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DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For Benzophenone, CAS No 119-61-9 (EC No 204-337-6)

Addressees: Registrant(s) of benzophenone (Registrant(s))

This decision is addressed to all Registrants of the above substance with active registrations on the date on which the draft for the decision was first sent, with the exception of the cases listed in the following paragraph. A list of all the relevant registration numbers subject to this decision is provided as an annex to this decision.

Registrants meeting the following criteria are not addressees of this decision: i) Registrants who exclusively use the above substance as an on-site isolated intermediate and under strictly controlled conditions and ii) Registrants who have ceased manufacture/import of the above substance in accordance with Article 50(3)of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) before the decision is adopted by the European Chemicals Agency (ECHA).

Based on an evaluation by the Danish Environmental Protection Agency as the Competent Authority of Denmark (evaluating MSCA), ECHA has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision is based on the registration dossier(s) on 3 July 2014, i.e. the day until which the evaluating MSCA granted an extension for submitting dossier updates which it would take into consideration.

This decision does not imply that the information provided by the Registrant(s) in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier(s) of the Registrant(s) at a later stage, nor does it prevent a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of Denmark has initiated substance evaluation for benzophenone, CAS No 119-61-9 (EC No 204-337-6), hereafter referred to as BP, based on registration(s) submitted by the Registrant(s) and other relevant and available information and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to carcinogenicity, wide dispersive use, consumer use and a high risk characterisation ratio (RCR), BP was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2013. The updated CoRAP was published on the

ECHA website on 20 March 2013. The Competent Authority of Denmark was appointed to carry out the evaluation.

In the course of the evaluation, the evaluating MSCA concluded that it would not be necessary to propose further tests on carcinogenicity in order to clarify the identified concern, but noted additional concerns regarding endocrine disrupting effects.

The evaluating MSCA considered that further information was required to clarify the concern on endocrine disrupting effects. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 17 March 2014.

On 29 April 2014 ECHA sent the draft decision to the Registrant(s) and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

By 3 June 2014 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA without delay. The evaluating MSCA considered the comments received from the Registrant(s) and the dossier update.

On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

In accordance with Article 52(1) of the REACH Regulation, on 23 July 2015 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, some Competent Authorities of the Member States and ECHA submitted proposals for amendment to the draft decision.

On 28 August 2015 ECHA notified the Registrant(s) of the proposals for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA reviewed the proposals for amendment received and amended the draft decision. Based on the Registrant(s) comments a Repeated Dose 28-Day Toxicity Study in rats with special investigations of thyroid effects was removed from the draft decision.

On 7 September 2015 ECHA referred the draft decision to the Member State Committee.

On 28 September 2015, in accordance to Article 52(2) and Article 51(5), the Registrant(s) provided comments on the proposals for amendment. In addition, the Registrant(s) provided comments on the draft decision. The Member State Committee took the comments on the proposals for amendment of the Registrant(s) into account. The Member State Committee did not take those of the Registrants' comments into account which were not related to the proposals for amendment, and therefore considered outside the scope of Article 52(2) and Article 51(5).

The discussion in the Member State Committee meeting on 27-29 October 2015 resulted in a change of the information requested in this decision. The initially foreseen experimental

study regarding thyroid disrupting activity *in vivo* (Larval Amphibian Growth and Developmet Assay (OECD 241) / Amphibian Metamorphosis Assay (OECD 231)) and testing for estrogenic activity in fish *in vivo* (Fish Sexual Development Test OECD 234 / Fish Short Term Reproduction Assay (OECD 229) / 21-day Fish Assay (OECD 230) were replaced by a request for further information on fate as further addressed in Section III below. A unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 29 October 2015. ECHA took the decision pursuant to Article 52(2) and Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) shall submit the following information regarding the registered substance subject to the present decision:

1. **Available information on metabolism in aquatic non-mammalian vertebrate animals and further information on fate including transformation of benzophenone with special emphasis on transformation products and kinetics in the aquatic environment and in aquatic toxicity test media;**

2. **Update of the Chemicals Safety Report.**

Pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) shall also submit the following information regarding the registered substance subject to the present decision:

a. **More detailed information on the use of the substance;**

b. **More information on personal protective equipment**
More information on personal protective equipment regarding e.g. the type of material, thickness and breakthrough times of the gloves and the duration of use for all exposure scenarios where the use of personal protective equipment is advised as further specified in section III, 2.b);

c. **Documentation that risks to workers and consumers are adequately controlled for all exposure scenarios**
as further specified in section III, 2.c);

d. **A more detailed description on how the Registrant(s) have estimated combined exposure (combined for all relevant emission/release cources/exposure routes)**
as further specified in section III, 2.d).

