North-East Atlantic Commission

NEA(05)5

Gyrodactylus salaris and the implications of the EU Biocides Directive

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1. At the Twenty-First Annual Meeting of the North East Atlantic Commission, the representative of Norway indicated that the European Union is in the process of implementing a Biocides Directive, a consequence of which will be a ban on the use of rotenone from 1 September 2006. He pointed out that the use of rotenone is a key tool in Norway for the eradication of *Gyrodactylus salaris* and that a workshop established by the Commission, which met in February 2004, had recommended the use of rotenone for the treatment of the parasite. He advised the North-East Atlantic Commission that Norway would be seeking to clarify with the European Commission how rotenone and other control measures can continue to be used after 2006. The representative of the European Union agreed to bring the Norwegian concerns to the attention of the authorities in Brussels and suggested that any Party affected by the proposed Directive should also record its concerns in writing to the Health and Consumer Protection Directorate (Directorate General SANCO) in Brussels.

2. The Norwegian Pollution Control Authority wrote to the Directorate General Environment in Brussels on 18 January this year, and this letter was circulated to the Heads of Delegations of the North-East Atlantic Commission. Norway has now received a response from the Directorate General Environment and I have been asked to make this letter available to the Commission. Both letters are attached (Annexes 1 and 2).

3. With regard to the Working Group on *Gyrodactylus salaris* which the Commission had agreed to establish, I have now been advised by Norway that the Chairman will be Stian Johnsen of the Norwegian Food Safety Authority. I have sent a draft agenda to Mr Johnsen for his consideration and the intention would be to hold the first meeting in October/November this year or in March/April 2006. The matter of the implications of the Biocides Directive for treatment of infected salmon rivers has been included on the draft agenda for the first meeting of the Working Group.

Secretary
Edinburgh
27 May, 2005

Annex 1 of NEA(05)5

[Re-typed for clarity]

Directorate General Environment
UNIT B.4
BU 5 2/151
1049 Brussels
Belgium

Norwegian Pollution Control
Authority
P.O.Box 8100 Dep. N-0032
Oslo, Norway
Visiting address:
Strømsveien 96

Att: Klaus Berend

Telephone: +47 22 57 34 00

Date: 18.01.2005
Our ref.: 2005/71 –
Your ref.:
Contact person:

Dear Klaus

Questions about biocide regulation and Rotenone

In Norway, rotenone has for a long time been used as a piscicide to fight the salmon parasite *Gyrodactylus salaris* in salmon rivers. Rotenone is identified as an existing active substance in the Annex I of the Commission Regulation 2032/2203/EC, but not included the review programme and listed in Annex II. According to the biocide regulation active substances not listed in Annex II have to be removed from the market by 1 September 2006. In the attachment we have described the problem of removing Rotenone from market from the Norwegian point of view. We would like to have your response to the questions we are putting forward in the attachment. Thank you in advance for your reply.

Yours sincerely

Eli Vike
Head of Section

Christian Dons
Project Co-ordinator

Enclosure: 1 attachment

Copy to: *Ministry of Environment, P.O.Box 8013, Dep., N-0030 Oslo*
Norwegian directorate for Nature Management, N-7485 Trondheim

Questions regarding the possibility of continued use of Rotenone in Norwegian rivers to eradicate the salmon parasite *Gyrodactylus salaris*

Background:

The substance Rotenone, is identified as an existing active substance in the Annex I of the Commission Regulation 2032/2203/EC, but is not included the review programme and listed in Annex II. Rotenone has been used as a piscicide in Norway to fight the salmon parasite *Gyrodactylus salaris*.

In Norway, the salmon parasite *Gyrodactylus salaris* has proved to be a deadly threat to Atlantic salmon (*Salmo salar*) since its introduction in 1975. In the 45 watercourses in Norway where parasite has been found, the stocks of salmon have been dramatically reduced or wiped out. Norwegian authorities have actively fought the parasite for a number of years. The strategy has included eradication of the parasite where possible in addition to active measures to reduce further spreading. In 2002 a new 10-year action plan was adopted. This plan is based on the existing strategy, but a number of additional measures have been included to improve the chances of success. Priority is also given to development of alternative methods for eradication of the parasite. However, even with alternative methods, small amounts of rotenone are probably required to treat small ponds and seepages connected to the rivers.

