Oeko Institut - ROHS Annex II Dossier for TBBP-A
Restriction proposal for substances in electrical and electronic equipment under RoHS – Draft Dec 4, 2019

International Bromine Council, BSEF Commenting Table – February 10, 2020

Page & Line Number	Oeko Institut Text	BSEF Comment/Response
Page 7, Context and Scope, 4th paragraph	Though no date on when the study was conducted is indicated, it is understood as a very recent data compilation. In August 2018, after the stakeholder consultation was closed, the BSEF provided an updated version of this assessment.	As mentioned in the Appendix of the updated report from 2018, the status report was from 12.12.2014 (contains the part II assessment: prioritization of the substance), which has not been updated. The final report was from October 2015, which has been updated in 2018.
Page 11, self-classification 3rd para.	According to the ECHA database 'C&L Inventory', which contains classification and labelling information on notified and registered substances received from manufacturers and importers, there is a total number of 501 notifications for tetrabromobisphenol A (as of September 2019).[9] Most notify-cations refer to the harmonised classification and specify TBBP-A as very toxic to aquatic life (Aquatic Acute 1, H400) and as very toxic to aquatic life with long lasting effects (Aquatic Chronic 1, H410). The joint classification (16 notifiers) and an additional 29 notifiers also refer to TBBP-A as suspected of causing cancer (Carc. 2, H351).	The REACH dossier classification should be quoted and there you will also find the rational for the carcinogenicity cat. 2 classification based on the NTP study that was published in 2014 and some follow up work in particular on the questionable relevance of the data for humans.
Page 12, section 1.3.3	TBBP-A is considered to meet all three of the OSPAR criteria for the PBT (persistent, bioaccumulative and toxic) assessment, though it is noted that TBBP-A is a borderline case regarding the bioaccumulation criterion (OSPAR 2011).[12] Despite the OSPAR listing, TBBP-A does not meet the criteria for a PBT or a vPvB substance under REACH.	TBBPA does not meet REACH Criteria for PBT. The criteria for bioaccumulation under OSPAR are different than the ones for REACH and hence the difference. Under OSPAR (2011) the cutoff value for BCF is 500 while under REACH it is 2000.

Page 14, first paragraph	The 2015 VECAP progress report declares that 46 % of TBBP-A sold in 2014 was handled according to the best practices as specified by VECAP "gold standard".	Please use the more up to date report of 2017 where more than 90% of TBBPA sold volume was gold standard in terms of best practices. https://bsef.com/wp-content/uploads/2018/08/2017_VECAP_progress_report.pdf
Page 16, last paragraph	It is noteworthy that TBBP-A can also be found in a wide range of non-EEE applications that do not fall in the scope of RoHS, presumably construction materials and textiles.	As far as the international Bromine Council and its member companies are concerned, we know of no such uses of TBBPA in textiles or in construction material
Page 17, section 2.3, 3rd paragraph	An overall increasing trend of the global market volume of TBBP-A was reported since the 1990s. Based on data from 2001, the EU RAR refers to a global consumption of ~ 120,000 t/a. A very similar estimation was independently reached by Morose (2006) who estimated a worldwide market demand for TBBP-A of 119,700 t/a in 2001. According to a report by the German Umweltbundesamt from 2008 145,000t/a TBBP-A were used globally (with 7,000 t/a being used in the EU).	In the Fraunhofer ITEM IPA update it is mentioned that "Updates on the global use of TBBPA published by IARC [63], from Covaci et al (2009) [41] as given by EBFRIP, report volumes between 104000 t/a and 170000 t/a between 1995 and 2004, with 170000 t/a representing 2004. However, as about 18% (~30500 t/a) are used for the production of derivatives and oligomers, maximally only ~139000 t/a of the global volume are used in ABS or laminates for printed circuit boards as a flame retardant." This should be added.
Page 18, Table 2-1	TPPBA	Typo: TBBPA should be written instead of TPPBA
Page 18, first paragraph	The European brominated flame retardant industry (2015) states that only 59 % of TBBP-A traded on the EU market could be accounted for while the rest end up in unknown destinations.[49]	The reference to the 2015 VECAP report is outdated. Please refer to 2017 VECAP report, link above.
Page 18 – 1st paragraph	Thus, these data as well as sales numbers of EFRA must also be viewed with caution, as these numbers only represent TBBP-A manufactured or imported for use in manufacture taking place in the EU. However, the amount of TBBP-A being incorporated in imported goods that are placed on the EU market is unknown.	In the Fraunhofer ITEM IPA report (2018) an estimation of the TBBP-A imported in articles is given based on the global tonnage. "Using the ~139000 t/a TBBPA consumption worldwide as flame retardant (worst case and most recent available volume) in EEE and using the ~23% of the global WEEE being generated in the EU results in ~32000 t/a TBBPA in WEEE in Europe." The 23% is based on data of EEE in Europe (about 9.2 million t/a,

