



Bisphenol A in thermal paper

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Annex XV Restriction Dossier

LOUS Conference - 2016 April 28th

The proposal

Entry [#].

4,4'-isopropylidenediphenol (Bisphenol-A)

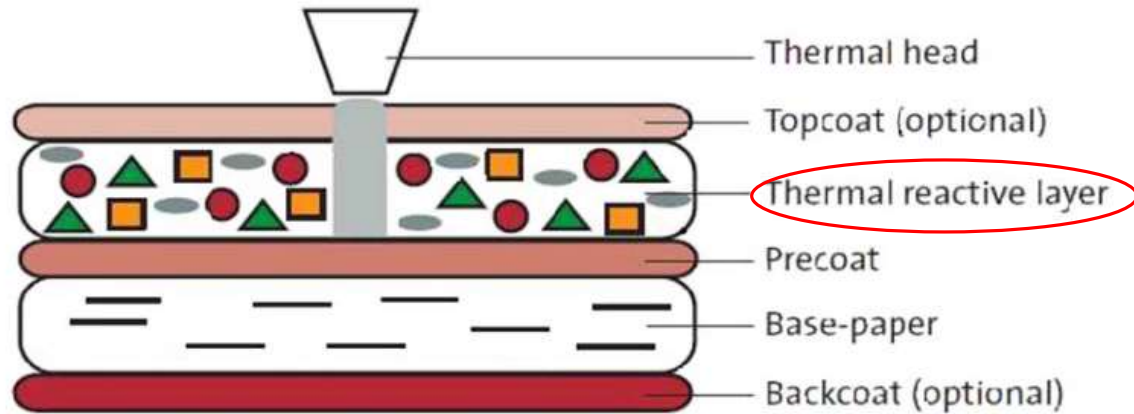
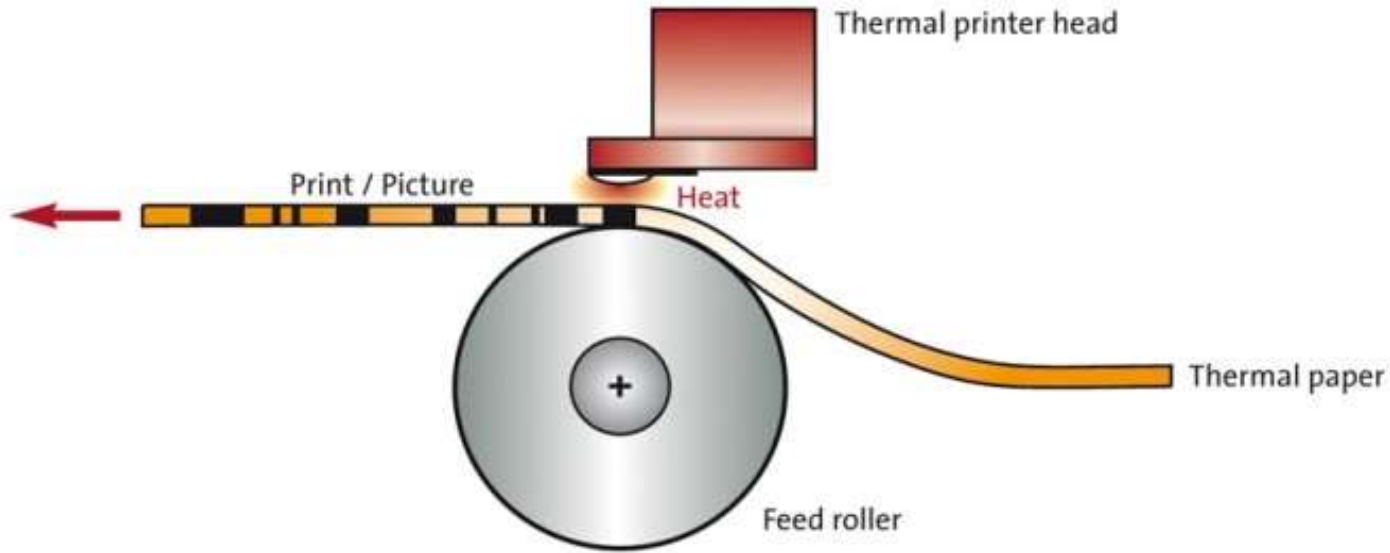
CAS No 80-05-7

