ii*) to demonstrate the overall presence during the entire monitoring period to illustrate to what extent the sampling wells have been affected by pesticides. The overall goal of the general monitoring program is very vague and the review sees opportunities for a more in-depth analysis of the aim of the program – to scrutinise this and evaluate subsequent adjustments of the monitoring program necessary to fulfil this goal.

The PLAP programme is designed to evaluate the risk of leaching to groundwater under Danish field conditions, with the specific aim to analyse whether pesticides applied in accordance with current regulations leach in unacceptable concentrations. This approach is therefore a basis for decision-making in the Danish regulation of pesticides, in contrast to the GVO data from the JUPITER database that aims to assess the overall groundwater situation. The latter includes results that originate from all different sources of pesticide application (i.e. also outside normal agricultural use and likely reflecting management practices/handling issues that are now outdated). GRUMO is not used as a control programme for the approval scheme and results from GRUMO are therefore not directly used for decision-making. However, the results from the program, with its strong focus on pesticides that are now banned and their degradation products, might contribute to a general perception by the public that the current use of pesticide is also to blame for pesticide occurrence in groundwater and that the regulation is not conservative enough. In fact, results from the GRUMO programme demonstrate that findings of currently used pesticides above the 0.1 µg/l threshold occurred in ≤0.7% of the samples collected during 2012 for single pesticides. The corresponding figure from the WWMP programme was ≤0.3%.

5.2 Opportunities for further development of the groundwater monitoring programme

Feedback of monitoring results to the authorisation procedure could enhance and ultimately improve the overall assessment procedure. Just monitoring however does not help, as results have to be put into context. In order to be effective, several aspects have to be known, amongst others, *(i)* the (relative) vulnerability of each of the monitoring sites, *(ii)* whether or not there was a (high probability of) use in the infiltration area of a well, and *(iii)* the age of the sampled water. Furthermore, it would be helpful to decide on the role of the monitoring, signalling function or ultimate decision criterion. In case of the latter, the set-up, including the decision criterion, of the monitoring programme has to be in line with the specific protection goal.

5.3 Reporting of monitoring results and mechanisms for feeding back into the registration procedure

The wealth of groundwater monitoring is a particular strength of the work in Denmark to prevent contamination of groundwater by pesticides. The programmes were presented to the review and concluded to be mature and well managed. The extensive monitoring programmes offer the possibility of undertaking a formal validation of the registration procedure with respect to groundwater, placing all the lines of evidence into context and determining how each element inter-relates. This is done informally at present, and the review heard that results from the groundwater monitoring programme are generally taken as positive evidence that the regulatory system is protective of Danish groundwater as most detections are for banned or heavily regulated compounds and newer groundwater is getting cleaner.

All monitoring programmes change over time to reflect knowledge obtained and to optimise with respect to time and effort. This is certainly the case for groundwater monitoring in Denmark. It is essential that the nature of any changes is communicated effectively so that the implications for results are clear to the end-user community and the general public. The review heard about various changes to the groundwater monitoring programme over time, but was not convinced that these changes were communicated effectively to end-users to place results into context.

The groundwater monitoring programme in Denmark is becoming more focused on vulnerable locations over time and it is targeting shallower groundwater more likely to contain pesticides. This means that the programme is becoming biased towards a greater likelihood of detecting target analytes. The review heard that the targeting on vulnerable locations is an active process, to better follow up on the Water Framework Directive, but that the implications for results are not accounted for in reporting the monitoring programme. The review heard that there are some wells that have been present throughout the monitoring programme. It would be very valuable to use data from these locations to look at long-term trends in pesticide contamination independent of the shift in the overall programme to more vulnerable locations. The review heard that a further assessment of monitoring locations is currently in process; it would be very helpful if the core of sites that has been present throughout the monitoring programme was maintained into the future, also from a statistical point of view.

The review heard that there have also been some implications for monitoring results from changes to analytical methodology. The example given was for an apparent small spike in glyphosate detections that was subsequently attributed to a change in analysis.