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **6 June 2016** an update of the registration(s) containing the information required by this decision[1], including an update of the Chemical Safety Report.

III. Statement of reasons

1. **Available information on metabolism in aquatic non-mammalian vertebrate animals and further information on fate including transformation of benzophenone with special emphasis on transformation products and**

[1] The deadline set by the decision already takes into account the time that registrants may require to agree on who is to perform any required tests and the time that ECHA would require to designate a registrant to carry out the test(s) in the absence of the aforementioned agreement by the registrants (Article 53(1) of the REACH Regulation).

kinetics in the aquatic environment and in aquatic toxicity test media

Based on the evaluation there are remaining concerns for thyroid disrupting and estrogenic effects of BP and its transformation products which need to be clarified for considering whether further Risk Management Measures (RMM) under REACH or other relevant legistation might be needed. Occurrence of endocrine disruptive (ED) related effects in one taxonomic group may raise concern for ED related effects in other vertebrate taxa because of the conservation of the elements of hormone systems between vertebrate species. Likewise mode of action activity measured in specific *in vitro* tests measuring molecular initiating or key events of the Adverse Outcome Pathway for the EATS modalities[2] may raise concerns (Ankley & Gray. 2013). Hence BP raises concern for potential endocrine disruptive effects in aquatic non-mammalian vertebrate animals including gill breathing animals (e.g. due to estrogenic and thyroidal activity). Such concerns for BP have not been confirmed in mammalian species based on a number of long-term rodent studies (NTP 2006, Hoshino et al. 2005, NTP 2000, Burdock et al. 1991). It has been shown that BP and its transformation products have different endocrine related properties as described below.

When tested *in vitro* in rat hepatocytes, Nakagawa et al. (2000) found that BP was converted to at least three metabolites, 4-hydroxy-benzophenone (4-OH-BP), its sulfate conjugate and benzhydrol. Furthermore, in male SD rats administered BP in corn oil by gavage, 4-OH-BP was isolated from the urine, and accounted for approximately 1 % of the administered dose (Stocklinski et al., 1980).

BP and several BP transformation products have been identified in the surface water and sediments (Pojana et al., 2007; Chen et al 2015). When an aqueous solution of BP was irradiated with UV or sunlight, the two metabolites 3-hydroxy-benzophenone (3-OH-BP) and 4-hydroxy-benzophenone (4-OH-BP) were formed (Hayashi et al., 2006). Hence current information on the environmental fate of BP indicates formation of hydroxylated transformation products by photolysis and such transformation is also likely to be caused by microbes degrading BP in the aquatic environment (Chen et al., 2015).

Both the internal metabolism of BP in organisms as well as different types of transformation processes in the environment have to be considered. Information about such transformations including pathways and the kinetics in the aquatic environment and aquatic test media are warranted to be established in more detail to decide whether further testing is needed and if so to decide on an appropriate test strategy with regard to the endocrine properties relevant for aquatic non-mammalian vertebrate wildlife. This is why the initially foreseen experimental studies as set out in the draft decision of the evaluating MSCA are not requested at this stage but replaced by a request for available information on metabolism in aquatic non-mammalian vertebrate species and further aquatic fate information following discussion of the Member State Committee and also based on comments made by the Registrant(s) on the proposals for amendment. While the Registrant(s) consider in contrast to the view of the evaluating MSCA that the available data would be sufficient to conclude that BP is not an endocrine disruptor, the Registrants(s) themselves proposed to provide further information on fate of BP and its hydroxylated transformation products in the aquatic environment. Thus a tiered approach towards clarifying the possible endocrine disrupting properties of BP is taken.