EC No 201-245-8

1. Thermal paper shall not be placed on the market after [36 months after the entry into force] if it contains this substance in concentration equal or higher than 0.02% by weight
2. The existing standard analytical methods for BPA have to be used

- ≈ Ban of BPA in thermal paper
- Concentration limit based on:
 - no safe concentration could be determined
 - below 1%, thermal paper gets inefficient
 - limit proposed is the lowest as possible= average of LoDs= 0.02%
- Transitional period of 3 years based on:
 - Alternatives exist and some of them are already used
 - No information about a longer period got from the STOs so far

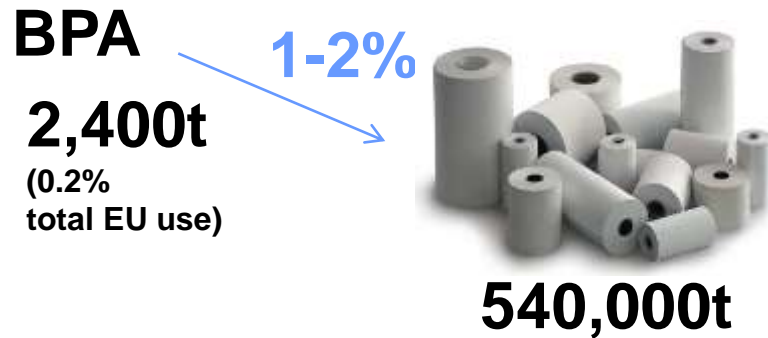
What is Thermal paper ?



BPA

- Color former
- ▲ Pigment
- Color developer
- Binder

Thermal paper applications / Scope of the restriction



Applications	BPA Use Share (2008-2012)	Tonnage of BPA-containing thermal paper (2012)
Point-of-sale receipts	65%	351,000t
Self-adhesive labels	20%	108,000t
Lottery tickets	≈10%	54,000t
Fax paper	≈5%	27,000t
Other	<0.5%	-
TOTAL	100%	540,000t

Scope = All types of thermal paper

- All types of thermal paper may contain BPA
- The RA has been carried out for POS receipts only (many data)
- Consistently, the SEA has been also carried out for POS receipts
- No assessment/evidence about the risks from other thermal papers BUT no information/reason to discard them from the scope
- The proposal is motivated on the grounds of adverse health effects for the unborn children of women exposed

A. Hazards/Exposure and Health Risk Assessment

Bisphenol-A

- CAS 80-05-7
- Current harmonized classification:
 - Repr. 2 – H361f;
 - STOT SE 3 – H335;
 - Eye Dam. 1 – H318;
 - Skin Sens. 1- H317;
- Repr 1B, H360F- French proposal (2011)-
adopted by RAC/Echa:



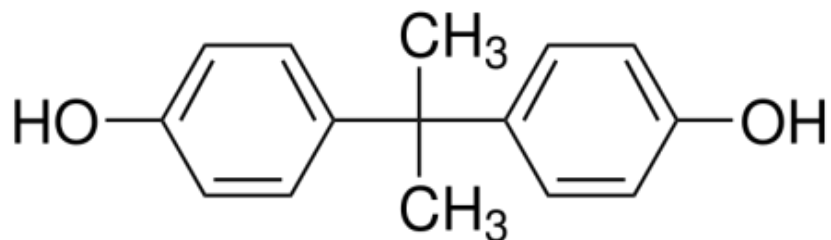
Corrosion



Health hazard



Exclamation mark



Classification of BPA



RAC proposes to strengthen the classification of bisphenol A

ECHA/PR/14/07

The French proposal to classify bisphenol A (BPA) as a presumed human reproductive toxicant which may damage fertility has been unanimously supported by RAC.

Helsinki, 19 March 2014 – The Committee for Risk Assessment (RAC) has adopted an opinion to strengthen the existing harmonised classification and labelling (CLH) of BPA from a category 2 reproductive toxicant to a **category 1B** reproductive toxicant regarding the adverse effects on sexual function and fertility in line with a proposal from the French competent authority.

BPA already has a harmonised classification in Annex VI to the CLP Regulation as a substance suspected to damage fertility, that may cause respiratory irritation and allergic skin reaction, and as a substance that causes serious eye damage. The RAC opinion solely covers the adverse effects on sexual function and fertility as only these types of main reproductive toxic effects were proposed for revision by France.