In contrast to the groundwater monitoring programme, drinking water monitoring (WWMP) is not targeted at vulnerable locations because sampling locations are dictated by the size of the water abstraction. If anything, this second monitoring programme may be biased towards non-detections because wells that are found to be contaminated may be closed and so will not be represented in subsequent monitoring. Again, the effect of this systematic bias over time needs to be communicated clearly and the implications for interpretation of results made available to end-users. The GRUMO and drinking water monitoring programmes are reported annually within the same dataset, thus providing some balance provided the two datasets are interpreted as giving an overall picture of groundwater contamination for Denmark.

In considering data from the monitoring programme as a whole, the review heard that even though the monitoring network is becoming more vulnerable and the analytical suite more targeted over time, the proportion of samples taken from 0-10m depth showing detectable residues of pesticides is decreasing over time. There are also indications that this trend is starting at the next level down (10-20 m). Given the slow rate of transfer through aquifer systems, it might be expected that there may still be an increase in detectable residues at deeper levels due to historical usage still working through the system. Such an increase at depth should not be taken automatically as evidence that the regulatory system is not effective.

The review felt that the levels of pesticide contamination reported within groundwater monitoring for Denmark were similar to those present in monitoring programmes for Sweden and the Netherlands. It was not clear from the information provided to the review to what extent point sources of contamination are differentiated from diffuse sources when reporting the results of groundwater monitoring. This is a critical point because the management action required to address the two issues is completely different. Point sources can be effectively managed by improving farmer education and working to prevent poor practice during the handling and use of pesticides.

Overall, the review felt that the monitoring datasets were not reported with sufficient resolution. Whilst the overall frequency of detection of pesticides needs to be reported, it is more instructive for the leaching assessment scheme to remove legacy contaminants from the dataset and then report frequency of detection for current-use pesticides. There seemed to be a requirement for more detailed investigation of individual cases where pesticides had been detected. The review received information from a consideration of glyphosate detections where this approach was taken and added significant value to the monitoring exercise. As a specific point, the review heard that where multiple analyses are carried out for a single sample then the maximum value is always used in reporting the data. Given that groundwater monitoring is a scientific rather than a political exercise, the review questioned whether this was a justifiable approach.

There are always challenges as monitoring programmes evolve over time, both in terms of monitoring sites and compounds included within the monitoring programme. For post-registration use this is not a big problem as long as the monitoring results are put into the context of the specific protection goal. This would mean that the results should be related to the conditions at the points of entrance (the infiltration area for the well) and the time of entrance. This is rather challenging, but internationally progress is being made towards this. See amongst others the presentations of the latest modelling workshop (Vienna, 2014).

6 MANAGEMENT

6.1 Management of point sources / non-agricultural sources

Denmark considers that there is no risk of leaching from paved areas, for reasons of no water movement through paved areas and often degradation in the building materials. Based on experience in the Netherlands, non-agricultural use may also lead to contamination of the groundwater. Many finding of the substance BAM (metabolite of dichlobenil) in groundwater are attributed to the use as weed killer in road verges and when constructing pavements. This seems to be in line with findings of pesticides in Danish groundwater, which are highly dominated by the herbicide atrazine (including its degradation products) and the degradation product BAM. These findings originate to a very large extent from applications outside of the agricultural field. Previous regulation permitted the application of these pesticides as total weed killers on e.g. farmyards, industrial areas, churchyards, in private gardens and along roads, i.e. on soils with little organic matter and with applied doses frequently far higher than normally applied in the field.
The presumption that there is no risk of leaching contrasts markedly to the approach taken for agricultural uses.

The use of herbicides as total weed killers outside arable land as well as point sources are of major importance as a source of today’s findings of pesticides in groundwater. Information to farmers on the importance of best management practices was previously lacking. Several investigations have demonstrated high concentrations of pesticides in water from farmyards due to spillage during filling and cleaning of spraying equipment. It was also common practice some decades ago to bury (e.g. in marl-pits) any leftover from the farm, including pesticide containers (containers that have later rusted away and with pesticide residues likely leaching to groundwater).

