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STATEMENT OF THE COUNCIL'S REASONS

Subject: Position of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council concerning the making available on the market and use of biocidal products

- Statement of the Council's reasons

Adopted by the Council on 21 June 2011

I. INTRODUCTION

The Commission adopted its proposal [1] for a Regulation concerning the placing on the market and use of biocidal products on 12 June 2009.

The Economic and Social Committee adopted its opinion on 17 February 2010. [2] The Committee of the Regions decided not to provide an opinion.

The European Parliament adopted its position at first reading on 22 September 2010. [3]

The Council adopted its position at first reading on 21 June 2011.

II. OBJECTIVE

The aim of the proposal is to revise and replace Directive 98/8/EC concerning the placing of biocidal products on the market, to tackle identified operational weaknesses of the existing regulatory framework, to improve and update certain elements of the authorisation and mutual recognition system and to prevent future problems.

III. ANALYSIS OF THE COUNCIL'S POSITION AT FIRST READING

1. General

The European Parliament adopted several hundred amendments to the Commission proposal. Many are acceptable to the Council and it has therefore included them in its position at first reading (wholly, in part, or in principle).

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1 doc. 11063/09 - COM(2009) 267 final
2 OJ C 347, 18.12.2010, p. 62
3 doc. 13881/10

The Council did not accept the other amendments because their meaning was unclear, their added value was unclear or because they were not consistent with other parts of its position at first reading.

The Council's position at first reading also includes a number of changes other than those envisaged in the European Parliament's position. Section 4 below describes the principal changes of substance. In addition, there are drafting changes to clarify the text and to ensure the overall coherence of the proposed Regulation.

The Commission has indicated that it can accept the Council's position at first reading.

2. EP amendments included in the Council's position at first reading

The Council's position at first reading incorporates the following amendments, either fully or partly, or text with the same or partly the same objective as the proposed amendments: 1, 2, 3, 4, 5, 6, 7, 9, 10, 13, 17, 20, 21, 22, 23, 25, 27, 30, 31, 32, 33, 34, 35, 37, 38, 39, 43, 44, 49, 52, 53, 54, 55, 56, 58, 62, 63, 69, 70, 71, 75, 79, 80, 82, 83, 85, 86, 87, 88, 89, 90, 91, 93, 94, 95, 96, 112, 115, 116, 123, 124, 125, 126, 137, 139, 142, 143, 144, 156, 160, 161, 165, 167, 168, 169, 170, 171, 172, 178, 179, 180, 181, 183, 184, 185, 186, 187, 189, 190, 194, 199, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 218, 219, 220, 225, 226, 227, 228, 229, 230, 231, 232, 234, 235, 239, 241, 242, 247, 248 249, 255, 256, 257, 266, 267, 269, 272, 275, 276, 277, 279, 292, 293, 294, 295, 296, 298, 299, 300, 301, 302, 303, 308, 310, 311, 312, 316, 319, 320, 323, 324, 325, 326, 327, 328, 329, 331, 332, 341, 346, 347, 349, 354, 359/rev, 360 and 361.

However:

- the statement of the purpose of the Regulation in Article 1(1) reflects the proposed legal basis (Article 114 TFEU);
- the reference to the drinking water Directive is in Article 2(3) rather than 2(2);
- while the Council accepts the need to address nanomaterials, because of rapid developments in the field, at this stage it has only included a definition, a statement that approval of active substances does not cover nanomaterials, except where explicitly mentioned, and a reference to the need for technical guidance to be elaborated to take account of the latest scientific information;
- rather than adding a definition of "manufacturer", the necessary clarification appears in Article 83;
- the reference to the POPs Regulation appears in Article 2(3) rather than 5(1);
- requiring a substitution plan for biocidal products containing active substances meeting the exclusion criteria would unnecessarily duplicate the requirement for a comparative assessment under Article 21;
- the Council's position at first reading would open the Union authorisation procedure to all other biocidal products except for those of product-types 14, 15, 17, 20 and 21 from 2020, since a reasonable phase-in period is necessary for the Agency and it would not be appropriate to include the five product-types for which conditions of use differ the most widely within the scope of the procedure; it also provides for the Commission to make a report on the application of the Union authorisation procedure by the end of 2017, in which report the Commission can review whether adjustments are needed to the scope foreseen for 2020;
- only those Annexes containing technical provisions (i.e., Annexes II, III and IV) should be adapted to scientific and technical progress via delegated acts;
- helpdesks should not be mandatory, but an option that Member States can choose as a way to fulfil their obligation to provide advice to applicants.