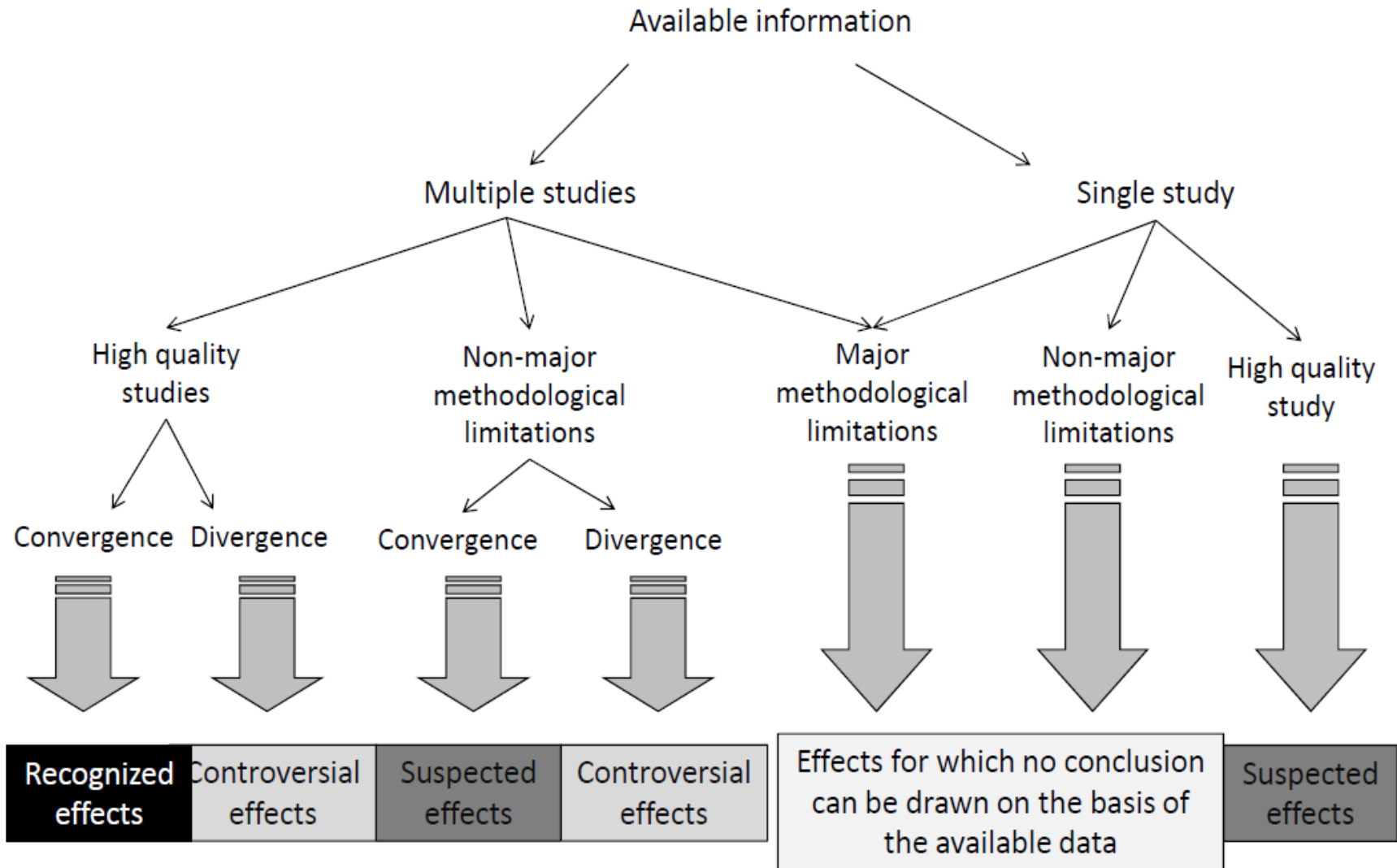
RAC adopted its opinion by consensus after comparing the available evidence with the CLP criteria. The studies performed according to standard test guidelines were given the most weight. RAC concluded that there were adverse effects on reproductive capacity (functional fertility) following oral exposure to BPA in a multi-generation guideline study in mice and in rats. Impaired female reproductive capacity was also observed in several supplementary non-guideline studies. In addition, toxic effects in reproductive organs were observed in several of the studies.



Methodology for the Human Risk Assessment (HRA)

- Past expert assessment reports...
- Articles published from 2010 to 2012, taken into account in the analysis:
 - Epidemiological studies (methodological weaknesses)
 - Experimental studies using oral and also subcutaneous route of exposure- at low doses < 5 mg/kg bw/d
- DNEELs derived from oral studies (most reliable).
- HRA only based on experimental data.