Our experience, from past treatments with rotenone, show that it kills all fish and affects aquatic insects in the treated part of the river. All species are, however, re-established in a relatively short time after a rotenone treatment.

On the European level, the threat posed by *G. salaris* has been recognized for a number of years by the North Atlantic Salmon Conservation Organization (NASCO). In the meeting of the North-East Atlantic Commission of NASCO 7 - 11 June 2004, a number of measures to reduce the threat from the parasite were agreed. As part of this it was noted that all European countries with stocks of wild Atlantic salmon should develop contingency plans for handling possible outbreaks of infections. It was further noted that use of rotenone is a key tool for the eradication of the parasite. A ban on the use of rotenone might therefore be of concern to relevant authorities in these countries.

As long as Rotenone is considered to fall under the scope of the biocide directive the Norwegian pollution control Authority is aware that marketing and use of Rotenone as a biocide has to be excluded by 1 September 2006. As far as we can see the two options for further use of Rotenone under the biocide directive are either to notify Rotenone as a new active substance, or apply for use under the "Essential use Application" (art. 15.1. in the biocide directive). In the last case we know that an exemption will have to be limited in time. The option to notify Rotenone will have economic and resource consequences for Norwegian authorities. Application for use under art. 15.1 will give a problem due to the time limitations, since only 1-2 rivers can be treated per year and no complete cessation in the need for Rotenone treatment can be foreseen within 2010.

However, the question is whether there are other options to be able to continue to use Rotenone to fight *Gyrodactylus salaris* in Norwegian salmon rivers. Norway's particular responsibility to protect the Atlantic salmon raises the question if this use of Rotenone will

require authorization under the biocide directive. Can this case be looked upon as an emergency situation to protect an endangered species and accordingly the biodiversity even if the "emergency" situation will have to last for several years, because all rivers cannot be treated at the same time for technical and economical reasons? Furthermore it is important to clarify whether use of Rotenone for treatments of *Gyrodactylus salaris* carried out by the authorities will need authorisation under the directive. The condition is of course that Rotenone will be imported only for this use by the authorities and that no marketing of Rotenone will take place.

Question:

1 Will this use of Rotenone require authorisation of the product under the biocide directive?
2. If it does, what are the options for future use (Art. 15. 1/emergency use/essential use) by the Norwegian directorate for Nature Management and the Norwegian veterinary authorities as long as the national use in Norway does not involve commercial marketing and sales?
3. Are there any other legal possibilities for authorities to continue to use Rotenone for fighting *Gyrodactylus salaris*?

Annex 2 of NEA(05)5

[Re-typed for clarity]

European Commission
Directorate-General
Environment
Directorate B – Protecting the Natural Environment
ENV.B.4 – Biotechnology & Pesticides

Brussels, 25 FEV. 2005
EM/eh D(2005)4003

Ms Eli Vike
Mr Christian Dons
Norwegian Pollution Control Authority
P O Box 8100 Dep
N-0032 OSLO

Subject: Questions about biocide regulation and Rotenone

Dear Ms Vike and Mr Dons,

With regard to your letter of 31 January 2005, in which you ask a number of questions about the withdrawal of the active substance Rotenone from the market by 1 September 2006, please note the following.

As you correctly point out in your letter, Rotenone has only been identified in the framework of the review programme for existing active substances used in biocidal products, which has been established by Article 16(2) of Directive 98/8/EC (the so-called 'Biocides Directive'). As such, it cannot be placed on the market for use as a piscicide beyond 1 September 2006. The only derogation to this rule would be a temporary authorisation of the product for 120 days according to Article 15(1) of the Directive, provided of course that the use of Rotenone would be controlled and limited and that it is used to combat an "*unforeseen danger which cannot be controlled by other means".*

According to the same provision, the Member State has to inform immediately the Commission and the other Member States of such a measure and provide reasons to justify it. Following a vote in the Standing Committee on Biocidal Products, the Commission can then extend the above-mentioned period or decide that the measure may be repeated[1].