When the metabolism of BP in aquatic non-mammalian vertebrate species and the aquatic fate properties, and if needed also the endocrine properties of BP and its aquatic

[2] EATS modalities: the endocrine modalities covered by the OECD Conceptual Framework for Endocrine Disruption and the OECD Guidance Document No 150 (OECD 2012c): Estrogen and androgen receptor and thyroid hormone mediated modalities as well as interference with steroidgenesis.

transformation products for aquatic non-mammalian vertebrate wildlife, eventually have been clarified, it will be possible to conclude whether BP should be regarded as an endocrine disrupter for environmental species, and if so, to assess the need for appropriately revised risk management measures under REACH or any other relevant legislation.

Concern for thyroidal activity:

Recent *in vitro* studies show that BP decreases the activity of the enzyme thyroid peroxidase (TPO), which is essential in thyroid hormone synthesis. BP is therefore potentially a thyroid hormone disrupting substance (Song et al., 2011; Song et al., 2012).

Several long-term toxicity studies in rodents have been performed, none of which provided evidence for concluding that BP causes thyroid disruption (NTP 2006, Hoshino et al. 2005, NTP 2002, NTP 2004a, NTP 2000, Burdock et al. 1991). There is nevertheless still some concern about potential thyroid disrupting effects of BP in aquatic non-mammalian vertebrate animals due to *in vitro* findings (c.f. above) and the potential difference of sensitivity between vertebrate species (Miyata & Ose, 2012; ; Borgert et al., 2014). Therefore, initially an Amphibian Metamorphosis Assay (AMA (OECD 231)), and later alternatively a Larval Amphibian Growth and Developmet Assay (LAGDA, OECD 241) were considered to be requested on BP. However, available information indicates that BP may be transformed by photolysis and microbes in aquatic systems (Hayashi et al., 2006, Chen et al., 2015). In contrast to the parent substance, BP, the photolytic transformation product 4-OH-BP (investigation of the other photolytic transformation product 3-OH-BP was not reported) has no effect on the TPO activity *in vitro* (Song et al., 2012). Therefore if such a transformation takes place very rapidly under environmental conditions the TPO decreasing activity of BP may not occur in aquatic non-mammalian vertebrate organisms, because they may then not be significantly exposed to BP. Hence, more information on the fate, including transformation of BP, is needed both in relation to transformation kinetics and chemical identity of transformation products. Also metabolic rates of BP in aquatic non-mammalian vertebrate animals may be relevant to take into account based on existing available information in this regard. Such information is warranted before deciding whether further test data on amphibians should be requested to investigate the effect of BP on the thyroid hormone system and to define the testing strategy. The Registrant(s) shall review and use all available existing data and, if not sufficient, consider to genererate new relevant and sufficient aquatic fate data. Available information about metabolism in aquatic non-mammalian vertebrate animals is as mentioned also relevant to provide in this regard. If it turns out that the now requested fate information is not sufficient, further specific fate studies may need to be requested to create a proper basis for deciding on further thyroid relevant testing if any.

Concern for estrogenicity and anti-androgenicity

A range of *in vitro* studies and QSAR predictions indicates that BP itself does not bind and activate the estrogen receptors, whereas this is the case for the 3-OH BP and 4-OH BP transformation products. (Schultz et al. (2000), Nishihara et al. 2000, Nakagawa et al., 2000; Yamasaki et al., 2002; Suzuki et al 2005; Hayashi et al., 2006; Kerdivel et al 2013). BP and its hydroxylated metabolites have been investigated in several *in vitro* studies for endocrine disrupting properties. BP itself showed no effect on MCF-7 cell proliferation (Nakagawa et al., 2000), no effect on estrogen receptor (ER)-mediated transcriptional activation in a reporter gene assay in human cervical carcinoma cell (Yamasaki et al., 2002), no binding affinity to the ER (Hayashi et al., 2006) and no estrogenic activity in a luciferase reporter assay in MCF7-cells (Suzuki et al 2005).