6.2 Effectiveness of taking action in the vicinity zones

The regulatory decision regarding pesticide leaching to groundwater appears to be binary at present. Either a compound passes the risk assessment scheme and remains on the market, or it fails some aspect of the scheme and is taken off market. This approach is precautionary and can be supported as a political stance as long as there are sufficient active substances on the market to support Danish agricultural systems, including the need to manage pest resistance. As the availability of active substances becomes more restricting to Danish agriculture, a more nuanced approach would identify a third category of active substances that could be used safely in certain circumstances, but would require some form of restriction to use in others. The review considered the opportunities for taking management action in the vicinity zones around groundwater abstraction points. The very detailed understanding of the hydrogeological context across Denmark provides a solid basis for such an approach.

Currently drinking water boreholes are protected by a no-entry zone with 10 m radius and a mandatory protection zone with 25 m radius where growing of crops and application of pesticides and fertiliser are prohibited. The review heard that significant work has also been undertaken to define Vicinity Zones around boreholes; these are zones where it is considered that a reduction in inputs at the soil surface may be justified to reduce leaching of nitrate and pesticides. A grant was made available by the Danish government (5 million DKK) to support definition of the zones, but the decision on whether or not to implement a vicinity zone is a local decision. Municipalities have devolved and local authority to restrict the use of any pesticide in the vicinity zone; farmers must be compensated for any restriction (because a restriction is being placed on a usage activity deemed to be legal through the centralised pesticide authorisation process) and the cost for this compensation is included into the tariff for the water that is supplied.

The current system of management within vicinity zones has some important drawbacks:

i. The decision on whether or not to define a vicinity zone is locally devolved and does not seem to be directly influenced by the intrinsic vulnerability of the borehole;
ii. The water market in Denmark is highly decentralised and very fragmented with ca. 60% of the market run by public companies and ca. 40% in private ownership. Some water companies are run on a voluntary basis. Overall, levels of knowledge about the processes governing pesticide leaching are likely to be rather low across such a diverse water sector, so decisions about pesticide restrictions at local level may not always be optimal.
iii. Restrictions on farmer practice within the Vicinity Zones involve a cost premium imposed on users of the water; this may be a disincentive to taking action.
iv. Options with central funding for management interventions within the Vicinity Zones are rather blunt, involving conversion to organic agriculture or conversion to forestry.
v. Agricultural extension is a vital element for effective management interventions. Extension in Denmark is undertaken by independent consultants paid by the farmers.

The review heard that there has been an assessment of vulnerability to pesticide leaching for sandy soils across Denmark. Work on loamy soils has not yielded an accepted assessment of vulnerability to date. Technical issues relating to soil vulnerability involve: a) inconsistencies in the definition of silt and fine sand (boundary defined at 20 or 63 microns in different categorisations); and b) the lack of a coherent, national soil surveying activity with the latest maps being based on kriging of historic data with correction against error residuals.

There seems to be good potential to take a more systematic approach to pesticide management within borehole vicinity zones. This would require the mandatory definition of vicinity zones, either for all water supply boreholes or for all boreholes within areas defined as vulnerable based on knowledge of soil type and hydrogeologic context. The regulatory decision-making process to protect groundwater from contamination with pesticides could be refined to include three options: (1) authorise without any restriction as risk of leaching to groundwater is acceptable; (2) do not authorise due to unacceptable risk of leaching to groundwater; (3) authorise but with a legal requirement for changes to use under some prescribed conditions. Changes to use under the latter decision could range from complete prohibition to use under the most vulnerable conditions, to restrictions on maximum use rate or window for application timing under less vulnerable conditions. By definition, there would be some circumstances where the normal authorised use could occur without restriction.

The review heard that there is already the legal possibility to include vulnerability maps into the authorisation of pesticides so that municipalities would be mandated to implement an action plan for vulnerable areas. Such maps would allow a range of mitigation measures to be declared onto the pesticide label for individual active substances as part of the authorisation procedure. It would standardise action at a local level, make best use of available information, and ensure that action was targeted at situations with unacceptable and/or uncertain risk.

