Un caso concreto di autorizzazione/sostituzione: esabromociclododecano

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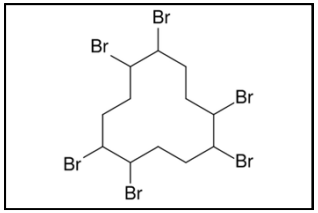
Domanda di autorizzazione

- Esabromociclododecano (HBCDD) e isomeri incluso in allegato XIV REACH perché sostanza persistente, bioaccumulabile e tossica **(PBT)**

FUNZIONE: ritardante di fiamma

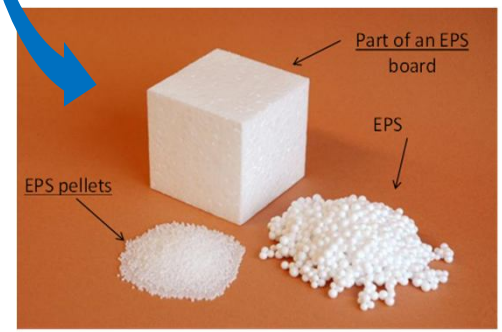


- Autorizzazione richiesta da 13 utilizzatori (formulatori) per due usi:
  - **Formulazione di polistirene espanso** (EPS) utilizzando HBCDD come ritardante di fiamma
  - **Produzione di articoli in polistirene espanso** (EPS) ignifugo per l'uso in **applicazioni edili**

- Commissione Europea ha concesso l'autorizzazione il 20 gennaio 2016 (Decisione 2016/C 10/04)

USI autorizzati

- **Uso 1**: Formulazione di polistirene espanso (EPS) ignifugo in granuli (pellet) solidi non espansi utilizzando l'HBCDD come additivo ritardante di fiamma (per applicazioni edili)
- **Uso 2**: Produzione di articoli in polistirene espanso (EPS) ignifugo per uso in applicazioni edili