However the metabolites/transformation products such as 4-OH-BP, showed estrogenic activity on MCF-7 proliferation (Nakagawa et al 2002), and both 3-OH-BP and 4-OH-BP

increased estrogenic activity in a luciferase reporter assay in MCF7-cells (Suzuki et al 2005), activated ER mediated transcription (Yamasaki et al., 2002) and showed binding affinity to the ER (Hayashi et al., 2006).

Suzuki et al. (2005) furthermore found that both 3-OH-BP and 4-OH-BP acted as weak anti-androgens in an ARE-luciferase reporter assay.

Overall, based on the results from the performed in vitro assays, it is shown that even though BP itself has no estrogenic potential, the hydroxylated BP metabolites and environmental transformation products can bind and activate the estrogen receptor. Inhibition of androgen receptor activation is another potential mechanism of action.

In an uterotrophic assay BP was given orally to ovariectomized (OVX) SD rat (Nakagawa & Tayama 2002), and significantly increased uterine weights were observed. Furthermore, increased luminal epithelium height, increased thickness of the stromal layer in the uterus and histological changes in vaginal cornification were seen, also indicating an estrogenic activity *in vivo*. In another study intraperitoneal doses to OVX F344 rats (Suzuki et al., 2005), also significantly increased uterine weights. This indicates that BP can yield an estrogenic response when using oral or intraperitoneal dosing in rats.

In a uterotrophic assay performed with BP on juvenile rats (subcutane injection (SC)) no effect on uterine weight was observed (Nakagawa & Tayama 2001). A similar result was obtained in immature rats in a study by Yamasaki et al (2002) using the same administration route. In an uterotrophic assay using immature rats, there was also no uterine response after SC injection (Hayashi et al. (2006).

However, the BP metabolite 4-OH-BP has been shown to elicit an estrogenic effect in several uterotrophic assays (Nakagawa & Tayama, 2001 ,Yamasaki et al., 2002, Hayashi et al. 2006). Also 3-OH-BP showed effect, but 4-OH-BP was the more potent of the two metabolites (Hayashi et al., 2006).

Hence uterotrophic assays using SC administration of BP in immature rats were negative, whereas studies using intraperitoneal (ip) injection or oral gavage in mature OVX rats and in juvenile rats were positive (CERI 2001 a & b). Also studies using SC injection with hydroxylated BP metabolites in immature rats were positive. It does not seem likely that the reason for the different findings with BP were caused by use of either OVX or immature animals but rather that the observed uterotrophic effects of BP were only seen after oral or intraperitoneal dosing of BP, because these were caused by BPs metabolism to its hydroxylated forms. *In vitro* BP seems to acquire estrogenic activity after ring-hydroxylation (Nakagawa & Tayama 2002) and it is likely that phase 1 metabolic reaction metabolites of BP – mainly occurring in the liver by CYP enzymes - are indeed formed by ring-hydroxylation also *in vivo* after oral and ip dosing due to extensive first path liver metabolism but not to a sufficient extent after SC injection due to insignificant first path hepatic metabolism.

In summary, the concern about estrogenic activity is raised by the estrogenic activity in vitro by the hydroxylated metabolites of BP combined with estrogenic activity observed in rodent uterotrophic assays using oral or intraperitoneal dosing of BP (implying occurrence of first pass metabolism i.e. significant hydroxylation of BP) as well as in uterotrophic assays with the metabolites 3-OH-BP and 4-OH-BP.

Some long-term toxicity studies in rodents have however been performed, none of which provided evidence for concluding that BP causes endocrine disruption due to its estrogenic properties (Hoshino et al., 2005, NTP 2000). It is however noted that some parameters

which are especially sensitive to estrogenic substances (e.g. mammary gland histology or quantitative assessment of follicular maturation) were not investigated in the available rodent toxicity studies.