Decision tree to qualify the effects of BPA



Hazard Identification

- ”**recognised**” effects in animals used as end point for RA
- Effects on the female reproductive system
 - Increase in the occurrence of ovarian cysts;
 - Increase in the frequency of endometrial hyperplasia;
 - Disruption of ovarian cycles.
 - Effects on the brain
 - Impairment of memory and learning concurrent with
 - Decrease in the expression of various subunits of glutamate NMDA
 - Effects on metabolism and obesity
 - Increase in body weight, increase in cholesterol in females
 - Effects on the mammary gland
 - ductal hyperplasia and the effects on the architecture of the mammary gland, including effects on terminal ducts (TD) and the terminal buds (TEB) as critical effects for the HRA

Characterization of the hazard

Table B: Effects and related DNELs selected for the HRA.

Critical effects	Study reference	Route of exposure	NOAEL	Internal NOAEL**	Internal DNEL
			(µg/kg/d)	(µg/kg/d)	(µg/kg/d)
Brain and behaviour	Xu <i>et al.</i> , 2010a	oral	50	1.5	0.005
Female reproductive system	Rubin <i>et al.</i> , 2001 ⁵	oral	100	3	0.01
Metabolism and obesity	Miyawaki <i>et al.</i> , 2007 ⁹	oral	87*	2.6	0.009
Mammary gland	Moral <i>et al.</i> , 2008 ³	oral	25	0.75	0.0025

*: NOAEL calculated from the LOAEL.

** : internal NOAL is calculated from NOAEL by using a 3% value for bioavailability

EFSA t-Tdi= 4 µg/kg pc/ j ↔ internal 0,12 µg/kg pc/j

BPA contamination data : thermal receipts

	SCL, 2011	Biedermann <i>et al.</i> , 2010	EWG, 2010	Danish EPA, 2011	Östberg et Noaksson, 2010 cité dans Danish EPA, 2011	Mendum <i>et al.</i> , 2010	Schreder, 2010	Liao and Kannan, 2011b	Geens <i>et al.</i> , 2012
Country	France	Switzerland	USA et Japan	Danmark	Sweden	USA	USA	USA, Japan, Korea Vietnam	Belgium
Sampling places	Supermarkets, shops, stations-service, banks	Chromatograms shops, cinemas...	Shops, supermarkets, public institutions	Supermarkets, shops, banks	Récolte par 4 familles suédoises	Not precised	Shops and restaurants	Supermarkets, shops, banks, stations service, restaurants, fast-food	Banks, shops, restaurant, parkings...
Number of receipts tested	50	13	36	12	16	10 (tickets non imprimés)	22	103	44
Number of receipts with BPA	36 (soit 72 %)	11 (soit 85 %)	16 (soit 44 %)	9 (soit 75 %)	100 %	8 (soit 80 %)	11 (soit 50 %)	97 (soit 94 %)	44 (soit 100 %)
BPA concentration in receipts (% m/m)									
Moyenne	1,33 %	1,33 %	1,9 %	1,14 %	1,58 %	1,24 %	1,70 %	0,0211 %2	1,46 %
Min – Max	0,8–1,9 %	0,8–1,7 %	0,8–2,8 %	0,87-1,70 %	0,58-3,2 %	0,3–1,5 %	0,9–2,2 %	<10-7–1,4 %	0,9-2,1 %
LD / LQ	LD : 0,01% LQ : 0,02%	LQ : 0,00005%	non précisé	LD = 0,00005%	LD = 0,00005%	LD : 0,09% LQ : 0,26%	LD : 0,005%	LQ : 10-7%	LQ = 0,000001%
Analytical method	LC-MS/MS	HPLC/fluo	HPLC/ CoulArray	HPLC/GC/MS	-	GC/FID	GC/MS	LC/MS-MS	GC-ECNI/MS
Other bisphenols searched	BPS	-	BPB, BPS, BPF	BPS	-	-	-	-	-
12									