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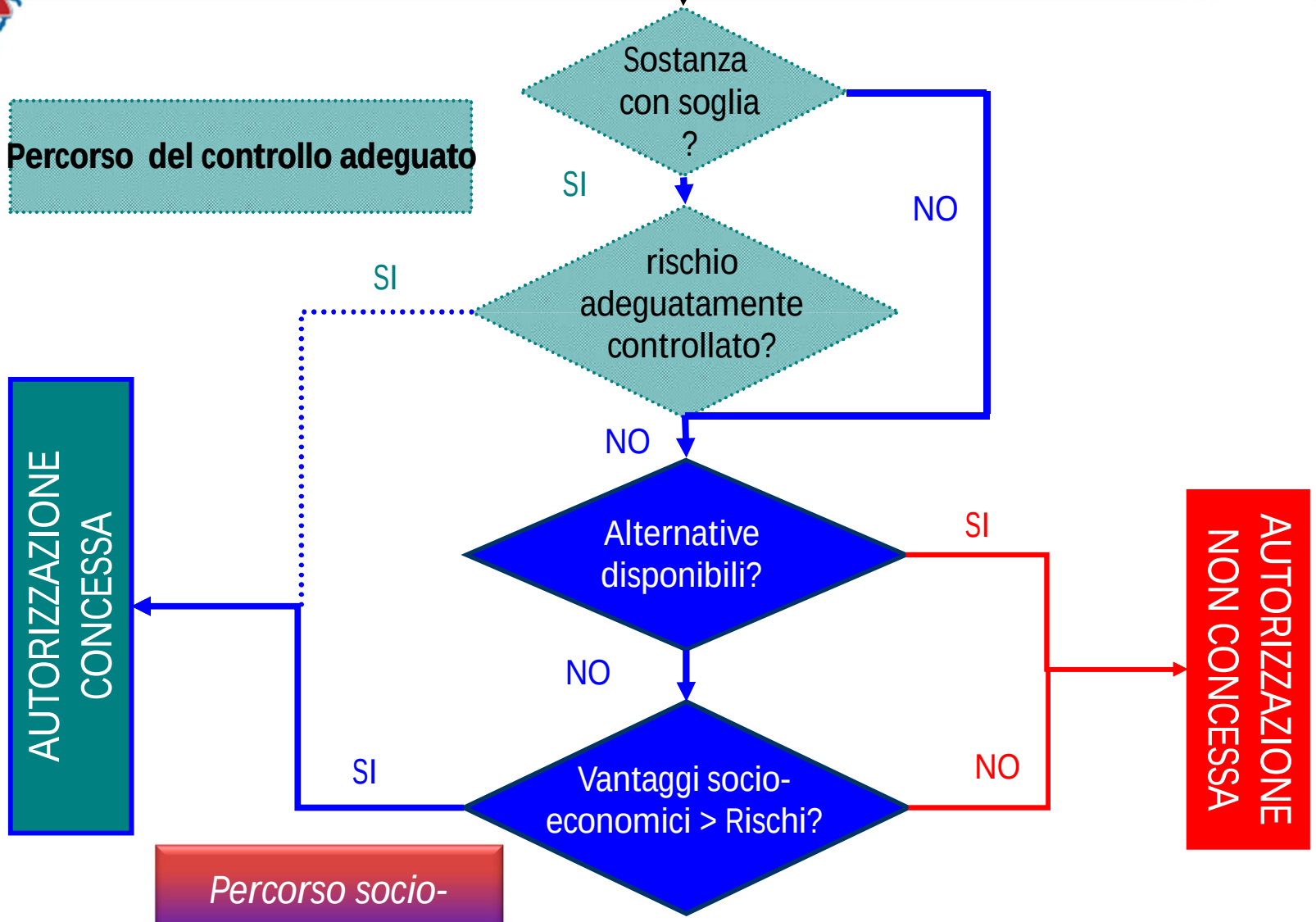
