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Proposed policy decree

Policy decree of the Board for the Authorisation of Plant Protection Products and Biocides of [date] on the implementation of Article 44 of Regulation (EC) No. 1107/2009 in the context of active substances and metabolites from plant protection products that structurally exceed the authorisation criterion for surface water (Policy decree on the implementation of Article 44 of Regulation (EC) No. 1107/2009 regarding structural exceedances of the authorisation criterion in surface water Ctgb 2024).

The Board for the Authorisation of Plant Protection Products and Biocides, having regard to Article 44 in conjunction with Articles 4 and 29 of Regulation (EC) No. 1107/2009 in conjunction with Regulation (EU) 546/2011 and Article 4:81, first clause, of the General Administrative Law Act;

Decree:

Article 1. Definitions

For the purposes of this policy decree, the following definitions are used:

Pesticides Atlas: digital application (<https://www.bestrijdingsmiddelenatlas.nl>) published by the Centre for Environmental Sciences Leiden and funded by the Ministry of Infrastructure and Water Management, in cooperation with Rijkswaterstaat WVL, UvW, RIVM and Ctgb, in which a national picture of active substances in relation to various standards, including the authorisation criterion for plant protection products, in surface water is given on the basis of monitoring data from regional water authorities.

Ctgb: Board for the authorisation of plant protection products and biocides;

Plant protection product: a plant protection product as referred to in Article 2, first clause, of Regulation (EC) No. 1107/2009;

Monitoring point: location where substances are measured, usually several measurements per year.

Metabolite: Metabolic degradation product of an active substance.

Monitoring results: results at monitoring points concerning active substances and/or metabolites in surface water as reported in the Pesticides Atlas.

46 *Non-verifiable*: result from a monitoring point reported as "not found, above the standard (non-
47 verifiable)" in the Pesticides Atlas as a result of the reporting limit (above the authorisation criterion)
48 of the analytical method used at the monitoring point.

49
50 *Exceedance*: result from a monitoring point where the 90th percentile concentration of
51 measurements within a calendar year of an active substance or metabolite above the authorisation
52 criterion has been reported in the Pesticide Atlas.

53
54 *Exceedance index*: point-based index representing the degree of exceedance of a substance, where
55 an exceedance of 1 to 5 times the permitted value yields 1 point and exceedances higher than 5x the
56 permitted value yield 5 points. The total number of points is divided by the total number of
57 monitoring points for the substance in question.

58
59 *Authorisation criterion*: authorisation criterion (plant protection product) as reported in the
60 Pesticides Atlas.

61
62 *Authorisation standard*: authorisation standard for a plant protection product based on studies with
63 aquatic organisms.

64
65 *Regulation (EC) No. 1107/2009*: Regulation (EC) No. 1107/2009 of the European Parliament and
66 Council of 21 October 2009 concerning the placing of plant protection products on the market and
67 repealing Council Directives 79/117/EEC and 91/414/EEC (OJEU, L 309);

68
69 *Active substance*: an active substance as referred to in Article 2, second clause, of Regulation (EC) No.
70 1107/2009;

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72

73 Article 2. Structural exceedances of the surface water authorisation criterion

74

75 The Ctgb considers an active substance/metabolite for which the authorisation criterion is exceeded
76 in surface water to be a structurally exceeding substance when the monitoring results for this
77 substance meet each of the following criteria:

78

79 a) The exceedance index in the list of substances with the most severe exceedances (the
80 'top exceedances' list) as reported in the Pesticides Atlas in relation to the authorisation
81 criterion has a value of:

82 ▪ ≥ 0.1 in each of the three available calendar years preceding the date of
83 evaluation

84 or

85 ▪ $\geq 0,01$ in each of the three available calendar years preceding the date of
86 evaluation, where at least one of the following criteria is also met:

87 - a significant correlation of exceedances with one or more authorised
88 land use types is present

89 - $\geq 25\%$ of the monitoring points are non-verifiable.

90

91 b) As reported in the Pesticides Atlas, the average number of monitoring points that have
92 shown exceedances during the 3 available calendar years preceding the date of
93 evaluation is ≥ 5 .

94

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97 Article 3. Reassessment

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99 1. The Ctgb considers the structural exceedance of the authorisation criterion for surface water by
100 an active substance or metabolite (as referred to in Article 2 of this policy decree) as an
101 indication (as referred to in Article 44, first clause, of Regulation (EC) No. 1107/2009) that plant
102 protection products based on this active substance and/or the metabolite(s) formed from it may
103 no longer comply with the authorisation requirements in Article 29 of Regulation (EC) No.
104 1107/2009.