		https://ec.europa.eu/eurostat/statistics-explained/index.php/Waste_statistics_-_electrical_and_electronic_equipment#EEE_put_on_the_market_and_WEEE_collected_in_the_EU) Divided by the EEE in the whole world (about 40 million t/a, United Nations Environment Program 2009, cited in Premalatha et al 2014). The global tonnage is indeed not based on recent data. If we assume as a worst-case that the global EEE market is increasing due to increasing market in developing countries (e.g. of computer housings), the global tonnage of TBBP-A was still increasing since 2004 as well. However, based on this assumption the global WEEE tonnage is increasing as well, and as the EEE put on the market in Europe is nearly constant (see Eurostat link given above), the percentage of WEEE in Europe is decreasing. Overall TBBP-A in WEEE in Europe is nearly constant and the estimated amount of about 32000 t/a in WEEE (mainly imported good) is still reliable.
Page 19, question	Specific information is requested on the concentration of TBBP-A used in relevant applications, such as: • Thermoplastics for housings / enclosures, • Resins for printed wiring boards; • Resins for other applications.	See derivation of 32000 t/a in WEEE (mainly imported goods) described in the Fraunhofer ITEM report or comment above. In addition, in the report it is mentioned that “According to Gensch et al. ~90% of TBBPA used as flame retardant in general are used reactively, while 10% are used additively. However, different values exist in literature concerning this fraction. As an example, the Canadian assessment of TBBPA estimates a fraction of 10-20% of the overall TBBPA used as a flame retardant to be used additively and a share of TBBPA being used as a reactive flame retardant in epoxy and polycarbonate resins and/or

		electrical and electronic equipment ranging from 70 to 90%." For the emission estimation, 15% has been assumed to be used as additive (32000 t/a * 15% = 4800 t/a), and 85% as reactive (32000 t/a * 85% = 27200 t/a; as only < 0.002%, or < 0.006% of originally used are in the printed wiring boards as residue, the emission from reactive is < 1.632 t/a). As mentioned in the Fraunhofer report "TBBPA levels in ABS may go up to 22.0% [3, 5, 41, 45] while lower levels of ~14% have been reported for HIPS by Covaci et al. (2009)." As far as we know, levels of TBBPA in ABS are usually 12%-16%
Page 19, section 3	The most recent report of DEPA (2015), [53] which was prepared for the purpose of justifying the selection of TBBP-A for CoRAP inclusion, summarised that there is potential for endocrine disrupting effects and toxic effects on reproduction and development (see explanation in the following section).	The follow up of the DEPA justification report for CoRAP inclusion was a formal substance evaluation with the request by DEPA (DEPA 2017), as rapporteur for the evaluation, for studies in order to conclude the evaluation. Data are due in 2021. Pending this process and review by DEPA of the results, there is no basis for concluding any ED effects on any human health arising from TBBPA
Page 20, 3rd para.	The acute toxicity of TBBP-A is reportedly rather low by all routes of exposure (oral, dermal, inhalation) as well as for repeated dose toxicity. Information on effects is not available.	For repeated dose toxicity detailed information concerning possible effects is given in a tabulated form in the last update of the Fraunhofer ITEM IPA report from 2018. Furthermore, the EU REACH dossier contains updated information on toxicity endpoints that can be used.
Page 20, 4th para.	The consultants note however that the EU RAR is older (2008) and based on data generated prior to its publication. It thus needs to be assumed that the statements of Environment Canada/Health Canada cited by DEPA (2015) regarding human toxicity and endocrine properties may be based on more recent data. The current substance evaluation under REACH based on DEPA (2015) anyhow aims to generate current data regarding	This is correct and it is therefore better to wait for the results of the new generated data under REACH substance evaluation, which are expected in 2021, before concluding on any of the suggested hazard endpoints. The reason Denmark the sEV Rapporteur under REACH asked for the additional studies was the fact that the existing data did not allow a conclusion on possible ED properties. This should be respected here as well by the Oeko

	endocrine disruption and PBT properties.	Institut. In addition, the EU REACH dossier contains updated information and more details on the endpoints and Oeko Institut could have been consulted this rather than speculating on statements of third parties that do not contain sufficient underlying data and did in fact not conclude. For the last update of the Fraunhofer ITEM Assessment of TBBPA (2018) several more recent studies published later than 2015 were evaluated and taken into further consideration.
Page 21, section 3.3	**Section 3.1 Non-testing information opposing existing DNELs**	This section isn't part of the draft Oeko Institut methodology and is very speculative, i.e. an attempt to show why DNELs for BPA (and not TBBPA) should be used for the risk assessment. Data pertinent to TBBPA and these end points are being generated via studies agreed with DEPA as part of the REACH substance evaluation now ongoing with studies due for completion in 2021. It therefore makes more sense to wait for the outcome of the substance evaluation (ED) rather to speculatively "read across" effects from BPA in this manner. General comments: • This attempted "read across" is not appropriate as there are sufficient data for TBBPA itself to assess the hazard and derive guidance values. There is no need to fill data gaps with read across. • To perform a valid read across a comprehensive evaluation a of the data per endpoint needs to be performed. This is not the case in this document,

		• Experimental data demonstrates the lack of similarity in metabolism and do not support a read across approach, • The studies cited in the RoHS proposal do not provide adequate support for use of non-testing information. • There is a lack of logical scientific rational provided for the use of BPA DNELs instead of DNELs derived from the substance data. They are not based on similar effects.
Page 21, Section 3.3	TBBP-A molecules exhibit a notable structural similarity to bisphenol A (BPA) molecules and furthermore there is "some evidence that TBBP-A can degrade to give bisphenol A under certain anaerobic conditions, and that bisphenol-A is stable under these same conditions", according to the EU RAR (2008).	This sentence is scientifically not justified. There are considerable differences between the molecules and in particular with regard to receptor interactions it is well known that exchange of one substituent can alter the binding affinity completely. Thus, the analogy to BPA is scientifically not sound. Furthermore, the sentence links human health hazards with environmental degradation under very specific anaerobic conditions, while metabolism in mammals to BPA does not occur. This link is thus also not scientifically plausible. Additionally, the EU risk assessment on bisphenol A in the addendum of 2008 looked at the possible formation of Bisphenol A from TBBPA and concluded there were no risks to soil or sediment from the concentrations predicted from the degradation of TBBPA to Bisphenol A.
Page 22, 2nd paragraph	With regard to the structural similarity of BPA and TBBP-A, it can be anticipated that both substances show similar PBT & ED properties. Thus, DNELs of BPA might be applied for TBBP-A ad interim until the results of the ongoing substance evaluation led by the Danish EPA (Danish Ministry of the Environment) (see section 1.3.1) are available	It is not reasonable to put forward that DNELs for BPA should be taken into consideration, as several reliable studies have been performed with TBBPA itself and the DNELs were derived according to the ECHA REACH Guidance. Therefore, it makes sense to wait for the outcome of the substance evaluation (ED) as correctly noted by Oeko Institut, TBBPA is undergoing a substance evaluation under REACH.

