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COMMISSION IMPLEMENTING DECISION

of 16.3.2022

**refusing an authorisation under Regulation (EC) No 1907/2006 of the European
Parliament and of the Council to Bilbaina de Alquitranes S.A. for a use of pitch, coal
tar, high-temperature**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC¹, and in particular Article 64(8) thereof,

Whereas:

- (1) Pitch, coal tar, high-temperature ('CTPht') is listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of that substance are subject to the authorisation requirement in Article 56(1)(a) of that Regulation.
- (2) On 20 March 2019, Bilbaina de Alquitranes S.A. ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of CTPht as a binder in the production of clay targets.
- (3) On 4 January 2021, the Commission received the opinions on the application adopted by the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency² and sent to it pursuant to Article 64(5), third subparagraph, of Regulation (EC) No 1907/2006.
- (4) RAC concluded in its opinion that it is not possible to determine a derived no-effect level (DNEL) for the carcinogenic properties and a predicted no-effect concentration (PNEC) for the PBT and vPvB properties of CTPht in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore CTPht is a substance for which it is not possible to determine a threshold for the purposes of Article 60(3), points (a) and (b), respectively of that Regulation. As a result, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to that substance and an authorisation may therefore only be granted with respect to that substance under that Article 60(4).
- (5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the chemical safety report are not appropriate and effective to limit the risk to human health and the environment posed by the use of CTPht

¹ OJ L 396, 30.12.2006, p. 1.

² <https://echa.europa.eu/documents/10162/fdad0528-0c86-2285-be81-f2f22ee286ba>

described in the application. In particular, as regards workers' exposure, RAC noted that the applicant failed to demonstrate both that the hierarchy of control is respected at the transfer stations for solids, as they do not prevent worker exposure and that the efficiency of the general ventilation is ensured.

- (6) As regards risk for consumers, i.e. shooters and persons handling the clay targets, RAC is of the view that even if the risk management measures may provide some degree of reduction in exposure potential, the applicant has not demonstrated that they are sufficiently effective in limiting the exposure to CTPht.
- (7) As regards risk for the environment and humans exposed via the environment, RAC is of the view that the applicant has not demonstrated that releases to air have been prevented or minimised as far as technically and practically possible, considering the absence of any treatment of exhaust emissions, in particular from moulding machines, mixer units and holding tanks during the production of clay targets. Moreover, RAC pointed out that 100 % of CTPht is released to the environment during the clay targets service life. Although the collection of larger fragments from some of the shooting grounds may provide some degree of reduction in the potential for release, the applicant has not demonstrated that this is sufficiently effective in limiting the release of CTPht to the environment. RAC was unable to propose additional conditions for authorisation that could make the operational conditions and risk management measures appropriate and effective in limiting the risk for the environment and humans exposed via the environment. Having evaluated the RAC assessment, the Commission agrees with its conclusions.
- (8) In its opinion, SEAC raised substantial reservations on the quantitative and qualitative elements of the applicant's assessment of the socio-economic benefits and the monetised risk to human health and the non-monetised risk to the environment associated with the use of CTPht described in the application. In particular, SEAC noted RAC's conclusion that the applicant had significantly underestimated the releases of CTPht by a factor of 3000 - 7400, resulting in a significant underestimation of the risk. The applicant estimated the benefits of continued use due to profit losses and direct job losses over the review period requested (seven years) to be between 11 and 110 million euro. SEAC considered this to be a higher bound estimate of the monetised benefits. SEAC adjusted the estimated benefits to one-year profit losses to 1 to 10 million euro by also omitting the indirect employment impacts in order not to overstate the long-term welfare impacts. SEAC then compared the monetised risk and benefits and concluded that the range of the estimated monetised benefits partially overlap with the range of the estimated monetised human health impact.
- (9) Moreover, SEAC noted RAC's concerns on the environmental risks related to the PBT and vPvB properties of CTPht. Those concerns are due to a significant underestimation by the applicant of the release of polycyclic aromatic hydrocarbons (PAHs) to the environment during the article service life, corresponding to 70 to 700 tonnes per year, according to RAC's analysis. The related estimated cost of avoiding these releases of the substance is estimated by SEAC to be between 0,4 euro and 40 euro per kilogram when using one-year profit loss, and between 2 euro and 230 euro per kilogram based on the applicant's estimate of seven-year profit loss.
- (10) Having evaluated SEAC's assessment, the Commission, taking into account the significantly underestimated risk to human health and the environment, as well as the resulting low cost of avoiding those releases even with the higher bound estimate of the monetised benefits, concludes that the applicant has failed to demonstrate that

socio-economic benefits outweigh the risk to human health and the environment arising from the continued use of the substance.