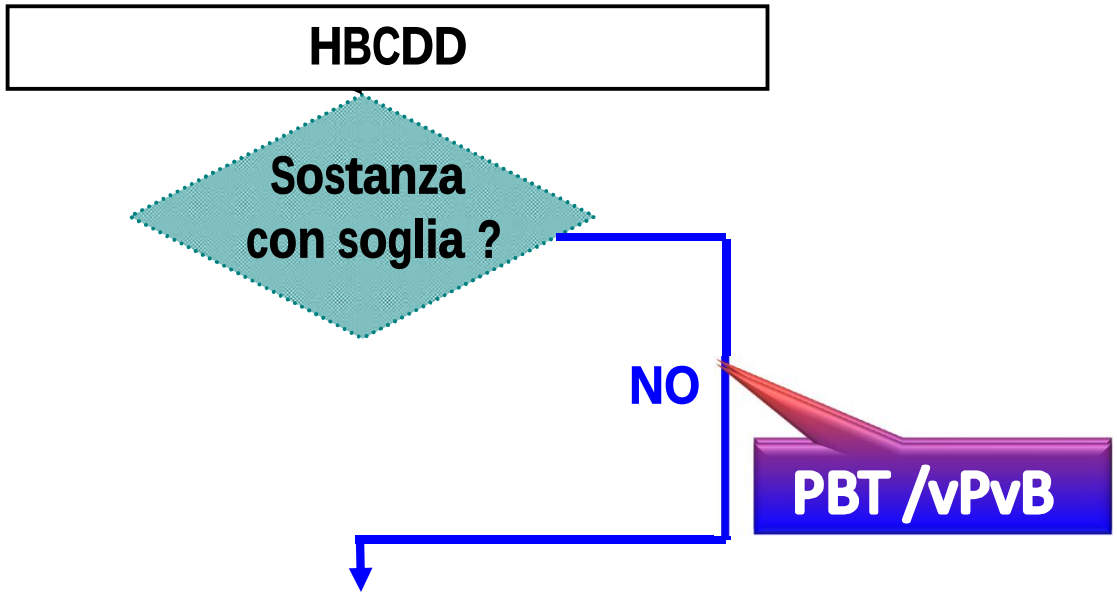
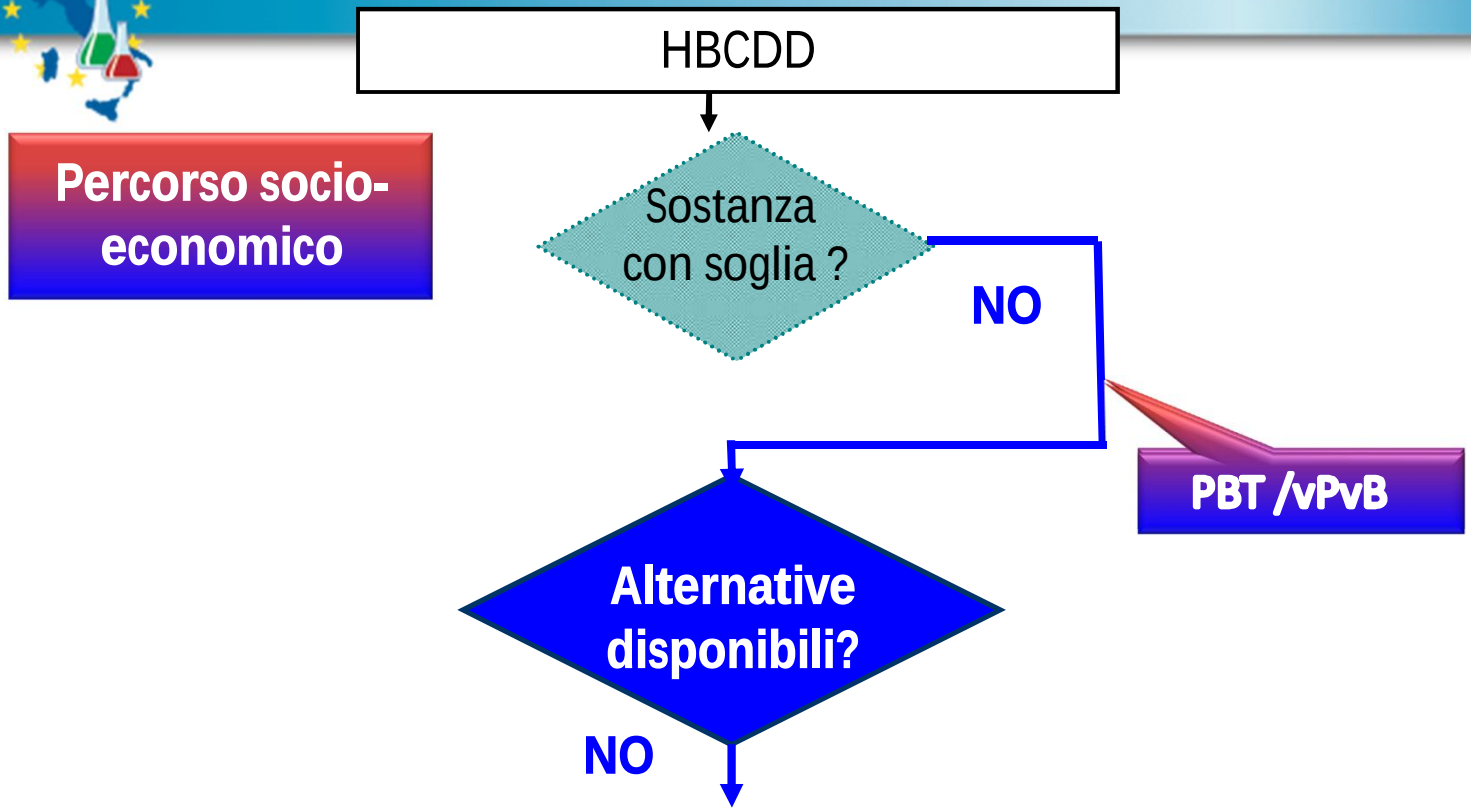
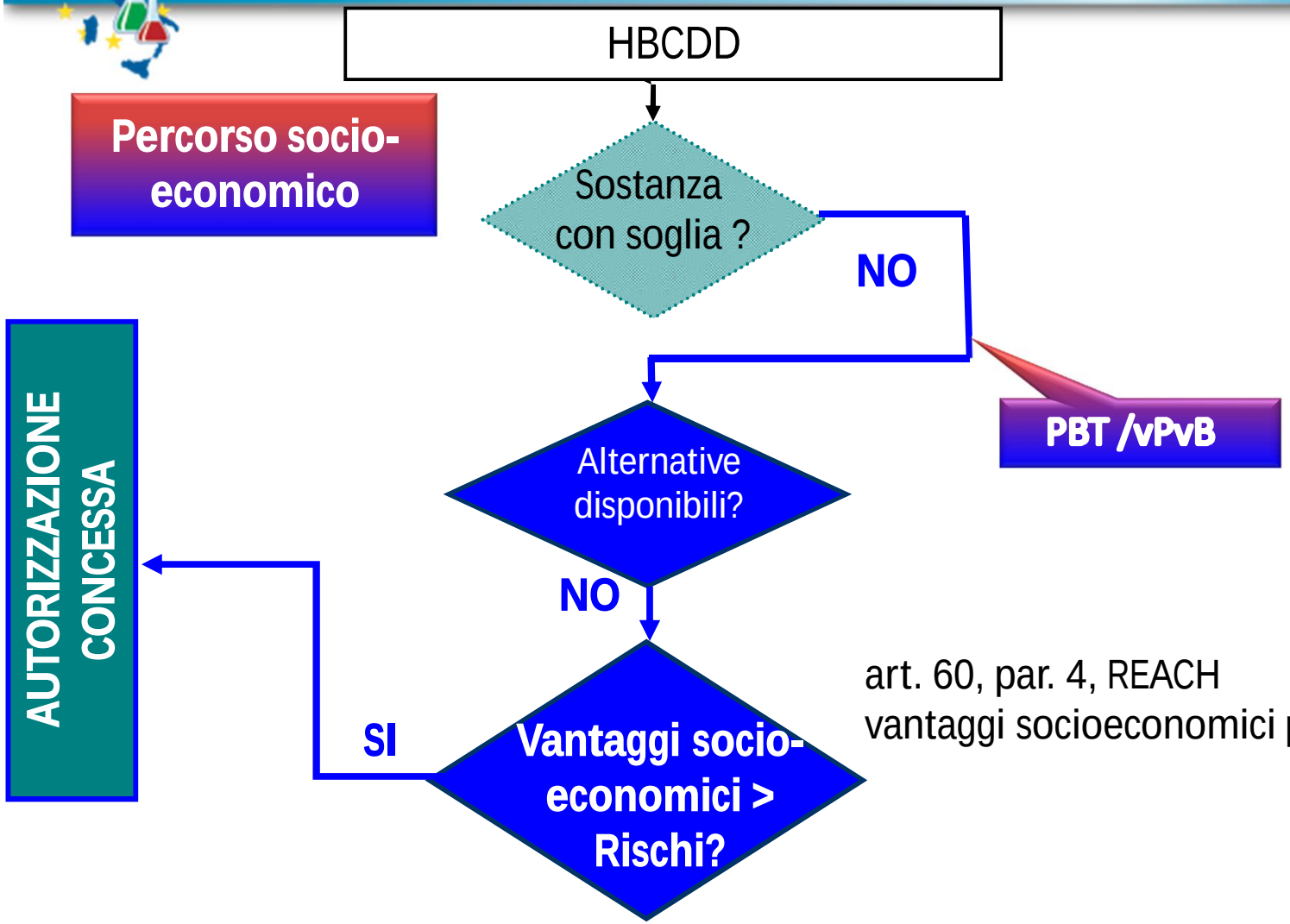