Page 22, 2nd paragraph	Since the ED expert group of ECHA is currently reviewing TBBP-A concerning its possible endocrine disrupting properties, the upcoming results of that assessment should be heeded for in the RoHS substance evaluation.[60]	Again, trying to anticipate an outcome from an evaluation that is currently ongoing. Since the evaluation and review by experts is ongoing, it makes sense to wait for their conclusion.
Page 23, section 4	Nevertheless, some preliminary information on adverse impacts on biota has been **established** as a result of various studies:	This is not correct, the potential adverse effects mentioned in this section **are not based** on information that has been **established.** These were raised as concerns which are currently under evaluation. Please revise accordingly the sentence.
Page 23, section 4	The persistency of one transformation product of TBBP-A, monomethyl ether TBBP-A (Phenol, 4,4 -(1-methylethylidene)-bis[2,6-dibromo-): Further information will be requested in respect to the bioaccumulation potential and potentially hereafter on the chronic toxicity towards aquatic organism and/or mammalian species.	This is not the case, the persistency of the TBBPA monomethyl ether is under evaluation and only if data will show that it is persistent additional studies will be requested for the other end points mentioned
Page 24, section 4.2	According to the EU RAR (2008), TBBP-A may cause long-term adverse effects to organisms in the aquatic environment. This conclusion is based on the toxic effects seen in acute toxicity assays with fish and daphnia (L(EC)50 <1 mg/l), the lack of biodegradation seen in standard ready biodegradation tests and the high bioconcentration factors (BCF>100) measured in fish (ibid).	BCF > 100 is not considered as a high bioconcentration factor based on REACH criteria. TBBPA has a low BCF as it is lower than the cut-off of 2000 for bioconcentration.
Page 25,	Table 4.1	It is not helpful to just state PNEC values of different origin without disclosing the underlying data base and the methodology used. To really judge the comparability and applicability of one or the other value this information needs to be provided.

Page 26, section 5.1, 1st paragraph	Notably, TBBP-A is used as a reactant in the manufacturing of FR4 printed wiring boards (PWB).	Rephrase: TBBPA is used reactively in the manufacture of FR4 printed wiring circuit boards (PWB) during which it is covalently bonded into the epoxy resin matrix
page 26 , section 5.1 last 2 paras.	Taverna et al. (2017)68 for instance, examine typical EEE flame retardants as part of the material flows in the Swiss WEEE treatment system. In this study, 220 tons of WEEE with a typical composition with regard to the WEEE categories69 was examined based on the statistical WEEE composition of Switzerland in the year 2009. This study found that, out of the 18 flame retardants examined, TBBP-A was the most abundant one with a mean concentration of > 600 mg/kg waste in composite samples from all output streams of WEEE processing. With focus on TBBP-A, the following three output streams (out of 13 examined in total) are important: - PWBs (representing 2 % of the total WEEE output mass flow), - polymer components from dismantled EEE housings (5 % of the total WEEE output mass flow), - polymer particle fraction generated by shredding of WEEE (23 % of the total output mass flow). In these three outputs, TBBP-A was always found to be the most abundant flame retardant. For the PWB output stream, TBBP-A was found with an average concentration of 390 mg/kg by far more than from other FR (next followed by DecaBDE with 110 mg/kg). In polymeric computer and notebook housings TBBP-A was present with 4,000 mg/kg (next followed by DBDPE with 1,400 mg/kg); and finally, an average concentration of 1,700 mg/kg was detected in the polymer particle fraction with diameters < 25 mm (next followed by DBDPE 1,100 mg/kg).	The estimation of Fraunhofer ITEM resulted in an average concentration in WEEE of 522 mg/kg. This estimation is based on the derived tonnage of TBBPA in additive use/ABS (= 4800 t/a; see above) divided by the complete tonnage of all WEEE in Europe (about 9.2 million t/a). If only the waste stream of category 3 and 4 will be used (about 2 million t/a), the concentration will be about 2400 mg/kg. This estimation based on the global tonnage of WEEE, the WEEE in Europe and the percentage of additive use (about 15%) together with a global tonnage of TBBPA results thus in similar values as measured by Taverna et al (2017). Overall, this supports that the estimation done in the Fraunhofer ITEM report is a very good best guess of the tonnage imported to Europe, and the derived emission values are reliable.