Thermal receipts uses

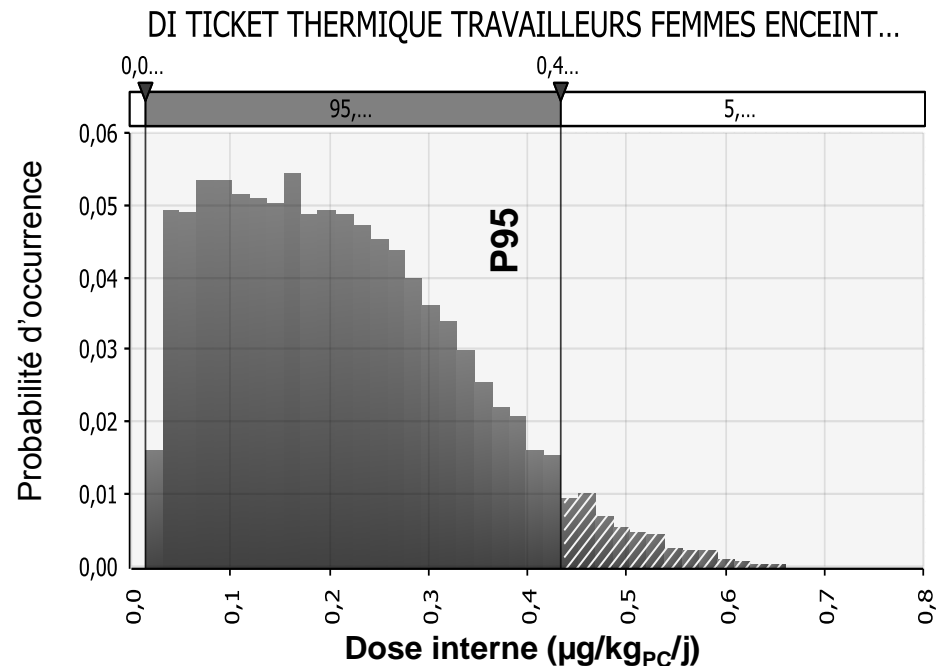
Occupationnal exposure – Pregnant women



$$DJE (\mu\text{g}\cdot\text{kg}^{-1}\cdot\text{j}^{-1}) = \frac{F (\mu\text{g}\cdot\text{cm}^{-2}\cdot\text{h}^{-1}) \times D (\text{h}\cdot\text{j}^{-1}) \times S (\text{cm}^2)}{Pc (\text{kg})}$$

Dose interne ($\mu\text{g}/\text{kg}_{PC}/\text{j}$)

Minimum	0,01
P5	0,05
P25	0,11
P50	0,20
P75	0,29
P90	0,38
P95	0,43
Maximum	0,71
Moyenne	0,21



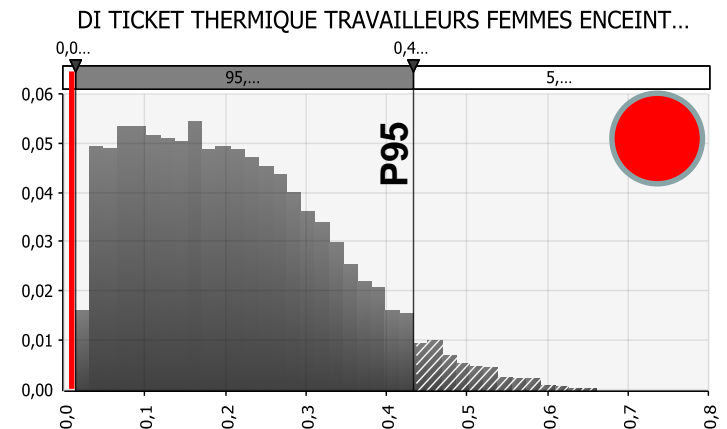
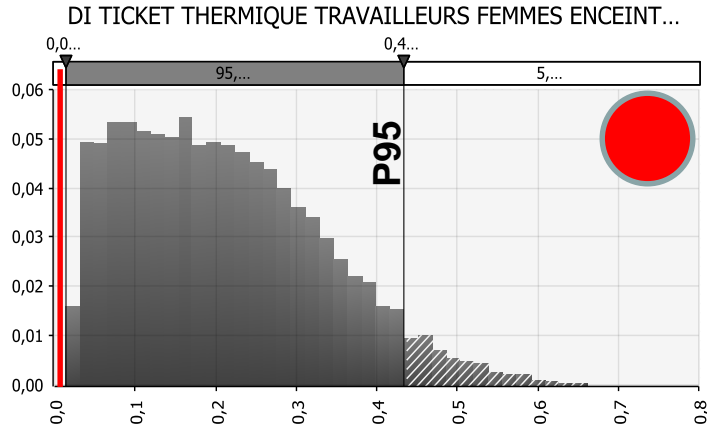
Brain and development