Due to the positive *in vitro* studies and uterotrophic studies in rats there is however concern about potential estrogenic disrupting effects of the hydroxylated transformation products of BP in aquatic vertebrate non-mammalian animals. The positive uterotrophic assays in rat studies raise concern for the possibility of adverse effects caused by the estrogenic activity of hydroxylated BP metabolites in fish, because fish may be more sensitive to some estrogenic substances acting via the estrogen receptors than mammals (Dang, 2010). C.f. also the OECD validation of OECD 234 where it was shown that a xenobiotic estrogen like 4-tert pentylphenol, besides causing Vitellogenin increase in male fish (indication of an estrogenic mode of action), also changed the phenotypic sex ratio in several fish species (i.e. caused an adverse population relevant effect (OECD 2011 and OECD 2012)).

An Fish Sexual Development Test (FSDT) test was initially considered to be requested on BP, but due to the fact that the estrogenic activity is related to the hydroxylated transformation products of BP and not to BP itself (Hayashi et al., 2006; Kerdivel et al., 2013), this request was removed after discussion by the Member State Committee.

Hence at this stage, more information on the fate in aquatic media including transformation of benzophenone is needed both in relation to transformation kinetics and chemical identity of transformation products. Furthermore any relevant available information regarding the metabolism of BP in aquatic non-mammalian vertebrate taxa, such as fish and amphibians may also be relevant. Such information is warranted for deciding whether a further *in vivo* data on aquatic non-mammalian vertebrate animals targeting estrogenic effects should be requested and to define a proper testing strategy. The Registrant(s) should review and use all available existing data and, if not sufficient, consider to genererate new relevant and sufficient aquatic fate data. If it turns out that the currently requested fate information is not sufficient, further specific fate studies may need to be requested to create a proper basis for deciding on the need for further relevant testing regarding estrogenic effects in aquatic non-mammalian vertebrate animals and for establishing an appropriate test strategy

Therefore pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide the following:

Available information on the metabolism of BP in aquatic non-mammalian vertebrate animals and further information on fate including transformation of BP with special emphasis on transformation products and kinetics in the aquatic environment and in aquatic toxicity test media. It is in the discretion of the Registrant(s) to perform further fate studies and submit the in dossier update(s).

2. Update of the Chemicals Safety Report

A LOAEL of 15 mg/kg derived from a 2-year carcinogenicity study has been used as basis, which can be seen as a cautious approach. In the opinion of the Registrant(s) the use of the LOAEL of ca. 6 mg/kg derived from a two-generation study may have some disadvantages, as the liver hypertrophy seen in rats was not correlated with an increase in liver weights and may therefore be an adaptive but not a true adverse response. ECHA agrees to this and has amended the Decision accordingly.

However, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) shall also submit the following information regarding the registered substance subject to the present

decision:

a. More detailed information on the use of the substance

The use of BP is described very sparsely and more details are required in the registration dossier. It is well known that BP has many uses. Other uses, than those described in the chemical safety report (CSR) have to been considered in developing the relevant exposure scenarios, keeping in mind that BP is also used for industrial use: e.g. as a photoinitiator in coatings, in the production of furniture, rubber and plastics (c.f. further the SPINatabase http://195.215.202.233/DotNetNuke/default.aspx). Based on available data it seems likely that there is a potential for BP exposure of both professionals and consumers.

It is not possible, by reading the CSR, to identify which type of BP containing articles the production/formulation of articles/preparations ends up with. Hence, it is not possible to identify which potential groups of populations that may be exposed to such BP containing articles. It may be assumed that BP may end up as a fragrance and hence that exposure scenarios already developed for consumers may apply, e.g.:

- air care, instant action (aerosol sprays)
- polish, spray (furniture, shoes)
- laundry and dish washing products.

However, the use of BP as e.g. a photoinitiator in coatings is described as a process only and nothing is mentioned regarding the application of these coatings and who (professionals, consumers) may be exposed. Hence clarifications are required.

It is a concern that based on the provided information it is not possible to conclude whether all relevant exposure scenarios for all relevant groups of populations and all relevant environmental compartments have been considered.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) shall submit the required information.

b. More information on personal protective equipment

Personal protective equipment (PPE) like e.g. gloves and respiratory protection, is recommended in the technical dossier. However, no details are provided regarding PPEs (e.g. type of material, thickness and breakthrough times of the gloves).