ANNEX 1 INFORMATION SOURCES

Relevant research projects

Distinction between pesticide sources (Skelnen mellem pesticidkilder): http://mst.dk/service/publikationer/publikationsarkiv/2013/okt/skelnen-mellem-pesticidkilder/

A pesticide contamination – 15 years after (En pesticidforurening – 15 år efter): http://mst.dk/service/publikationer/publikationsarkiv/2012/jun/en-pesticidforurening-%E2%80%93-15-aar-efter/

Determination of the frequency, distribution and quantitative effects of macropores, which connect the soil surface directly with field drains (Undersøgelse af makroporekontinuitet ved markdræn og effekter af direkte forbundne makroporer på jords filterfunktion): http://mst.dk/service/publikationer/publikationsarkiv/2013/okt/undersoegelse-af-makroporekontinuitet-ved-markdraen-og-effekter-af-direkte-forbundne-makroporer-paa-jords-filterfunktion/

Prediction of climatic impacts on pesticide leaching to the aquatic environments: http://mst.dk/service/publikationer/publikationsarkiv/2013/apr/prediction-of-climatic-impacts-on-pesticide-leaching-to-the-aquatic-environments/

Flerdimensional modellering af vandstrømning og stoftransport i de øverste 1-2m af jorden i systemer med markdræn: http://mst.dk/service/publikationer/publikationsarkiv/2012/jul/flerdimensional-modellering-af-vandstroemning-og-stoftransport-i-de-oeverste-1-2m-af-jorden-i-systemer-med-markdraen/

Documentation provided by the Danish EPA

- Danish Framework for the Assessment of Plant Protection Products (2013)
- Comparison of Northern Zone groundwater models (2013)
- Projekt om grundvandsbeskyttelse i andre lande mht pesticider (2013)
- Guidance document on work-sharing in the Northern Zone in the authorization of plant protection products (2013)
- Nyeste VAP rapport og GRUMO rapport
- Vaskepladsbekendtgørelsen
- Bentazonrapporten
- Glyphosatredegørelsen

ABBREVIATIONS

DegT50	Degradation half-life
DT50	Dissipation half-life
DK	Denmark
DKK	Danish Crowns
EC	European Commission
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
ERA	Environmental Risk Assessment
EU	European Union
FOCUS	FOrum for the Coordination of pesticide models and their USe
GEUS	Research Institute for Denmark and Greenland
GRUMO	Groundwater Monitoring Programme
GVO	General groundwater monitoring programme, includes GRUMO and WWMP
GW	Groundwater
Koc	Sorption constant related to organic carbon
MACRO	Simulation model for PPP leaching
MRL	Maximum Residue Limit
nf	Freundlich exponent
PEARL	Simulation model for PPP leaching (Geo indicates spatially distributed)
PECgw	Predicted Environmental Concentration in groundwater
PELMO	Simulation model for PPP leaching
PG	Protection Goal
PLAP	Pesticide Leaching Assessment Programme (=VAP)
PPP	Plant Protection Product
SPG	Specific Protection Goal
WWMP	Waterworks' Well Monitoring Programme

REFERENCES

Brüsch, W., et al. (2013). The Danish Pesticide Leaching Assessment Programme. Monitoring results 1999–June 2012. Copenhagen, GEUS.

Dubus, I. G., et al. (2003). "Sensitivity analyses for four pesticide leaching models. ." Pest. Manag. Sci. doi: 10.1002/ps.723 **59**: 962-982.

EC (2003). Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC. 25 February 2003. Available from:.

EFSA (2010). "Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002)1." Efsa Journal **8**(10).

EU (2009). "REGULATION (EC) No 1107/2009 of the European Parliament en of the Council of 21 October 2009 concerning the placing of plant protection products on the market." Official Journal of the European Union **L 309**: 1-50.

FOCUS (2000). FOCUS groundwater scenarios in the EU review of active substances., EU.

FOCUS (2009). Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 1, 604 pp., Sanco.

Stenemo, F. and A. L. Alvin (2013). Comparison of Northern Zone groundwater models. Uppsala, Geosigma.

Thorling, L., et al. (2013). Grundvand. Status og udvikling 1989 – 2012. Teknisk rapport, GEUS 2013. Copenhagen, GEUS.