$RT_{\text{final}} = 0,005$
 $\mu\text{g}/\text{kg}/\text{j}$



Female reprotoxicity

$RT_{\text{final}} = 0,01$
 $\mu\text{g}/\text{kg}/\text{j}$

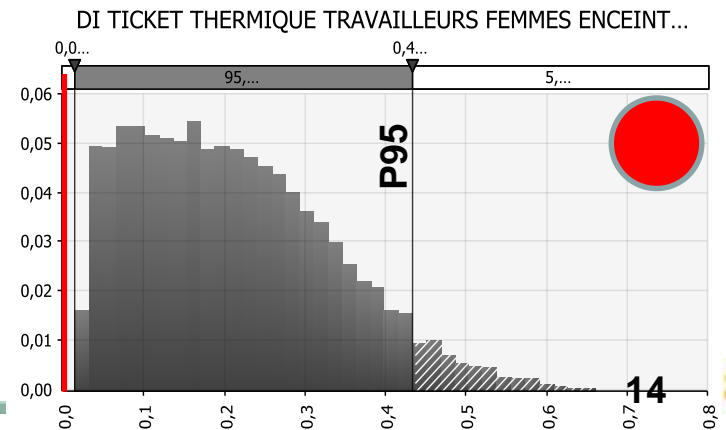
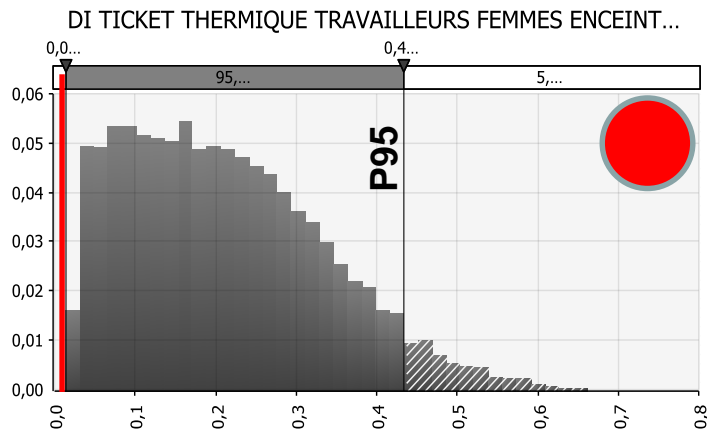


Metabolism and obesity





$RT_{\text{final}} = 0,009$
 $\mu\text{g}/\text{kg}/\text{j}$

Mammary Gland

$RT_{\text{final}} = 0,0025$
 $\mu\text{g}/\text{kg}/\text{j}$



Assessment of health risks: Anses

Exposed population: Pregnant women Target population: offspring	Critical effects			
	Brain and behaviour 	Female reproductive system 	Metabolism and obesity 	Mammary gland 
Occupational cashier/teller scenario (P95 = 0.43 µg/kg/d)	Existence of risk exposure situations RCR = 43	Existence of risk exposure situations RCR = 21.5	Existence of risk exposure situations RCR = 24.85	Existence of risk exposure situations RCR = 86
Consumer scenario (P95 = 0.08 µg/kg/d)	Existence of risk exposure situations RCR = 16	Existence of risk exposure situations RCR = 8	Existence of risk exposure situations RCR = 8.89	Existence of risk exposure situations RCR = 32



Assessment of health risks: RAC

Table 19 **Worker** exposure assessment with different exposure determinants using the absorption flow model and deterministic modelling (DNEL= 0.2 µg/kg bw/d)

	Absorption flow (µg/cm ² /h)	Duration of exposure (h)	Surface area (cm ²)	BW (kg)	Total BPA dose dermally absorbed (µg/kg bw/d)	RCR
Median (realistic) case	0.09	10	12	70	0.154	0.77
Reasonable worst case	0.258	10	12	70	0.442	2.21
	0.09	24	12	70	0.370	1.85
	0.09	10	111	70	1.427	7.14*