Domanda di autorizzazione
Sostanza con soglia ?
SI
NO
Percorso del controllo adeguato
rischio adeguatamente controllato?
SI
NO
Alternative disponibili?
SI
NO
Vantaggi socio-economici > Rischi?
SI
NO
AUTORIZZAZIONE CONCESSA
AUTORIZZAZIONE NON CONCESSA
Percorso socio-economico



- le sostanze PBT/vPvB possono accumularsi a grande distanza dalla fonte di rilascio, in aree remote e incontaminate
- potenziali effetti nel lungo termine (trasferimento lungo la catena alimentare)
- conseguenze difficilmente reversibili
- valutazione di rischio non fornisce sufficienti garanzie: sia la previsione degli effetti sia quella dell'esposizione sono soggette a grandi incertezze



- *Applicanti forniscono informazioni su 7 sostanze alternative con dati non conclusivi sul profilo di pericolo e di rischio*
- *un copolimero a blocchi di stirene e butadiene bromurato (PFR), avrebbe caratteristiche e disponibilità sufficiente per soddisfare la domanda prevista entro il 2017 (bridging application)*



art. 60, par. 4, REACH
vantaggi socioeconomici prevalgono sui rischi

Decisione della Commissione Europea

Usi autorizzati- scadenza 21 agosto 2017

- *A norma dell'art. 60, par. 4, del REACH* ***i vantaggi socioeconomici prevalgono sui rischi*** *della sostanza per l'ambiente e non esistono idonee sostanze o tecnologie alternative in quantitativi sufficienti*

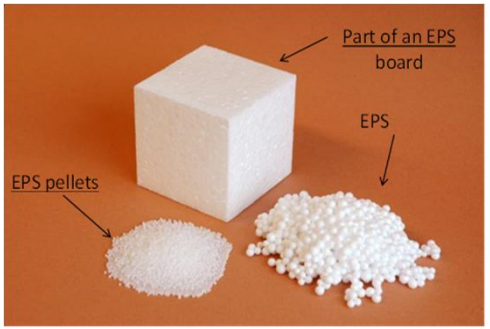
- *un ritardante di fiamma polimerico, concluse le prove e le procedure di certificazione, è un'alternativa valida e disponibile in quantitativi sufficienti per soddisfare la domanda prevista entro il 2017*