Page 26, section 5.1 last paragraph	In polymeric computer and notebook housings TBBP-A was present with 4,000 mg/kg (next followed by DBDPE with 1,400 mg/kg);	It seems there is a typo here – what is a polymeric computer? Are you referring to computer and notebook housings of polymeric material?
page 28, section 5.1.2, 2nd paragraph	PWBs may contain residues of not-reacted TBBP-A in traces only. According to Rachmilevich (2015), to which several stakeholders refer to (e.g. MedTech 2018, JEITA 2018), the unreacted residues of TBBP-A in epoxy based PWBs can be considered as very low.	A recent study (Levchik, S (2020)) using FR4 PWCBs from a number of manufacturers confirms no detectable levels of unreacted TBBPA found. http://pcb.iconnect007.com/index.php/article/121573/residualfree-tbbpa-in-fr-4/121576/?skin=pcb#121573 This information will be provided to the IPC (Association Connecting Electronic Industries) for inclusion in their next revision of their *IPC-WP/TR-584: IPC White Paper and Technical Report on the Use of Halogenated Flame Retardants in Printed Circuit Boards and Assemblies.* In addition, the information will be supplied to the International Electrotechnical Commission (IEC – Geneva Switzerland) for consideration in their standardization activities
page 29, section 5.1.2 Question	Questions for stakeholders participating in the stakeholder consultation: Specific information – beside what is already referred to here – is requested to clarify the amount of unreacted TBBP-A in PWBs in percentage weight (%/w) at the homogenous material level of the epoxy resin, i.e., excluding copper, glass fibre etc.	The measurement has already been included in the Fraunhofer ITEM Assessment of TBBPA for BSEF (2018) - "TBBP-A concentrations in samples at different production stages of PWBs (CCL, unclad laminates, prepregs) from four different manufacturers were found to be lower than the methods' detection limits of either 10 or 20 ppm which is estimated to be less than 0.006 % of the original used TBBP-A". The test reports states that copper has been removed from prepregs, and unclad laminates has been used which do not contain glass fibre. The results are thus of the epoxy resins excluding copper, glass fibre, etc. However, the concentrations are below detection limits, and thus the emission values used are still worst-case and overestimate the actual concentrations.

page 29, section 5.1.2 1st paragraph	Hence, it has to be noted that **WEEE containing reacted TBBP-A in its polymeric backbone is not subject to the scope of this dossier**. In other words, epoxy-based PWBs that are found in WEEE are not considered to contain TBBP-A in relevant amounts	We agree with this assessment.
page 29, last paragraph	Overall, WEEE categories 3 and 4 play the major role concerning housings (additive use), whereas all WEEE categories are relevant for printed wiring boards (reactive use), since these are present in almost all pieces of equipment	Assume this refers to personal computers, printer, notebooks, tablet, mobile phones (cat 3); TV sets (cat 4). This is correct.
page 30, section 5.2.2 2nd paragraph	The following assessment applies under the condition of separate collection and treatment of current operational conditions in the EU	BSEF agrees, the assessment should be focused on operational conditions pertaining to the EU and requirements of EU legislation in particular the WEEE Directive - 2012/19/EU https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012L0019
page 30 section 5.2.2, 3rd bullet	Plastics recovery: ABS, originating from plastic parts that are free of flame retardants is recovered to a certain extent. ABS, containing flame retardants is usually incinerated and recycling processes for TBBP-A-contaminated plastic housings have not been reported	This is not fully reflecting the reality on the ground with respect to EEE plastics recycling. Treatment of BFR containing plastics such as ABS is in accordance with the WEEE CEN standards 50625 series. Only ABS plastics with a Br content above 2,000 ppm (the CEN Standard cut off to ensure legacy BFRs are removed from the material stream) are sent for incineration, ABS with values below 2,000ppm are recycled with other non-BFR ABS from WEEE.
page 30 section 5.2.2 5th bullet	Co-incineration of bromine-free plastic waste as substitute fuel in cement kilns.	High bromine content ABS and other plastics are indeed treated in cement kilns in the UK
page 31, section 5.2.2, 1st paragraph	Recycling of polymers (epoxy resins or ABS) containing TBBP-A is usually not practiced in the EU because market demand for recycled polymers containing flame retardants is missing. Hence, additive TBBP-A expected to be found in WEEE that contains ABS parts (such as inner and outer plastic housing,	This is not factually correct as mentioned above or reflecting current polymer recycling in the EU. The reality, is that ABS containing TBBPA is recycled along with other BFRs based on the WEEE CEN standard 50625 series where plastics with a Br level > 2,000ppm are deemed not to have legacy BFRs and can be recycled with non-BFR ABS. The Oeko Institut is referred to the

	front or rear cover plates) need to be separated and disposed of.	European Electronics Recyclers Association website and its brochure on treatment of BFR-containing plastics: https://www.eera-recyclers.com/files/eera-bfrs-folder-online.pdf
page 31, 2nd paragraph	PWBs are usually sent to copper smelters for metal recovery. The reacted TBBP-A, contained in epoxy resin based PWBs, is usually co-incinerated in process of metal smelting where waste gas cleaning devices are expected to be installed.[83] The bromine is thus removed as a salt, which is disposed of in landfills.	BSEF agrees but notes that some smelters are also focusing recovery of precious metals and critical raw materials. The Umicore smelter near Antwerp is one such smelter operation.
page 31, section 5.3, first 2 bullets	• Manual dismantling of WEEE (e.g. housings) is unlikely to cause airborne emissions due to the high vapour pressure of TBBP-A. However, dermal contact of workers to TBBP-A bearing plastic parts could be a possible exposure pathway if personal protection equipment (gloves) is insufficiently used. • Manual dismantling of PWBs seems to be of low relevance due to chemically bound state of TBBP-A in the polymeric resin. Yet, dermal contact of workers to un-reacted TBBP-A (concentrations below 0.006 % see 5.1.1.) cannot be ruled out.	From visits to recyclers, shredding is now a mechanical process with very little worker exposures – gloves are generally mandatory; there is little to no manual dismantling of PWBs. The comments made here are not based on any evidence or data. There is now new data (mentioned above) indicating that there is no detectable un-reacted TBBPA.
page 31, section 5.3, last bullet	Uncontrolled heating and burning of TBBP-A bearing plastics can lead to the formation of dibenzo-p-dioxins and furans,[84] in particular in the presence of copper. However, this risk is not specific to TBBP-A, but applies to all species of brominated flame retardants in WEEE.	This is not an issue in the EU under WEEE compliant operations. It is also not specific to flame retardant additives, but polymers in general. Under controlled conditions – smelters, ASWI, cement kilns in the EU the emission of such species in strictly controlled and monitored.
page 32, section 5.4, 3rd paragraph	In terms of suspected pathways of TBBP-A release, shredding of mixed WEEE and pre-sorted ABS fractions are the most relevant processes as they may cause TBBP-A bearing dust emissions at the working place and into the environment. In particular, polymer particles with diameters below 25 mm are seen of high	It is recommended that Oeko Institut consult and solicit information and data from EERA – the European Electronics Recyclers Association – with respect to data on this issue.