105

106

107 2. The Ctgb may reconsider the authorisation of products based on active substances and/or the
108 formed metabolites that structurally exceed the authorisation criterion in surface water, as
109 referred to in Article 2, in accordance with Article 44 of Regulation (EC) No. 1107/2009, whereby
110 for the 'fate and behaviour in surface water' component, the exposure in surface water is re-
111 estimated according to the most up-to-date available knowledge and methodologies as
112 described in the *Evaluation Manual* on the Ctgb website. This re-estimated exposure in surface
113 water is then compared to the authorisation standard of the respective product for aquatic
114 organisms in surface water in the 'risk assessment for aquatic organisms' section.

115

116

117 Article 4. Effective date

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119 1. This policy decree will be published in the *Staatscourant* with explanatory notes.

120 2. This policy decree takes effect one day after this publication.

121

122 Article 5. Citation title

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124 This policy decree shall be cited as: Beleidsregel toepassing artikel 44 Verordening (EG) nr.
125 1107/2009 bij structurele overschrijdingen van het toelatingscriterium in oppervlaktewater Ctgb
126 2024.

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128

129 *Ede, [date]*

130

131 *The Board for the Authorisation of Plant Protection Products and Biocides,*
132 *Represented by,*

133

134 *The Chair,*

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137 Explanatory notes

138
139 When plant protection products enter surface water, they can have negative effects on organisms
140 living in that water. Therefore, the Ctgb assesses whether the use of a plant protection product for
141 which an authorisation is applied for does not lead to unacceptable effects on such aquatic
142 organisms. For this purpose the Ctgb tests against the authorisation standards for surface water, in
143 accordance with applicable European regulations and guidelines. The Ctgb authorises the product in
144 question only if the assessment shows that the proposed use is not expected to result in
145 exceedances of the authorisations standards in surface water. In some cases, the authorisation
146 standards used by the Ctgb may differ per product, for instance due to information from more recent
147 assessments. In the Pesticides Atlas, the most stringent relevant authorisation standard is referred to
148 as the authorisation criterion.

149
150 To watch over water quality, various monitoring programmes in the Netherlands measure plant
151 protection products in surface water. These data are collected and published in the Pesticides Atlas.
152 The monitoring data show that exceedances of the surface water authorisation criterion by active
153 substances and/or metabolites from authorised plant protection products occur in the Netherlands.

154
155 The Ctgb may review an authorisation under Article 44 of Regulation (EC) No. 1107/2009¹ if there are
156 indications that the authorisation requirements are no longer met. Monitoring data indicating
157 exceedances of the authorisation criterion may be such an indication if it is plausible that these
158 exceedances result from the authorised use of authorised plant protection products in accordance
159 with the legal conditions for use.

160
161 *Causes for exceedances of the authorisation criterion in surface water*

162
163 Exceedances of the authorisation criterion in surface water can have various causes. Incidental
164 exceedances are expected to occur, for example, due to incorrect use – in violation of the legal
165 conditions for use – or due to incidental frequent use in a particular region or incidental weather
166 conditions such as an exceptionally dry or wet year. The European authorisation policy cannot
167 prevent occasional exceedances, but aims at an overall 90th percentile protection level that is used as
168 a 'realistic worst case'.

169
170 However, some active substances or metabolites from plant protection products show a *structural*
171 pattern of exceedances of the authorisation criterion. When such exceedances occur, they may be
172 related to the authorised use of plant protection products in accordance with the legal instructions
173 for use.

174
175 *Criteria for substances that structurally exceed the authorisation standard*

176
177 Criteria are needed to distinguish structural exceedances of the authorisation criterion by active
178 substances or metabolites from plant protection products from incidental exceedances.

179
180 The Ctgb considers exceedances of the authorisation criterion for surface water to be 'structural'
181 when such exceedances occur frequently, over several years and at several monitoring points. When
182 exceedances are reported in the Pesticides Atlas in the last three available years, this is considered
183 an indication of structural exceedance of the authorisation criterion. If significant correlations of
184 exceedances with certain crops can be shown in the Pesticides Atlas, this may be an additional
185 indication that exceedances are related to specific authorised uses of plant protection products.