As the period of 120 days can be extended or repeated, this might also solve your concern that within that period "only 1-2 rivers can be treated per year". In addition, you write that you are giving priority to the development of alternative methods (to Rotenone use) of eradicating *Gyrodactylus salaris*, which would reduce the need for rotenone to 'only small amounts' to treat small ponds and seepages. It is, therefore somewhat difficult to understand, why the temporary

[1] Of course, if the justification provided by the Member State is not adequate, the Commission may also decide for the measure to be revoked.

authorisation solution of Article 15(1) does not meet your needs, once the alternatives are available.

Until such time, there could be another solution; as you know, the Commission has been made aware that in certain cases there is a need to extend the phase-out period for non-notified active substances contained in biocidal products that have an essential use and no technically or financially viable alternatives. We have therefore suggested to introduce a provision in the forthcoming 3rd Review Regulation that would allow Member States who need an extension of the phase-out period beyond 1 September 2006 (and up to 14.5.2010 at the latest) to submit an application using the specific form developed for this purpose. In their application, the Member State must explain why they consider the use of the biocidal product as essential; also, they must give information on efforts undertaken to find alternative solutions and/or submit a complete dossier for the evaluation of the active substance in order to be included in the positive list of the Directive. On the basis of this information a decision may be taken following a vote in the Standing Committee on Biocidal Products. It might also be possible to introduce a more permanent solution for such cases into the Directive, when it will be reviewed in the light of the report[2] from the Commission in accordance with Article 18(5).

Such an extension of the phase-out period for reasons of essential use of the substance is distinct from Article 15.1 of the Directive, which only provides for temporary authorisation of a biocidal product. There would be no time constrains to the approval and subsequent use of the Rotenone in bodies of water but this would only be allowed until the end of the transitional period (14.5.2010). Thereafter, the use of Article 15(1) provides for a 120 days authorisation limit but may be granted whenever the conditions are met. It is for you to estimate the needs for Rotenone treatment after 1 September 2006 and apply for the most appropriate derogatory measures.

Coming to your other questions: the Directive makes no distinction between authorisation for placing on the market of a biocidal product for use by public authorities and authorisation for placing it on the market for use by private (physical or legal) persons. The fact that it is a public authority using the substance in question does not dispense Rotenone from having to undergo an evaluation of the risk it may represent for human and animal health and the environment according to the provisions of the Biocides Directive[3].

Finally, Article 2(1)(h) of the Directive provides that "importation of a biocidal product into the customs territory of the Community shall be deemed to constitute placing on the market for the purposes of this Directive" *mutatis mutandis*, the importation for use of Rotenone by the Norwegian directorate for Nature Management and the Norwegian veterinary authorities constitutes placing of the biocidal product on the EEA market and as such it will have to be authorised according to the provisions of the Biocides Directive.

To resume, we foresee only two possible solutions to your problem: either a complete dossier for the evaluation and inclusion of Rotenone in the positive list of the Directive is prepared and submitted by the Norwegian authorities to a Rapporteur Member State of their choice (preferably before 1 March 2006, so placing on the market can continue until the evaluation is completed); or, if as you say the needs are limited, Norway could apply for one or both of the above-described derogatory measures (temporary authorisation or extension of the phase-out period

[2] This report will be submitted by the Commission to the Council in 2007.

[3] Rotenone, when used as a piscicide, is definitely a biocidal product and as such it falls within the scope of Directive 98/8/EC.

based on essential use of the substance), while actively pursuing the search for alternative means to combat infestations by *G. salaris.*

Yours sincerely,

Klaus Berend
Deputy Head of Unit