	relevance for TBBP-A releases (Taverna et al. 2017).	
page 32 , section 5.4, Question	As the extrapolation of Fraunhofer ITEM and IPA is based on outdated numbers from 2004 (e.g. a tonnage of 32,000 t/a TBBP-A used as FR in the EU and several assumptions), stakeholders are requested to provide comprehensive data on the TBBP-A releases from WEEE in Europe [g TBBP-A/ t treated WEEE].	As mentioned already above, the global tonnage is indeed outdated, but the estimation of the average concentrations in WEEE of 522 mg/kg is still a best guess and reliable. This value is in a similar range as measured by Taverna et al (2017). If we assume as a worst-case that the global EEE market is increasing due to increasing market in developing countries (e.g. of computer housings), the global tonnage of TBBP-A was still increasing since 2004 as well. However, based on this assumption the global WEEE tonnage is increasing as well, and as the EEE put on the market in Europe is nearly constant (see Eurostat link given above), the percentage of WEEE in Europe is decreasing. Overall TBBP-A in EEE in Europe is nearly constant and the estimated amount of about 32000 t/a in EEE (mainly imported good) is still reliable. Considering the percentage of additive use, this tonnage can be re-calculated into a tonnage of TBBP-A in e-waste which is about 4800 t/a and thus the average concentration in all WEEE is about 522 mg/kg, and in WEEE of cat 3 and 4 only about 2400 mg/kg. This is supported by the measurements of Taverna et al (2017). it is expected that the same concentration is in dust as in the shredder material. This is also supported by measurement of TBBP-A in dust at recycling sites (see Fraunhofer ITEM report). The further estimation of releases to the environment considers only the percentage of WEEE treated at recycling sites in Europe, and the assumption that 0.1% is in the PM10 fraction. The latter one has been taken from the ROHS dossier for DEHP. The release at a typical recycling site is based on the assumption

		of 250 t/d treated WEEE, and the average concentration of 522 mg/kg (it is expected that the same concentration is in dust as in the shredder material. It is not expected that this typical recycling site will only treat specific waste streams, and thus the average value seems to be more appropriate than max values in specific waste streams.
page 32, section 5.4, 7th paragraph	Regardless the poor information on environmental entry pathways, inter-compartment transport and transformation, TBBP-A has been detected in various environmental compartments related to the disposal phase (such as dust deposited in soil).	No reference is provided nor data on levels
page 32, section 5.4, last paragraph	**Releases of toxic degradation products -**Thermal waste treatment processes, applied to plastic parts containing additive TBBP-A, are suspected to result in a release of bromine in form of chemical compounds of low molecular weight, specifically hydrobromic acid (HBr). That substance can act as a precursor to the formation of brominated dioxin species if the WEEE undergoes crude thermal treatment processes in presence of copper (which is almost certainly the case if PWBs are combusted in open fire). However, the aforementioned pathway to the formation of brominated pollutants is not specific to TBBP-A. It can occur with any brominated compound that has been added to EEE during their manufacturing	This section is not of relevance to the assessment of risks associated with waste treatment in accordance with EU waste legislation including WEEE, the Waste Framework Directive or the Industrial Emissions Directive which regulates inter alia thermal treatment of waste (incineration). Non-standard or informal treatment of electrical and electronic waste in non-OECD countries is a concern. However, this needs to be addressed via the appropriate legal base, in particular the application of the Basel Convention and the stopping of illegal export of EEE waste to countries without the proper infrastructure for managing and treating such waste.
Page 33, section 5.5	This includes mechanical treatment of residual waste, incineration in municipal waste incinerators but also landfilling or transboundary movements outside the EU cannot be ruled out. WEEE, exported towards non-OECD countries is likely to be subjected to all sorts of informal recycling and waste treatment processes, such as uncontrolled combustion, grilling, desoldering, uncontrolled dumping of residues, and generally uncontrolled treatment under crude circumstances. Due to	As mentioned in other sections, it has been noted that the export of WEEE to non-OECD countries for treatment with the consequences of these treatments is a problem that is not specific to TBBPA. This is an issue related primarily to illegal export of waste from the EU. It cannot be addressed via a RoHS restriction, but by definitive action by the EU to ban the export of WEEE waste and