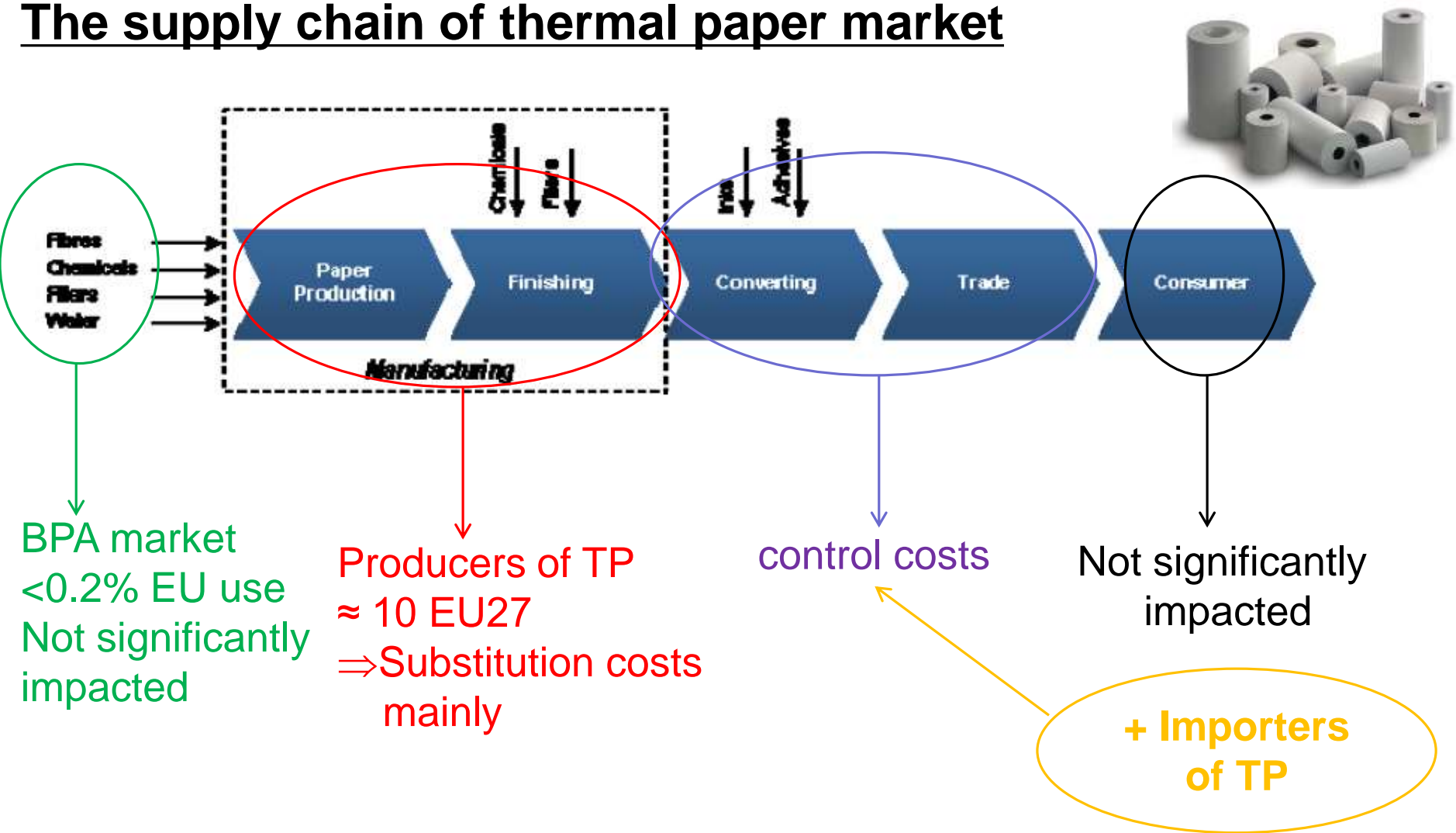
* The scenario using a surface area of 111 cm² might also be considered to be a worst case exposure scenario.

And for consumer RCR < 1

B. Socio-Economic Analysis

SEA – Impacts and proportionality

The supply chain of thermal paper market



SEA – Costs assessment

- Cost-Benefit approach (chemical substitution only)
- Data collected from publicly available sources + consultations
- Costs assessment based on:
 - Substitution costs (direct costs)
(manufacturers of thermal paper mainly impacted)
 - Compliance control costs (no standard method)
(manufacturers+importers/retailers expected to be impacted)
- **Uncertainties** (prices of alternatives, amount to be replaced, annual growth of thermal paper market, etc.)
- Sensitivity analysis on several parameters



Overall, the annual costs of the restriction proposed for the thermal market (substitution and compliance control costs) are estimated to range from around €0.6 million (low range) to around 274.2m (high range, probably overestimated)) with a more realistic average between €1.1 million and €39.2 million over 2019-2030.