- *I titolari dell'autorizzazione presentano alla Commissione trimestralmente una relazione sulla disponibilità del ritardante di fiamma polimerico e sui progressi compiuti verso la sostituzione dell'HBCDD*

Criticità della Valutazione del Rischio del RAC (1)

Uso 1: Formulazione di polistirene espanso (EPS) utilizzando HBCDD come ritardante di fiamma

Conclusione: mancanza di informazioni e difficoltà di sviluppare una valutazione di impatto adeguata per una PBT, non consentono di affermare che il rischio residuo sia ridotto al più basso valore tecnicamente e praticamente possibile



Criticità della Valutazione del Rischio del RAC (2)

Uso 2: Produzione articoli in polistirene espanso (EPS) ignifugo per uso in edilizia

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incertezze maggiori, legate a stima dei rilasci nelle fasi di demolizione e smaltimento, avvengono con ritardo di decenni dopo la vita di servizio, particolarmente diffusi e difficilmente controllabili

Conclusione: la mancanza di informazioni pertinenti e la difficoltà di sviluppare una valutazione di impatto adeguata per una PBT, non è possibile affermare che il rischio residuo sia ridotto al più basso valore tecnicamente possibile

Raccomandazioni aggiuntive

- Uso 1, 2:
  - programma di monitoraggio nei siti di formulazione e produzione EPS per valutare fattori di rilascio ed emissioni nel periodo di autorizzazione
  - rapporto annuale con i risultati del monitoraggio, da fornire alle autorirà nazionali di vigilanza
  - rapporto trimestrale alla Commissione sui progressi relativi alla sostituzione con pFR
  - sostituzione appena disponibile l'alternativa (anche prima della scadenza)

- Uso 2:
  - documenti guida per DU su OC/RMM previste nella domanda di autorizzazione (es.: decostruzione manuale e incenerimento rifiuti) e le migliori pratiche (es.: taglio a filo caldo di EPS)

Regolamento POP

- a marzo 2016, HBCDD inserito nell'allegato I del regolamento POP (Commission Regulation (EU) 2016/293)
- produzione, immissione sul mercato e uso deve essere proibita
- Il divieto non si applica se la concentrazione di HBCDD ≤ 100 mg/kg (0.01% in peso)
- gli articoli contenenti HBCDD già in uso prima del 22 marzo 2016 continuano a essere usati e posti sul mercato

Grazie

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

- i richiedenti sono tenuti a fornire agli utilizzatori a valle della loro catena di approvvigionamento una guida su OC/RMM descritte come obbligatorie nella domanda di autorizzazione (ad esempio decostruzione manuale e incenerimento dei rifiuti) e le migliori pratiche (ad esempio taglio a filo caldo di EPS tavole) per ridurre al minimo le emissioni per tutti gli scenari di esposizione nelle fasi del ciclo di vita come previsto nel CSR
- Su richiesta, gli attori industriali e professionali dovrebbero fornire organismi di controllo nazionali documentazione che descrive il modo in cui attuare le OC/RMM ad essi applicabili e le “best practice” consigliate dai richiedenti
- sostituire con il polimerico ritardante di fiamma ("PFR") non appena l’approvvigionamento è sufficiente e disponibile e non oltre il 21/08/2017
- Monitoring arrangements
- Converters of unexpanded EPS to expanded EPS covered by this authorisation should put in place a monitoring programme to quantify release factors and emissions of the substance during the conversion life-cycle for the period of the authorisation
- The monitoring programme should consider the emission to air, water and land from all the conversion sites.
- Annually, converters covered by this authorisation should prepare a report which contains the results from the monitoring programme. The annual report should also include details of the methodology used to obtain the results e.g. sampling points and frequency (at least monthly) and details of any relevant analytical methodology.
- Upon request, converters covered by this authorisation should provide national enforcement bodies with the annual reports.
- Any review report in terms of Article 61(1) of the REACH Regulation should include the results of the monitoring performed by the applicants at their own industrial sites

Is the exposure from the use adequately described?

- RAC considers that the emissions to the environment for this use have not been adequately described in the application
- As a consequence, RAC was unable to evaluate the appropriateness and effectiveness of implemented and proposed OC and RMM in reducing the risks

Would the alternatives lead to overall reduction of risk?