	their content of precious metals, PWBs are particularly prone to crude recycling treatment, including open burning, roosting, and hydro chemical acid leaching. The presence of reacted TBBP-A in FR4 PWB does impose special precautions to be applied in informal recycling businesses. The fate of plastic parts containing additive TBBP-A is uncertain. Some ABS plastic parts might be landfilled or burned while others are subjected to manual sorting and recovery of ABS. The latter pathway poses a risk of cross-contamination, which means an uncontrolled pollution of recycled ABS feedstock with a mixture of additives, among them TBBP-A. There is a risk of re-imports of products (not only EEE) containing cross-contaminated plastic recyclates into the EU.	WEEE shredded waste to non- OECD countries as well as ensuring that any waste legally exported is only sent to facilities with the capability to treat it in accordance with accepted standards.
Page 33 Section 6.1	Also dermal exposure should not occur because vapour release from the plastic surface is not relevant.	Later in the document it is mentioned that dermal exposure is relevant. Dermal exposure is assumed to be mainly based on the skin contact to shredding material or dust from these shredding materials. In this sentence only the relation to vapour release of the substance is given, which is indeed low, but which has no influence on potential dermal exposure. For this reason, the sentence should be deleted.
Page 34; section 6.2.1, 3rd paragraph	In contrast to the modelling carried out by Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018), the lowest possible default value concentration for the substance in preparation of <1 % was chosen, based on measured concentration of TBBP-A in Taverna et al. (2017) as follows:…….	Fraunhofer ITEM IPA used the 100% preparation to estimate the exposure. This has been reduced by the average concentration in electronic waste (this has been estimated to be 522 mg/kg). The estimated average concentration is similar to the values measured by Taverna et al (2017) considering that in the recycling plant not only high contaminated waste streams are present. The ECETOC TRA calculation is expected to be a very conservative worst case (tier 1 exposure estimation for screening) due to the fact that for < 1% substance in preparation, the resulting dermal exposure is reduced by only 1/10 in comparison to 100%

		preparation. Considering that concentration in waste streams are < 0.4% (< 4000 mg/kg), and in average even lower < 0.1%, the estimate based on 1/10 of 100% (=10%) indicates strong overestimation. In addition, the area of skin contact is with 1980 cm2 very high (1/10 of the whole body), as well as the skin contamination of 100 µg/cm2/d, so that the overestimation additionally increases. Finally, if ECETOC TRA exceeds the DNEL a refinement of the exposure estimation is recommended (Please note that this was not necessary based on the estimation by Fraunhofer ITEM IPA). Dermal exposure by direct contact to the shreddings is limited to the amount of TBBPA at the surface of the particles, if dermal contact to the particles is possible at all, which relates to the substance concentration directly. For this reason, dermal exposure might be significantly lower than the 1/10 of the exposure by the 100% preparation. If we assume that the exposure is 1/100 (= 1%) of the exposure by 100% preparation, which indicates still a worst-case, this result in a value of 0.0283 mg/kg/d, which is well below the DNEL of TBBPA. If we assume that dermal exposure is via dust and the worker has dust exposure of 100 µg/cm2/d, the exposure is max 100 ng/cm2 using a concentration in dust in recycling sites of < 1000 µg/g. This results in < 200 µg/person/day (using contaminated skin area of 1980 cm2) which corresponds to < 3 µg/kg/d. In both cases the transfer efficiency from the particles to the skin has not been considered so far, which additionally reduce the exposure value.Overall, the present ECETOC TRA estimates <u>are very conservative exposure values.</u>
Page 38, 4th para.	Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) used as inhalation DNEL of 300 mg/m3 and the oral DNEL of 2.5 mg/kg/day; applying these DNELs, Fraunhofer ITEM IPA,	By mistake the value of 300 mg/m3 has not been adapted in section 6.1.1 of the updated dossier by Fraunhofer ITEM (2018). However, as discussed below, there was also an error in the

	Wibbertmann and Hahn (2018) concludes that no risk could be expected for consumers. It should be noted that the actual DNEL for the general population for inhalative exposure according to the ECHA Brief profile on TBBP-A[101] is 4.3 mg/m3, which was mentioned by Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) in the section on human health hazard profile but has not been updated in the section on exposure.	exposure estimates by dust ingestion for the general public. **This has been corrected in the updated dossier but not adopted by Oeko Institut. As a result, the estimate is still significantly lower than the adapted DNEL** In section 6.2.1 the DNEL for worker has been used in the updated dossier. By mistake the value of 300 mg/m3 has not been adapted in section 6.1.1 of the updated dossier by Fraunhofer ITEM. However, as discussed below, there was also an error in the exposure estimates by dust ingestion for the general public. This has been corrected in the updated dossier but not adopted by Oeko Institut. As a result, the estimate is still significantly lower than the adapted DNEL, and even lower than the DNEL for BPA. In section 6.2.1 the DNEL for worker has been used in the updated dossier.
Page 43, section 7, first paragraph	The substance evaluation of the human health and environment hazards of TBBP-A under REACH is currently ongoing. EU wide, no conclusion is reached so far on whether TBBP-A has endocrine disruptive properties and whether it is to be considered as PBT or quasi PBT, respectively	The use the term "quasi PBT" is not a regulatory end point and should be removed from the text
Page 43, first paragraph	Any evidence regarding one of these properties would affect the impact and risk evaluation here at hand because as a result of both properties, the current DNELs and PNEC would no longer be applicable:	We agree the results of the REACH evaluation should be used for any assessment. It doesn't make sense to derive DNELs based on gaps in data that may need to be changed after the new data are available. However, we do not agree that the DNELs and PNECs would not apply anymore necessarily and therefore suggest replacing the word "would" with "may".
Page 43, 2nd paragraph	Having in mind that TBBP-A is currently under review by the ED expert group of ECHA concerning its possible endocrine disrupting properties, it is suggested here that similar hazards are to be expected for TBBP-A as for BPA.	See our comments above, earlier. The analogy is not scientifically based and should not be used. This is more superficial conjecture and opinion. It doesn't make sense and is not a responsible approach! If the ED expert is reviewing TBBPA, how can this current assessment use BPA instead – this is pre-empting any

