

**Review of Annex IV of Reg.
1907/2006**

**Contract No.
070307/2007/473055/MAR/D1**

DHI in association with:

- Milieu Ltd**
- Protection Through Knowledge (PKT) Ltd**

**European Commission
DG Environment
Report
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1 INTRODUCTION

DHI in association with Milieu Ltd and Protection Through Knowledge (PKT) Ltd conducted a review of Annex IV of the Regulation 1907/2006 (REACH). The services were conducted under the contract No.070307/2007/473055/MAR/D1 and the amendment No.1 hereto. The work was followed by the REACH Competent Authorities meeting, subgroup on Annexes (CA-subgroup). The CA-subgroup was comprised of Member States, industry representatives and NGOs.

The review of Annex IV of REACH consisted of the four following tasks:

1. Development of a proposal for the criteria for inclusion on Annex IV, the content of the minimum information package and the format for proposing a substance for inclusion on Annex IV
2. Act as a secretariat for the CA-subgroup
3. Review each proposal and prepare a paper summarizing the review for the CA-subgroup
4. React to comments from the CA-subgroup and prepare briefings for the DG Environment on relevant issue.

The tasks were carried out in the period from 2 August 2007 to June 2008. The final results from Task 1 and Task 3 are presented within this report including the following subjects:

The criteria document

Review of existing entries

Review of proposals for insertion or deletion from Annex IV.

The deliverables from Task 2 and Task 4 such as minutes from meetings and briefing documents are not directly included in this report but included as part of the deliveries related to Task 1 and Task 3 where relevant.

2 TASK 1

During task 1, a draft proposal on the criteria for inclusion on Annex IV and deletion from Annex IV including information requirements was prepared by DHI, Protection Through Knowledge (PTK) Ltd., and Milieu Ltd. The draft was prepared on the basis of comments to a former draft version 2007.08.27 received from the Commission, the meeting of the CA-subgroup on 1 October 2007 and subsequent comments from the CA-subgroup and relevant stakeholders. A format for submission of proposals were elaborated and included in the criteria document. The criteria were endorsed by the REACH Competent Authorities on 19 October 2007.



The evaluation of the existing entries in Annex IV was carried out based on information collected from easily accessible data sources and the approach described in section 5.2 of the criteria document (Appendix 1) was taken. The criteria endorsed by the CA-subgroup for inclusion of substances in Annex IV were applied bearing in mind the historical evidence on existing entries in Annex IV, which means that the burden of proof was directed at identifying evidence of human health or environmental effects according to the criteria. The initial evaluation of the existing entries in Annex IV was presented at the CA-subgroup meeting on 18 December 2007. Stakeholders were invited to submit additional data to the Commission before 31 January 2008 either supporting or disputing the preliminary findings of the evaluation. The final evaluation took into account the additional data submitted by the stakeholders and the results of the evaluation were updated according to the submitted additional data.

The reports on the results from Task 1 are presented in the Appendices:

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| Appendix 1 | Criteria for inclusion of substances in Annex IV of Regulation (EC) No. 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH) |
| Appendix 2 | Review of Annex IV of the Regulation No. 1907/2006 (REACH) Evaluation of existing entries. |

3 TASK 2

The project group acted as a secretariat for the CA-subgroup. The contractor participated in the CA-subgroup meetings on the 1 October 2007, 18 December 2007, 26 March 2008 and 23 May 2008, presented relevant issues and provided updates on the status of the review process related to evaluation of the existing entries and the proposals for insertion or deletion from Annex IV. Furthermore the work consisted of the preparation of draft minutes for the subgroup meetings, drafting of documents and summaries in relation to the evaluations.

Procedures for handling and filing of the incoming proposals for insertion or deletion from Annex IV were developed and applied during the project period. CDs containing the file on the documentation of the incoming proposals were sent to DG Environment 29 October 2008.

4 TASK 3

In Task 3, all the received proposals from stakeholders or other interested parties were reviewed and evaluated. A short summary of each individual proposal was prepared and a conclusion was drawn whether the proposal passed or failed the endorsed criteria.

The work related to the evaluation of submitted proposals for insertion or deletion from Annex IV consisted of the elaboration of a format and a methodology to be used in the review. All incoming proposals were evaluated against the endorsed criteria and information requirements. As a result of the evaluation, a short summary of each individual



proposal was prepared and a conclusion was suggested on whether the proposal passed or failed the criteria. The results of the review are presented in the appendix:

Appendix 3 Review of Annex IV of the Regulation No. 1907/2006 (REACH)
Review of proposals for insertion or deletion of substances from Annex IV of REACH.

5 TASK 4

The project group reacted to comments from the CA-subgroup and provided inputs to the Commission for further administrative processing. The reactions included clarifications and draft replies to different stakeholders on technical aspects of the work undertaken by the project group during the evaluations. This task also encompassed re-evaluations of proposed new entries or proposed deletions of existing entries based on additional information submitted from CAs or from other stakeholders. The results of the re-evaluation of the existing substances are included as part of the review of the existing entries on Annex IV presented in Appendix 2.



L I S T O F A P P E N D I C E S

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