Department for Environment Food & Rural Affairs

Authorisation Decision
by Rebecca Pow MP
Parliamentary Under Secretary of State
On behalf of the Secretary of State for Environment, Food and Rural Affairs
Decision date: 9 December 2022

Application Ref: AFA001-01

UK REACH authorisation Number:

Authorisation number	Authorisation holder	Authorised use
UKREACH/22/05/0	Rolls Royce plc	The processing of a stop-off formulation containing Bis(2-ethylhexyl) phthalate (DEHP) during the diffusion bonding and manufacture of aero engine fan blades.

Preliminary Matters

- Bis(2-ethylhexyl) phthalate (DEHP) is listed in Annex XIV to EUR 2006/1907 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH)[1]. As such, DEHP is subject to the authorisation requirement referred to in Article 56(1) of that Regulation.
- DEHP was included in Annex XIV because it is toxic for reproduction.
- Rolls Royce plc, now of Kings Place, 90 York Way, London, N1 9FX ('the Authorisation Holder') was granted authorisation for this use of DEHP on 7 August 2014 under the EU REACH Regulation ('the Original Authorisation'). The application for the Original Authorisation contained measured exposure data ('the Original Exposure Data').
- The Authorisation Holder submitted a review report to the European Chemicals Agency on 21 August 2020, 18 months before the Original Authorisation expiry date of 21 February 2022.

[1] This is a reference to the retained version of Regulation (EC) No 1907/2006, which is available online at https://www.legislation.gov.uk/eur/2006/1907/contents

- On 5 January 2021, the Authorisation Holder submitted a review report to the Health and Safety Executive ('the Agency').
- On 29 April 2022, the Agency sent its opinion ('the Agency Opinion') to the Secretary of State for Environment, Food and Rural Affairs, and Scottish and Welsh Ministers.

Decision

1. This Decision is addressed to the Authorisation Holder.

2. An authorisation is granted in accordance with Article 60(2) of EUR 2006/1907 for the following use of DEHP as set out in the table above titled 'UK REACH authorisation No.':

   The processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades.

3. The review period referred to in Article 60(9)(e) of EUR 2006/1907 is set at seven years. The authorisation will cease to be valid on 21 February 2029 unless the Authorisation Holder submits a review report in accordance with Article 61(1) by 21 August 2027.

4. The authorisation is subject to the following condition (as well as the requirement in Article 60(10) of EUR 2006/1907 to ensure exposure is reduced to as low a level as is technically and practically possible):

   a. The Authorisation Holder must adhere to the risk management measures (RMMs) and operational conditions (OCs) described in the chemical safety report referred to in Article 62(4)(d) of EUR 2006/1907[2].

5. In the event that a further review report is submitted in accordance with Article 61(1), the Authorisation Holder should:
   a. if they want to continue to rely on the Original Exposure Data, review and submit their conclusions on, whether:

      i. the Original Exposure Data is representative of all stages of the manufacturing process in place when the review report is submitted. If it is not, the Authorisation Holder should submit new measured exposure data;

      ii. the management systems and worker training ensure exposures are being kept to a minimum, including procedural information on training and emergency procedures, for example, spillages.

   b. if there have been any relevant changes since the Original Authorisation was granted, submit new measured exposure data to reflect those

[2] This is a reference to the chemical safety report dated November 2020 submitted by Rolls Royce plc on 5 January 2021 as part of the review report. The risk management measures and operational conditions are described in sections 9 (exposure assessment) and 10 (risk characterisation related to combined exposure).

changes. A relevant change is one which could impact the assessment of exposure levels, such as:

i. changes to the manufacturing process which could impact exposure levels.

ii. changes to the scientific or technical understanding of exposure to DEHP. This could, for example, include changes in the scientific consensus (such as changes to the derived no effect level (DNEL)) or technological advancements (such as changes to the limits of detection (LOD)).

6. This authorisation is not subject to any monitoring arrangements.

Background

7. This decision is made under Articles 61 and 64(8) of EUR 2006/1907.

8. In making this decision I have taken into account:

a. The review report submitted to the Agency.

b. The elements referred to in Article 60(2) and the considerations referred to in Article 61(3) of EUR 2006/1907.

c. The Agency Opinion.

Reasons

9. The Agency concluded that the risks to human health from the use of DEHP applied for are adequately controlled provided that the RMMs and OCs as described in the review report are adhered to.

10. Therefore, authorisation can be granted under Article 60(2) of EUR 2006/1907 for the use of DEHP, provided that those RMMs and OCs are applied.

11. The Agency concluded that the Authorisation Holder has demonstrated that there were no alternatives available with the same function and similar level of performance that were technically and economically feasible for the Authorisation Holder by the expiry date of the Original Authorisation. The Agency concluded that the revised substitution plan is credible for the review period requested and consistent with the analysis of alternatives and the socioeconomic analysis.

12. In its opinion, the Agency recommended that the review period referred to in Article 60(9)(e) of EUR 2006/1907 be set at seven years. This period was recommended taking into account:

a. that adequate control of the risks for workers has been demonstrated;

b. the lack of suitable alternatives at the time the review report was submitted;

c. the Authorisation Holder's historical and ongoing commitment to developing alternatives;

d. the progress made by the Authorisation Holder in developing the most likely alternative;

e. the Authorisation Holder's plan for substitution if the most likely alternative is successful; and

f. the time required to research a different alternative should the most likely alternative fail.

13. In its opinion, the Agency did not recommend any additional conditions or monitoring arrangements to those described in the review report. I agree with the Agency's conclusion that the OCs and RMMs that are in place are appropriate and effective to limit the risks to workers. Therefore, I agree with the Agency's recommendations.

14. In its opinion, the Agency identified the small number of samples that were collected as part of the Original Exposure Data, and the age of the exposure measurements as sources of uncertainty. However, the precautionary nature of the assumptions made in the exposure assessment and the very low risk characterisation ratios provided reassurance to the Agency that the risks of DEHP, as it is used in this process, are adequately controlled by the Authorisation Holder.

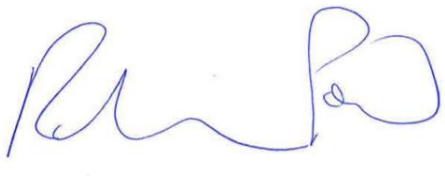
15. Therefore, the Agency recommended that if an additional review report is submitted, the Authorisation Holder should consider generating new measured exposure data ensuring that all stages of the process are covered. The Agency recommended that if the Authorisation Holder wishes to rely on the set of exposure measurements collected as part of the original application, it would be beneficial for the Authorisation Holder to reconsider why the data set from the original application is representative for all activities and provide further details about how worker training and management systems ensure exposures are always kept to a minimum. I agree with the Agency's recommendations.

16. In its opinion, the Agency identified the age of the Original Exposure Data as a source of uncertainty. In the event a further review report is submitted, more time will have passed since the Original Authorisation was granted and changes that could impact the exposure assessment may have taken place. This could, for example, include changes to the manufacturing process which could impact exposure levels, or to the scientific or technical understanding of exposure to DEHP. If any such changes have occurred, then I consider that the Authorisation Holder should submit new measured exposure data as part of its review report.

Conclusion

17. I conclude that, for the proposed use, the risk to human health from the use of DEHP is adequately controlled. I also conclude that circumstances have not changed such that the Original Authorisation should be withdrawn or amended.

18. The Scottish Ministers and the Welsh Ministers have given their consent to this decision in accordance with Articles 4A and 64(8) of EUR 2006/1907.



Rebecca Pow MP

On behalf of the Secretary of State for Environment, Food and Rural Affairs