		expert judgement and making the ED expert group redundant!
Page 43, 3 paragraph	ECHA (2014)	The reference to this document is not on the reference list.
Page 43, 4th paragraph	However, the risk characterisation ratios provided by the study of the Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) would no longer be valid if TBBP-A were to be recognised as endocrine disrupter and as a type of PBT substance.	Not sure what line of reasoning is being pursued here. Oeko Institut seems to have concluded that TBBPA is an ED on what basis? We are waiting for the results of the ongoing REACH evaluation which, when concluded provide a basis for experts to consider whether or not TBBPA is or is not an ED.
Page 43, 5th paragraph	As for human health it should further be noted that according to the Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018), the DNELs available come from the REACH registrants, thus from industry. These DNELS however have substantially decreased in the last years and have not been officially scrutinised by ECHA or any EU expert group	And indeed, if this is the case, and the authors believe that the results of the REACH evaluation and ED expert group discussion will affect the assessment, the RoHS assessment of TBBPA should be postponed. Another option would be to use the current data available on TBBPA but certainly not use BPA instead. To cast doubt on data without reviewing the underlying data that has been used is scientifically not supportable.
Page 43 & 44, Section 7.1	As according to the WEEE Directive[103] plastics used in EEE containing brominated flame- retardants have to be removed from any separately collected WEEE according to Annex VII on the selective treatment for materials and components of waste electrical and electronic equipment referred to in Article 8(2), any brominated flame retardant is understood to render the recycling of the plastic impossible. Standard procedures, especially semi-automatic treatment processes, may not be able to distinguish TBBP-A treated ABS polymers from other, possibly restricted polymer additives (e.g. Octa-BDE). This was the reason for DEPA (2010) to conclude that the presence of additively used TBBP-A plastic parts may hinder the recycling of the corresponding plastic. Recyclers[104] oppose that this would not seem to be of relevance currently as	The conclusion that TBBPA poses a problem for recycling is completely at variance with the actual reality on the ground with respect to recycling of WEEE plastics. The WEEE Directive (EC 2012/19) requires all **BFR containing plastics to be separately treated** – this means both restricted and non-restricted BFRs are included in this separated stream. Current density-based sorting technologies are more than capable of doing this. The separated fraction is further assessed/tested in accordance with WEEE CEN standards (50625: 2015 series) Standard 50625-3: 2015, enables further sorting of legacy BFRs based on bromine content. If it is above 2,000 ppm (plastics with bromine content above this value are deemed to have restricted BFRs), the fraction is removed for incineration or other thermal destruction such as in cement kilns. Below this value, the fraction is recycled with the rest of the

	ABS housings were usually not recycled (but incinerated) due to not economically relevant volume streams and chemical contamination. It is therefore concluded that TBBP-A used as additive flame retardant poses a negative impact on the recycling of WEEE.	various plastics streams (ABS, HIPS, etc) as they are deemed free of restricted BFRs. The efficacy of this test and cut-off value was recently validated in a research project in France (Hennebert & Filella (2018) (Hennebert P & Filella, M. Waste Management: 71 (2018. pp390-399). To realistically determine the actual impact on recycling requires more than just opinions. It requires a detailed assessment of flows, levels of BFRs and comparisons of treatment options available for high bromine content EEE plastics versus incineration. The EU has supported or is supporting some 20 million EUR worth of research and demonstration projects all aimed at improving the yield and quality of end of life EEE from recycling as well as addressing legacy BFRs. Therefore, at this point in timer the conclusion of the Oeko Institut the impact of TBBPA for recycling on is not sustained.
Page 44, section 7.2 4th para	If DNEL values of BPA are taken into account as suggested in section 3.3, in order to reflect the potential endocrine disrupting properties of TBBP-A, the estimated exposure by ECETOC TRA rather indicates a risk for workers via dermal exposure then via inhalation….. It is stressed again that this conclusion is based on DNELs that do not take into account potential endocrine disrupting properties. Workers of EEE waste processing plants are exposed to TBBP-A which is suggested by exposure estimations, by measurements of TBBP-A in EEE waste streams (see Taverna et al. 2017) and results from human biomonitoring (concentrations of TBBP-A reported in serum of workers) (for details see section 6.2.1). Based on these considerations and in contrast to Fraunhofer ITEM IPA, Wibbertmann and Hahn	As indicated above, exposure estimation for worker by Fraunhofer ITEM IPA is significantly lower than the estimation done by Öko Institute. This is the reason why Wibbertmann and Hahn concluded no significant impact. The ECETOC TRA calculation is expected to be a very conservative worst case (tier 1 exposure estimation for screening) estimate. Together with the uncertainty to use the DNELs for BPA, a clear impact cannot be seen. All measured values in workers are clearly below any concentration of concern. Overall, the exposure estimation does not indicate a proven concern for the worker. The inhalation DNEL will not be exceeded.