SEA – Benefits assessment

- Review of economic literature + computation of excess risks
- Benefits assessment based on:
 - A Semi-quantitative assessment



Health adverse Effect	Quantified/valued
Mammary gland	√ (breast cancer)
Metabolism and obesity	√ (cholesterol + body weight)
Female reproductive system	√ (endometriosis only)
Brain and behaviour	-


- Direct costs (medical costs) + Indirect costs (loss of productivity, ...)
- Uncertainties (number of women at risk, excess risks, attributability to BPA, etc.)
- Sensitivity analysis on several parameters

Overall, the total health benefits expected from the proposed restriction are estimated to range from at least €1,809,489 to €12,600,332 per year over 2019-2030.

Overview assessment – focus on proportionality

Costs	Benefits
<p>BPA market ≈ 0</p>	<p>Cholesterol [€8,424; €94,195] + [€35,147; €393,002]</p>
<p>Manufacturers of TP Substitution costs =€0.5 million-€274 million/year 2019-2030 with probable more realistic average between €1 million and €39 million</p>	<p>Breast cancer [€288,413; €2,403,440] + [€1,693,096; €14,109,132] (TEB) [€260,044; €2,167,036] + [€1,520,917; €12,674,305] TD) [€26,004; €216,704] + [€143,483; €1,195,689] (HD)</p>
<p>Convertors of TP + Traders/retailers Compliance control costs =€1.7 million -€3 million 2019-2030 (or €146,255-€254,472/year)</p>	<p>Body weight [€401,751 + €1,695,058]</p>
<p>Importers Compliance control costs (not assessed)</p>	<p>Endometriosis [€107,677 + €399,377]</p>
<p>Consumers/End users of TP No significant costs expected</p>	<p>+ other health benefits not quantified (brain and behaviour, etc.)</p>
<p>+ other economic costs not quantified</p>	<p>+ other economic benefits not quantified</p>
<p>TOTAL = realistic average €1.1 million-€39.2 million/year 2019-2030 (between €0.6 m-€274.2m probably overestimated)</p>	<p>TOTAL > €1.8 million to €12.6 million per year over 2019-2030 (probably underestimated)</p>

Analysis of Alternatives

- Extensive review of literature + publicly available data + data got from consultation/surveys
- Selection of 10 alternative dye developers 
- Analysis of technical alternatives



Technical Alternatives	
Alternative printing technics	matrix printing
	inkjet printing
	thermal transfer printing
Free-paper technics	E-ticket, mobile payment

Alternative chemicals	CAS number
BPS	80-09-1
BPF	620-92-8
BPAP	1571-75-1
1,2-diphénoxyéthane	104-66-5
D8	95235-30-6
D90	191680-83-8
DD70	93589-69-6
TGSA	41481-66-7
UU	321860-75-7
Pergafast (DP 201)	232938-43-1

Analysis of Alternatives

Conclusion:

- Alternatives exist
- Alternative chemicals are already used (substitution is underway)
- Some are technically and to some extent economically feasible
- BUT:
Most of them are surrounded with significant uncertainties as regards their feasibility and/or their hazards profile (e.g. BPS...) => might affect the human health impact assessment!
- The technical alternatives not considered as the most suitable



Thank you for your attention!
Christophe.rouselle@anses.fr



Connaissances relatives à la réglementation, à l'identification, aux propriétés chimiques, à la production et aux usages des composés de la famille des Phtalates (Tome 1)

Note d'accompagnement
Rapport d'étude

Mars 2018 — Adressé à la DGS



Connaissances relatives aux données de contamination et aux expositions par des composés de la famille des Perfluorés (tome 2)

Note d'accompagnement
Rapport d'étude

Mars 2018 — Adressé à la DGS



Évaluation des risques sanitaires des substances reprotoxiques et/ou perturbatrices endocriniennes dans les produits de consommation : le cis-CTAC

(n° CAS 51229-78-8)

Avic de l'Anses
Rapport d'étape collective

Mars 2018 — Adressé à la DGS



Évaluation des risques du bisphéno! A (BPA) pour la santé humaine

Tome 1

Avic de l'Anses
Rapport d'étape collective

Mars 2018 — Adressé à la DGS