- the applicant provides information on seven alternative substances with varying, and in no case conclusive, data on their hazard profile and resulting risks
- Only one of these alternatives, a brominated co-polymer of styrene and butadiene (pFR), is concluded to meet the basic technical requirements
- Based on the available data (including the probable absence of PBT concern), the applicants consider pFR to have a low hazard
- The applicants intend to use pFR as drop-in replacement for HBCDD after sufficient amounts become available

For non-threshold substances, or in case adequate control cannot be demonstrated, have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

- the authorisation was requested to address a short-term potential shortage in the availability of an alternative (i.e. a bridging application)
- SEAC concludes that the benefits of granting the authorisation may outweigh the risks (approximated by the potential emissions to the environment)
- This conclusion tends to be supported by the cost-effectiveness considerations outlined above. However, SEAC highlights the major uncertainties that remain in the cost-effectiveness assessment, both in terms of the emissions and cost-estimates that were used to underpin the calculations
- the date at which the applicants will be able to switch to pFR depends on the development of pFR supply as well as on completed testing and certification of FR EPS produced with pFR by the applicants and their downstream users
- Based on the information provided, SEAC concludes that the substitution of HBCDD with pFR can be expected to be feasible and that suitable alternatives will be available for the applicants between 2015 (i.e. at the sunset date) and 2017
- Alternative materials (e.g. PUR/PIR or mineral wool) or alternative methods (e.g. not flame retarded EPS) are available and commonly used on the market.

Proposed review period

- For the reasons described in the previous sections and reminding the unknown (but potentially severe) impacts any additional releases of HBCDD could have, RAC recommends that (in the event an authorisation would be granted for this use):
- the additional conditions and monitoring arrangements described are included in the authorisation decision;
- the authorisation should not exceed four years in order to limit the amounts released in the environment
- considering the different drivers for the availability of the alternatives and the information presented by the applicants SEAC finds that a 2 year review period could to be justified as this is a bridging application for an authorisation

Exposure assessment

Scope of the assessment and limitations

- HBCDD is a PBT “non-threshold” substance (no risk characterisation via PNECs, DNELs, RCRs, etc.)
- Applicants provided only environment exposure and no worker exposure assessment
- Task of RAC is to evaluate the appropriateness and effectiveness of proposed OC/RMM in reducing the risk and to evaluate if the emissions to the environment have been adequately described
- Appropriate sensitivity analysis performed by RAC allows the significance of the uncertainty in an exposure assessment to be evaluated

If adequate control is not demonstrated, is the remaining risk reduced to as low a level as is technically and practically possible?

- Because of the lack of relevant information provided by the applicant on the one hand and the challenges of developing an adequate impact assessment for a PBT on the other, RAC is unable to confirm that the remaining risk is reduced to as low a level as is technically and practically possible

THE OPINION OF SEAC

- SEAC has formulated its opinion on the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as documented in the application and on information submitted by interested third parties as well as other available information.
- The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.
- SEAC took note of RAC's confirmation that it is not possible to determine a PNEC or RCRs for the persistent, bioaccumulative and toxic properties of the substance in accordance with Annex I of the REACH Regulation.
- SEAC confirmed that there do not appear to be suitable alternatives in terms of their technical and economic feasibility for the applicants at the time the application was submitted.
- SEAC took into account RAC´s assessment on the emissions and the risk. Furthermore, SEAC evaluated the applicants´assessment of (a) the potential socio-economic benefits of the use, (b) the potential adverse effects to human health or the environment of use and (c) the assessment used to compare the two. SEAC considered that the large uncertainties in the socio-economic analysis make it difficult to use cost-effectiveness as the sole basis on which to conclude on if the benefits of an authorisation would outweigh the risks. However, based on the general consideration that this authorisation was requested to address a temporary shortage in the availability of a suitable alternative to HBCDD (i.e. a

Are alternatives technically and economically feasible?

- Only one of these alternatives, a brominated co-polymer of styrene and butadiene (pFR), is concluded to meet the basic technical requirements
- pFR in general will be a technically feasible alternative once successful testing and certification of FR EPS produced with pFR has been completed
- applicants consider pFR as an economically feasible alternative, even if it is more costly than HBCDD
- **SEAC finds the economic feasibility of pFR as the main alternative to be adequately described**