The information required for skin protection equipment includes amongst others the type of material and its thickness, the typical or minimum breakthrough times of the glove material and the type and quality of other personal protective equipment required.

For air-purifying respirators, information on the proper purifying element (cartridge or canister), the adequate particulate filters and the adequate masks, or selfcontained breathing apparatus for the scenarios where the use of respiratory protection is required.

PPEs are produced of different type of materials, thickness, design etc. and not all are well suited to protect against exposure to all substances, mixtures and materials. A concern is raised if workers are not properly informed to use the right type of e.g. gloves to protect themselves against exposure to chemicals. The use of unsuited material may even result in higher level of exposure, than not using any protection at all, as the inside of contaminated gloves, may be covered with migrated substance – and the skin inside a glove is often humid – corresponding to exposure under occlusion. The only information found in the CSR is related to the recommended level of protection, e.g. Gloves 95, without any further information.

The Registrant(s) concerned shall therefore provide information on type of gloves and type of respiratory protection where relevant, taking into account breakthrough times for gloves and clothing and type of filter for the specified respiratory protective equipment.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) shall submit the requested information.

c. Documentation that risks to workers and consumers are adequately controlled for all exposure scenarios is required

High risk characterization ratios (RCRs) have been identified related to exposure via the inhalation and dermal routes. In many of the scenarios/contributing scenarios RCR has been estimated to be 1 and close to 1 ([redacted] - 1). High RCRs indicate a need for clarification. This is especially a concern considering the current poor description of risk management measures in the registration dossier and the serious effects which BP may cause. The Registrant(s) are requested to reconsider the RCRs, refine the exposure estimations with the use of e.g. higher tier exposure assessment tools, and submit further information on RMMs (Risk Management Measures).

d. A more detailed description is required on how the Registrant(s) have estimated combined routes (combined for all relevant emission/release sources/exposure routes)

Pursuant to the REACH regulation (Annex I, 1.4.1): if more than one route of exposure is likely to occur, then a DNEL shall be established for each route of exposure and for the exposure from all routes combined.

(Annex I, 5.2.4) An estimation of the exposure levels shall be performed for all human populations (workers, consumers and humans liable to exposure indirectly via the environment) and environmental spheres for which exposure to the substance is known or reasonably foreseable. Each relevant route of human exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure) shall be addressed.

In the CSR, Chapter 10.15.1. Human health (combined for all exposure routes), the Registrant(s) have stated that combined scenarios for all exposure routes are: "Not relevant". There are estimations of e.g. daily human intake and concentrations in food (9.14.2.1.3), which are not included in the RCR estimations. Therefore, a more detailed description shall be provided, stating how the Registrant(s) have estimated combined exposure routes (combined for all relevant emission/release sources/exposure routes) and inclusion of or justification for not including the information from 9.14.2.1.3 "Indirect exposure of humans via the environment". There is also a concern as RCR=1 in one already included exposure scenario y and furthermore, a number of ESs are in the close vicinity to 1 ([redacted]- <1). Finally, exposure to BP via dietary intake may result in a number of scenarios, where RCRs equal 1 or higher, indicating that the risk is not adequately controlled.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the concerned Registrant(s) shall include a combined exposure and risk assessment scenario or convincingly justify the reason for stating that combined scenarios for all exposure routes are: "Not relevant" (i.e. in that case to submit the relevant documentation for the adequacy of this statement).

The Registrant(s) expressed their consent to provide the requested information on the CSR in their comments on the draft decision submitted pursuant to Article 50(1) of the REACH Regulation.

3. Timeline for provision of the requested information

The draft decision foresaw initially a period of 18 months for provision of the requested information in dossier update(s). This period was considered sufficient to perform inter alia two experimental studies. The change in approach towards clarifying the concern for BP by requesting at this stage information on fate and not on hazard affects the timeline needed to provide the information. As no experimental study is requested, ECHA considers that a period of 6 month is sufficient and appropriate for the Registrant(s) to provide the requested information.

Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[3] by Leena Ylä-Mononen, Director of Evaluation

Annex 1: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.

[3] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

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