3. EP Amendments not included in the Council's position at first reading

The following amendments were not acceptable for the Council: 11, 12, 14, 15, 16, 19, 24, 26, 28, 36, 40, 41, 42, 45, 46, 47, 48, 50, 51, 57, 59, 64, 65, 66, 72, 73, 74, 77, 78, 81, 84, 92, 97, 98, 99, 101, 102, 103, 105, 106, 107, 108, 109, 110, 111, 117, 118, 119, 120, 121, 122, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 138, 140, 141, 145, 146, 147, 150, 157, 158, 159, 162, 163, 164, 166, 173, 174, 175, 176, 182, 188, 191, 192, 193, 195, 196, 197, 198, 200, 201, 203, 204, 205, 216, 217, 221, 222, 223, 224, 233, 236, 237, 238, 240, 246, 250 , 251, 252, 253, 258, 259, 262, 263, 264, 265, 270, 271, 274, 280, 281, 282, 283, 284, 285, 286, 287, 288, 291, 297, 306, 307, 309, 318, 321, 322, 330, 342, 343, 350, 353 and 358.

They were not acceptable for the following reasons:

- Rather than deleting the "comitology" recitals, as proposed in amendments 11, 12 and 15, the Council has replaced them, and that proposed in amendment 16, with recitals reflecting the new legal framework.
- Amendment 14 is not consistent with the purpose of recitals agreed interinstitutionally (to justify the body of the legal act).
- Since the Council proposes that the Regulation apply to food contact materials, like other treated articles, amendment 19 is not acceptable.
- Amendments 50, 59, 64, 72, 73, 74, 81, 92, 97, 98, 99, 101, 102, 103, 105, 106, 107, 108, 109, 110, 111, 119, 129, 130, 131, 132, 133, 145, 146, 147, 191, 205, 222, 223, 224, 236 and 342 are not consistent with changes that the Council has introduced, the key elements of which are set out in section 4 below.
- Amendments 24, 26, 36, 40, 41, 42, 162, 163, 164, 188, 195, 197, 217, 238 and 240 are, in the Council's view, superfluous or could create legal confusion.
- Amendments 28, 45, 46, 51, 57, 65, 66, 117, 118, 138, 140, 141, 200, 201, 203, 204, 318 and 350 would not, in the Council's view, provide clarification or added-value.
- Amendments 47, 122, 127, 128, 134, 135, 159, 173, 174, 175, 176, 182, 193, 196, 198, 216, 221, 237 and 353 would place an undue administrative burden on industry, competent authorities or the Agency and/or make the Regulation unduly rigid.

- Amendments 48, 77, 78, 166 and 358 provide for the adoption of delegated acts in cases where the Council considers implementing acts more appropriate.
- Amendment 84 is not acceptable as it would infringe the Commission's right of initiative.
- Amendment 136 is not acceptable as it would give a particular status to just one of the EU's official languages.
- To ensure the uniform application of the Regulation throughout the EU, the Commission should approve any national derogations from or variations to Union authorisations and any use of the safeguard clause (Article 76). Amendments 157, 158 and 233 are therefore not acceptable.
- Amendment 192 is not acceptable because it would permit the renewal of data protection periods.
- Amendments 246, 250 , 251, 252, 253, 258, 259, 262, 263, 264, 265, 270, 271, 274, 280, 281, 282, 283, 284, 285, 286, 287, 288 and 291 are not consistent with the approach to Annex II taken in the Council's position at first reading; amendments 297, 306, 307 and 309 are not consistent with the approach to Annex III and amendments 321, 322 and 330 are not consistent with the approach to Annex VI.