	(2018), an impact on worker in EEE waste processing plants is seen here.	
Page 45, section 7.3, 2nd paragraph	Based on assumptions on the house dust ingestion and inhalation as documented by Oomen et al. (2008) and the identified maximum concentration of TBBP-A in house dust (1,480 ng/g) a daily exposure via dust has been estimated as shown in the following table: If DNEL values of BPA are taken into account as mentioned in section 3.3, in order to reflect the potential endocrine disrupting properties of TBBP-A, a risk characterisation ratio of > 1 is reached for children that indicates a risk. The DNEL for bisphenol A for oral exposure is at 4 µg/kg body weight per day	In the update of the Fraunhofer ITEM assessment of TBBPA on behalf of BSEF (2018) the max value of 2300 ng/g has been used together with the assumptions of Oomen. However, it has been recognized in this update that an error in calculation has been made in the original report, resulting in revised exposure values in the range of ng/kg/d (child 23 ng/kg/d, adult 2.0 ng/kg/d) which are significantly below the TBBPA trigger values and even a factor of 174 or 2000 below the DNEL for bisphenol A for oral exposure (4 µg/kg body weight per day). **For this reason, a concern for the general public is not expected. We again wish to reiterate that the use of DNELs of BPA is completely inappropriate.**
Page 45, section 7.4, 3rd paragraph	It is an indication for its persistency and thus an indication that the normal risk assessment, by means of the ratio of the expected environmental concentration (Predicted Environmental Concentration, PEC) and an estimated non-effect threshold (Predicted No-effect concentration, PNEC), is not applicable. Substances with PBT properties have the potential to persist and thereby accumulate in the environment. ECHA (2014) emphasises that the effects of such accumulation are unpredictable in the long–term and that such accumulation is in practice difficult to reverse as cessation of emission will not necessarily result in a reduction in chemical concentration	It is not a generally accepted scientific principle that the authors of this document state that persistency alone would preclude a "normal" risk assessment in form of a PEC/PNEC ratio. Only for PBT substances or vPvB substances this is questioned in the regulatory context. We would like to reiterate that TBBPA is not a PBT – so the point is not relevant.
Page 49, 2nd paragraph	Whereas **additively used TBBP-A** was substituted by (organo-) phosphorus or nitrogen FR in polyurethane foams – to name one successful example	From information from BSEF member companies we can state categorically that TBBPA was never used in polyurethane foams.

Page 49, 3rd paragraph	Alternative brominated compounds include e.g. Decabromodiphenylehter or brominated epoxy oligomers (BEOs).[121] Nevertheless, substituting TBBP-A with those will not be expedient to phase out halogenated FR as such.	This exercise is about the assessment of TBBPA with respect to a possible restriction under the RoHS Directive. Speculative and "political" statements or goals relating to a very broad class of chemistry are thus not valid not warranted. Please remove this from the text. Decabromodiphenylether should in any case not be mentioned as an alternative as it is already phased out and restricted under RoHS.
Page 52, Table 8-3	TBBPA is bioaccumulative	This table is based on a Danish EPA report, but it is not correct that TBBPA is bioaccumulative and PBT
Page 53, 1st paragraph	The 100 ppm threshold corresponds to 0.1 % per weight which is the threshold applied for most RoHS restricted substances of Annex II.	0.1 % is 1000 ppm and not 100 ppm
Page 57, 2nd paragraph	In this respect, it is also worth mentioning the possible decrease in the amount of bromine sourced. For example, both in Jordan and Israel, bromine is sourced from the Dead Sea. In both countries, these chemical industries provide a significant source of income and employment, while also having an impact on the surrounding environment.	The Oeko Institut is asked to stick to assessment of TBBPA in the context of Article 6. Environmental issues related to bromine extraction are not part of the assessment.
Page 59, section 9.5 last bullet	• Total volume of ABS polymer assuming an average TBBPA load of 22 %: 36,000 tonnes/year.	On page 18 of updated Fraunhofer Institute assessment of TBBPA on behalf of BSEF from 2018, it is mentioned that concentration in ABS are up to 22%. However, it is possible that typical concentration is about 12-16%, and only in exceptional cases the concentration is up to 22%. In this sense it is questionable if the estimation of the tonnage of ABS products in the DEPA study is correct, and it has a high uncertainty. In the updated report of Fraunhofer ITEM the total amount of additively used TBBPA in WEEE in Europe is 4800 t/a and not 8000 t/a, together with the lower concentration of up to 16%, this would result in max 30000 t ABS polymer containing TBBPA.

		This estimation is only slightly lower to the estimation in the DEPA study of 36000 t/a (with 8000 t/a and 22%). ITEM assumes that this uncertainty is covered by the cost range of 5 – 30 million € /year.
Page 64, 1st bullet	• The current DNELs for TBBP-A do not take into account potential endocrine disrupting properties. Instead, DNEL values of bisphenol A should be taken into account in order to reflect the potential endocrine disrupting properties of TBBP-A.	The use of BPA DNELs as a proxy for TBBPA DNELs is not sound science. The assessment should be done after the results of the REACH evaluation and ED expert group are available, BPA cannot be used as a surrogate for TBBPA
Page 64, 2nd bullet	Based on these considerations, an impact on workers in EEE waste processing plants has been observed and the estimated exposure by ECETOC TRA rather indicates a risk for workers via dermal exposure than via inhalation.	The risks identified are based on BPA and not on TBBPA
Page 64, 3rd bullet	• The general population is exposed to TBBP-A by house dust ingestion and inhalation; estimations on worst case exposure to TBBP-A via house dust (ingestion + inhalation) and taking the DNEL for bisphenol A for oral exposure at 4 µg/kg bw/day, a risk characterisation ratio of > 1 for children indicates a risk.	The use of BPA DNELs as a proxy for TBBPA DNELs is not sound science. The assessment should be undertaken after the results of the REACH evaluation and ED expert group are available, BPA cannot be used as a surrogate for TBBPA. Please also see comments above, earlier, on the exposure assessment.
Page 64, 4th bullet	Substances with PBT properties have the potential to persist and thereby accumulate in the environment. ECHA (2014) emphasises that the effects of such accumulation are unpredictable in the long–term and that such accumulation is in practice difficult to reverse as cessation of emissions will not necessarily result in a reduction in chemical concentration.	What is the purpose of this section? This discussion is not relevant for TBBPA as it is not a PBT substance