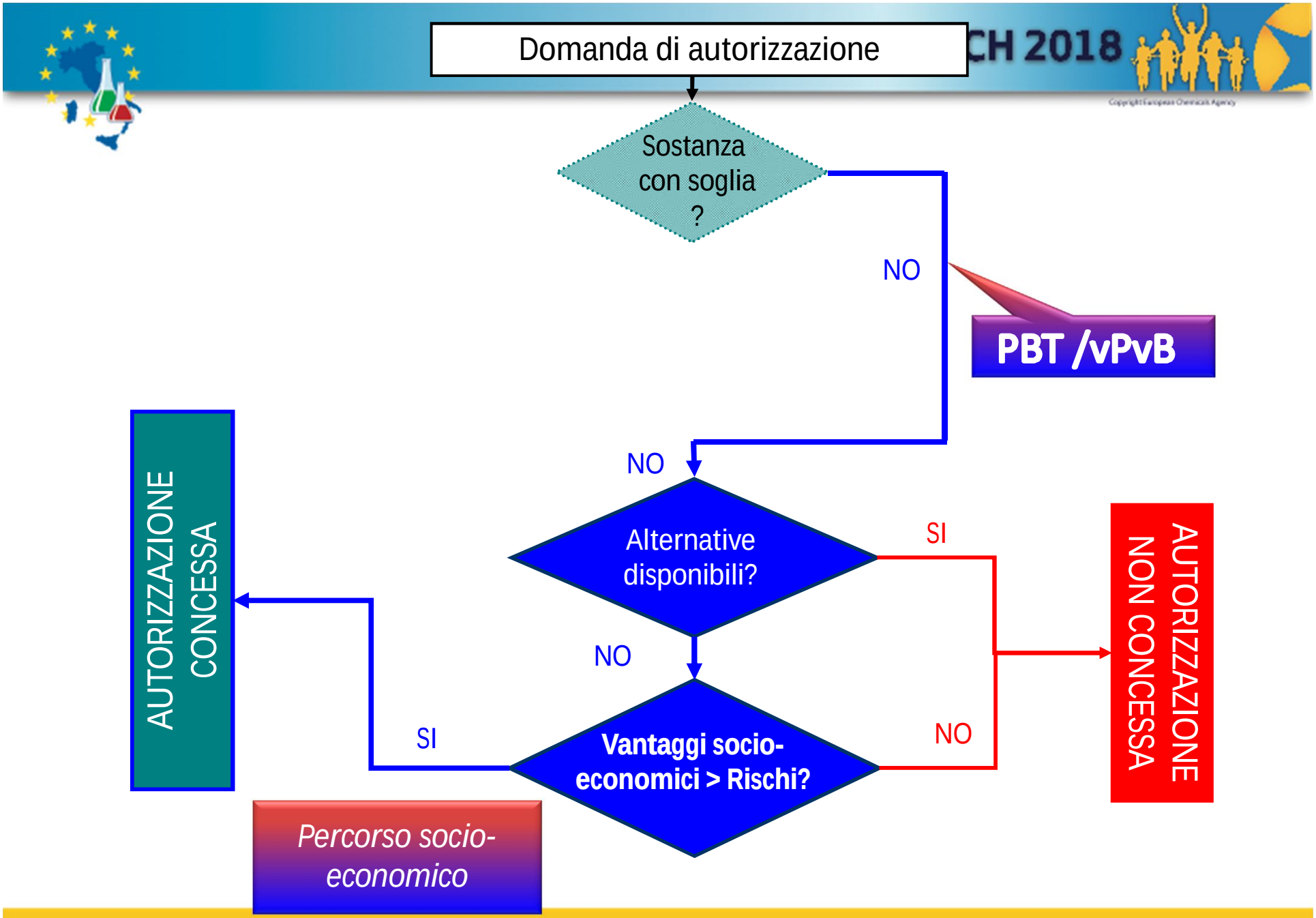
SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

- Conditions
- The following conditions are recommended in case the authorisation is granted:
- In addition to the mandatory implementation of the operational conditions and risk management measures described in the application the applicants should implement where possible the best practices in emission reduction described in section 6 of the justifications.
- For the applicants to substitute to the polymeric flame retardant ("pFR") as soon as sufficient supply is available and testing has been conducted with a positive result and no later than 21/08/2017. During the review period the applicants should communicate the progress of the work on phasing in the alternative pFR in terms of production capacity, sufficient supply and test results to the Commission in relation to the requirements of Article 61(1) of the REACH Regulation.
-
- Monitoring arrangements
- The following monitoring arrangements are recommended in case the authorisation is granted:
- The applicants performing Use 1 (i.e. "formulators") should put in place a monitoring programme to quantify release factors and emissions of the substance to environmental compartments during all activities described in Use 1 for the period of the authorisation.
- The monitoring programme should consider emissions to air, water and land from all the formulation sites.
- Annually, applicants should prepare a report that contains the results obtained from the monitoring programme. The annual report should also include details of the methodology used to obtain the results e.g. sampling points and frequency (at least monthly) and details of any relevant analytical methodology.
- Upon request, applicants should provide national enforcement bodies with the annual reports. Any review report in terms of Article 61(1) of the REACH Regulation should include the results of the monitoring programme