4. Other changes included in the Council's position at first reading

The changes of substance compared to the Commission's initial proposal concern principally: (a) consequences of the Lisbon Treaty; (b) the procedure for the approval of active substances; (c) ECHA's role; (d) products subject to a simplified authorisation procedure; and (e) fees.

(a) Consequences of the Lisbon Treaty

Like the European Parliament, the Council had to adapt the text of the original proposal to the new regime laid down by the Lisbon Treaty regarding powers conferred by the legislator on the Commission. However, the Council considered certain matters which the Parliament was prepared to delegate to the Commission, to be of such importance that they should be decided at the legislative level, i.e. by Parliament and Council jointly. The Council also considered certain decisions for which the Parliament had considered delegated acts appropriate to be in the nature of implementing measures rather than acts which supplement or amend the basic act. This is the case where the basic act provides sufficient detail, so that the Commission is left with little or no discretion, and also in cases where no actual amendment to the basic act would take place. The Council considers that the choices it has made are in conformity with the Treaty and that the overall result, particularly taking into account the greater involvement of the Parliament and Council reflected in the Council's position at first reading, represents a fair and balanced compromise.

(b) Procedure for the approval of active substances

Approval of active substances will, as at present, require the Commission to adopt a legal act. However, rather than amending the basic act repeatedly (the Commission has amended Directive 98/8/EC no fewer than 40 times), the Council considered free-standing implementing measures preferable to a list of approved active substances in an annex to the basic act. Since each authorisation under the Regulation would have to be published by virtue of Article 297 TFEU, and as the Commission would make this list publicly available, the approach would be just as transparent, if not more so. A corollary of this change is that the approval of active substances would take place via implementing acts rather than delegated acts.

This change to the procedure for the approval of active substances parallels that recently agreed for plant protection products. While they were listed in Annex I to Directive 91/414/EEC, Regulation (EC) No 1107/2009 provides for their approval via implementing acts, for their compilation into a free-standing list and for electronic public access to that list.

(c) ECHA's role

While considering that ECHA will have an essential coordination role to play in the approval of active substances and the Union authorisation of biocidal products, the Council considers that all stages of the evaluation of an application should remain the responsibility of the evaluating competent authority. It also considers it essential that all Member States be able to appoint a member of the Biocidal Products Committee and that there be close links between this committee and Member States' competent authorities.

(d) Products subject to a simplified authorisation procedure

The Council agrees that it is appropriate to encourage the placing on the market and use of products presenting a lower level of concern. However, rather than dropping the requirement for active substances to have been approved, as the Commission originally proposed, or requiring them to be approved in the same manner as all other active substances, as the European Parliament proposed at first reading, the Council suggests the establishment of a specific list of active substances presenting low concern and a simplified authorisation procedure for biocidal products containing those active substances. To encourage widespread marketing and use of such products, they could as a general rule circulate throughout the Union after authorisation by a single Member State and a simple notification procedure in other Member States. If another Member State raises objections, the dispute settlement mechanisms of the mutual recognition procedure would be applicable. This is an evolution of the concept and provisions that the Commission initially proposed for “low-risk products”.

(e) Fees

The Council considers that a different approach needs to be taken for fees payable to ECHA from those payable to Member States' competent authorities. While it is appropriate for the Commission to adopt an implementing act laying down the fees payable to ECHA (rather than delegated acts, as the Commission proposed), Member States should be free to set national fees, having regard to the general principles set out in Article 70(3) and any guidance adopted by the Commission.

(f) Other

The Council's position at first reading also contains changes to simplify and clarify the various procedures laid down in the Regulation, particularly those for mutual recognition.

IV. CONCLUSION

The Council believes that its position at first reading represents a balanced package. It looks forward to constructive discussions with the European Parliament at second reading with a view to the early adoption of the Regulation.