- (11) As a consequence, the applicant has failed to fulfil the condition laid down in Article 60(4) of Regulation (EC) No 1907/2006 that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance. Therefore, an authorisation for the use of CTPht as a binder in the production of clay targets cannot be granted.
- (12) A suitable alternative should be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible for the applicant or its downstream users, the applicant is required to submit a substitution plan. An alternative that provides the functionality and level of technical performance necessary for the use applied for should be considered to be technically feasible. Certain potential alternatives may provide some functionality but at some loss to performance or in a manner that involves technical compromises that would impair the functionality. In such cases, unless justified by particular circumstances, the Commission should not consider a potential alternative to be technically feasible for the applicant where the applicant has demonstrated that it or its downstream users are not able to accommodate such losses to performance or technical compromises by applying a reasonable additional effort, taking into account the circumstances of the case. Similarly, in order to be considered economically feasible, the use of the alternative should not lead to a negative economic impact of a magnitude that would jeopardise the economic viability of the operations related to the use applied for.
- (13) In its opinion, SEAC concluded that the applicant has not demonstrated the absence of suitable alternative substances or technologies, with the same function and similar level of performance, that are safer and technically and economically feasible. In addition, SEAC notes that other potential alternatives than those listed by the applicant exist, and that the reason for not shortlisting them is not always well justified.
- (14) As regards the technical feasibility of alternatives, after evaluating SEAC's assessment and all information available, the Commission acknowledges that there are at least two technically feasible alternatives to CTPht for the production of clay targets in the Union. However, one of the shortlisted alternatives, petroleum pitch, contains high levels of PAHs and, based on safety, RAC does not recommend substitution to that alternative. The other shortlisted alternative, pine (rosin) resin, is a low-PAH content binder that SEAC considers also technically feasible, despite, according to the applicant, a slightly worse performance as regards breakability, compared with targets produced with CTPht. The Commission agrees with SEAC that substitution to low-PAH content binders seems technically feasible. The Commission also notes that clay targets using other low-PAH content binders have not been assessed by the applicant, but are available in several Member States and are also used in international shooting competitions, including the Olympic Games.
- (15) As regards the economic feasibility of alternatives, SEAC acknowledged that the substitution of CTPht to pine (rosin) resin can lead to a loss of marketshare and profit for the applicant's two downstream users, but recognised that it is difficult to foresee the market's reaction and quantify the effect. Despite that there is no established threshold for economic feasibility, SEAC considered that the applicant has not shown that substitution is not economically feasible. Regarding the availability of alternatives, pine (rosin) resin is, according to the applicant, not available in sufficient

quantities in the Union in the short- to medium-term, while SEAC considered that the availability can increase with an increased demand. The Commission, after evaluating SEAC's assessment and having assessed all the available information, considers that the economic feasibility and short-term availability of pine (rosin) resin is uncertain for the applicant's two downstream users who are producing clay targets, as they will have to source a more costly raw material and, in addition, adapt their production processes, leading to downtime in manufacturing, resulting in a loss of their market share. Therefore, the Commission concludes that it is uncertain whether the technically feasible alternative is also economically feasible for the applicant's downstream users.

- (16) Taking into account the availability of suitable alternatives in the Union, the applicant submitted a substitution plan upon SEAC's request. SEAC assessed the substitution plan and concluded that it is not credible, due to a lack of clarity and of sufficient level of detail. The Commission, after evaluating SEAC's assessment, agrees with that conclusion.
- (17) The Commission acknowledges that there are suitable alternatives available in the Union for the same use applied for, as there are clay targets using other low-PAH content binders on the market in the EU. It is uncertain whether those alternatives are economically feasible for the two downstream users by the sunset date. The applicant was therefore required to submit a substitution plan. However, since the substitution plan submitted is not credible, the Commission considers that the applicant has not fulfilled this condition for granting an authorisation under Article 60(4) of Regulation (EC) No 1907/2006 either.
- (18) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to refuse the authorisation for the use of CTPht as a binder in the production of clay targets applied for.
- (19) The Commission has based its assessment on the relevant scientific evidence currently available, as assessed by RAC and SEAC and, after having carried out a detailed examination, based its conclusions on a sufficient amount of material and reliable information allowing it to conclude.
- (20) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is hereby refused in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the use of pitch, coal tar, high temperature (EC No 266-028-2; CAS No 65996-93-2) as a binder in the production of clay targets.

Article 2

This Decision is addressed to Bilbaina de Alquitranes S.A., Obispo Olaechea 49, 48903, Luchana-Barancaldo Vizcaya, Spain.

Done at Brussels, 16.3.2022

For the Commission

Thierry BRETON

Member of the Commission