186

¹ Article 44, first clause, in conjunction with Article 29, first clause, introductory phrase and part e) in conjunction with Article 4, third clause, introductory phrase and part e)

187 To give substance to the concept of 'frequent exceedances', the Ctgb uses the value of the
188 exceedance index from the 'top exceedances' list as calculated for the Pesticides Atlas. This 'top
189 exceedance substances' list and associated index is used in the Netherlands as a measure of the
190 severity of exceedances of the authorisation criterion in surface water. The exceedance index is a
191 combination of the frequency of exceedance and the level (severity) of such exceedances. For a value
192 of 0.01, the exceedance index means that a maximum of 1% of the monitoring points in the
193 Pesticides Atlas are in exceedance, and for a value of 0.1, a maximum of 10% of the monitoring
194 points are in exceedance. When a substance shows a high level of exceedance at one or more
195 monitoring points ($\geq 5x$ the permissible standard), the percentages of such monitoring points with
196 the corresponding index values are less than 1% and 10%, respectively.

197
198 If the value of the exceedance index in the Pesticides Atlas is 0.1 or higher, the Ctgb regards this as
199 an indication of structural exceedance of the authorisation criterion by the substance in question. A
200 value of 0.01 to 0.1 can also be indicative of structural exceedance of the authorisation criterion by
201 the substance in question. However, in that case additional evidence of structural exceedance is
202 needed, for example a significant correlation of exceedances with the authorised land use of plant
203 protection products based on the substance in question.

204
205 Monitoring sometimes uses a 'non-verifiable' analytical method, which cannot measure the
206 substance in question at concentrations corresponding to the authorisation standard. It is then
207 unknown whether the substance actually exceeds the authorisation standard. At several 'non-
208 verifiable' monitoring points, a significant correlation between exceedances of an active substance
209 and/or metabolite and the authorised land use of plant protection products based on that substance
210 may be present, but not statistically detectable. The higher the percentage of 'non-verifiable'
211 monitoring points, the less reliable the monitoring results are. When 'non-verifiable' analytical
212 methods are used at more than a quarter of the sampled monitoring points, an excessive impact on
213 the outcome of the correlations is expected. Therefore, for substances that are 'non-verifiable' at
214 more than a quarter of the monitoring points, it is assumed that a significant correlation with the
215 authorised land use of plant protection products could exist, even if significant correlations with land
216 use are absent in the Pesticides Atlas.

217
218 A key criterion for structural exceedances is that there must be a minimum number of exceedances,
219 which would exclude incidental exceedances. The latter could be due to incorrect use, for example,
220 and not to the authorisation conditions themselves. The number of monitoring points in the
221 Netherlands varies by substance. Consequently, the value of the exceedance index alone cannot be
222 relied upon. In practice, the number of monitoring points is around 500 for many substances; the
223 minimum is 1% of this (by analogy with an exceedance index value of 0.01). For a substance to be
224 considered structurally exceeding an authorisation standard, exceedances must be measured at a
225 minimum of five monitoring points (averaged over three years).

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227

228 *Reassessment pursuant to Article 44 Regulation (EC) No. 1107/2009*

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230 In accordance with Article 44 of Regulation (EC) No. 1107/2009, structural exceedances of the
231 authorisation criterion by an active substance and/or its metabolites may trigger a review of the
232 authorisation of plant protection products intended for professional use that are based on this
233 substance. Non-professional use of such products is generally excluded from review, as this use is not
234 expected to contribute significantly to structural exceedances of authorisation standards.

235

236 The assessment framework used in the risk assessment of plant protection products is not static but
237 evolves over time. New knowledge and methodologies are becoming available, enabling increasingly
238 adequate estimates of, among other things, the exposure of aquatic organisms in surface water to
239 active substances and metabolites in plant protection products. Authorised plant protection products
240 require periodic renewal in accordance with Article 43 of Regulation (EC) No. 1107/2009, at which
241 time the product is re-assessed according to the current state of science and knowledge. By using the
242 latest methodologies to estimate emissions to surface water, the renewal under Article 43 of
243 products based on substances that exceed authorisation standards often leads to the assignment of
244 drift-reducing measures or amendments to the authorisation. In the case of plant protection
245 products based on substances that structurally exceed the authorisation standards, an additional
246 interim reassessment of the aspect of exposure in surface water – prior to the periodic reassessment
247 required under Article 43 – may reveal whether it is necessary at that time to amend or withdraw the
248 authorisation under Article 44 of Regulation (EC) No. 1107/2009.

249

250 There may be procedural reasons not to carry out an interim reassessment of a plant protection
251 product based on a substance that structurally exceeds the authorisation standard, for example
252 when the product has already been reassessed under Article 43 of Regulation (EC) No. 1107/2009 or
253 when it is expected that the substance will lose its approval and an interim reassessment is therefore
254 not advisable.

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