- HBCDD was included in Annex XIV of REACH because the inherent substance properties fulfil the criteria of Art. 57 (d) and of Annex XIII 1.1, 1.2 and 1.3. PBT and vPvB substances are of specific concern due to their potential to remain and accumulate in the environment over long time periods
- Historical cases have shown that the effects of such accumulation are unpredictable in the long-term and that exposure is practically difficult to reverse, because an elimination of emissions will not necessarily result in a measurable reduction in chemical concentrations
- The properties of the PBT and vPvB-substances lead to an increased uncertainty in the estimation of risk to human health and the environment when applying quantitative risk assessment methodologies
- For PBT and vPvB substances a PNEC in the environment cannot be established using currently available methods and, accordingly, the quantification of risks is not foreseen in REACH
- This means that, and as prescribed in section 4 of Annex I of REACH, a quantitative risk characterisation using a PNEC cannot be carried out with sufficient reliability

Is the substance a threshold substance?

- HBCDD è stato incluso nell'allegato XIV del REACH perché è una sostanza persistente, bioaccumulabile e tossica (PBT)
- possono permanere nell'ambiente e accumularsi anche a grande distanza dalla fonte di rilascio, in aree remote e incontaminate
- effetti nel lungo termine di tale accumulazione (soprattutto a causa del trasferimento lungo la catena alimentare);
- un'interruzione dell'immissione nell'ambiente della sostanza non necessariamente si traduce in una riduzione delle concentrazioni.
- Historical cases have shown that the effects of such accumulation are unpredictable in the long-term and that exposure is practically difficult to reverse, because an elimination of emissions will not necessarily result in a measurable reduction in chemical concentrations
- The properties of the PBT and vPvB-substances lead to an increased uncertainty in the estimation of risk to human health and the environment when applying quantitative risk assessment methodologies
- For PBT and vPvB substances a PNEC in the environment cannot be established using currently available methods and, accordingly, the quantification of risks is not foreseen in REACH
- This means that, and as prescribed in section 4 of Annex I of REACH, a quantitative risk characterisation using a PNEC cannot be carried out with sufficient reliability


Domanda di autorizzazione
Sostanza con soglia ?
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NO
Alternative disponibili?
SI
AUTORIZZAZIONE NON CONCESSA
NO
Vantaggi socio-economici > Rischi?
SI
NO
AUTORIZZAZIONE CONCESSA
Percorso socio-economico

- The opinion of RAC assesses the risk to human health and/or the environment arising from the use of the substance – including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives
- The opinion of SEAC assesses the socio economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as described in the application
- Opinion adopted on 08 January 2015

- The authorisations referred to in paragraphs 1 and 2 shall be subject to the following conditions:
- (a) the risk management measures and operational conditions described in the chemical safety report submitted pursuant to Article 62(4)(d) of Regulation EC) No 1907/2006 corresponding to the respective uses7 shall be fully applied;

- (b) the authorisation holders and the producers of EPS articles to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 shall set in place a monitoring programme in order to quantify release factors and emissions of HBCDD to air, water and land during all the activities in the uses referred to in Articles 1(1) and (2). The monitoring programme shall establish the methodology to be used to obtain the results, including sampling points and frequency (which shall be at least monthly), and the details of any relevant analytical methodology. Reports containing the details of the methodology used and the results of the monitoring programme shall be prepared. The first report shall be prepared by 31 December 2016 and a second one by 21 August 2017. These reports shall be submitted to the competent authorities of the Member State where the use takes place for enforcement purposes, in an official language of that Member State.
- (c) the authorisation holders shall submit a report on a three-monthly basis to the Commission providing updated information on the available quantities of pFR on the market and on the progress in testing and certifying that substance with a view to its use in the uses referred to in paragraphs 1 and 2 in substitution of HBCDD. The first report is due by *[three months of the date of this Decision].*

- 4. The authorisations referred to in paragraph 2 shall be subject to the following conditions:
- (a) guidance on operational conditions and risk management measures and on best practices for using EPS articles containing HBCDD in order to minimise emissions for all life-cycle stages of EPS articles, as foreseen in the CSR, is provided by the producers of EPS articles to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 to industrial and professional actors down his supply chain, in an official language of the Member State where the use takes place.
- (b) producers of EPS articles to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 provide, upon request by the competent authority of a Member State, information on the quantities of EPS articles containing HBCDD supplied by them to industrial and professional actors in that Member State.