



CHEMTrust

Protecting humans and wildlife
from harmful chemicals

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chemtrust.org



内分泌かく乱物質に関するEUの規制の変遷 —ならびに最新の展開

The EU regulatory saga on Endocrine Disruptors
- and latest developments

ピア・ジュール・ニールセン
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JEPA
2020年12月9日
JEPA

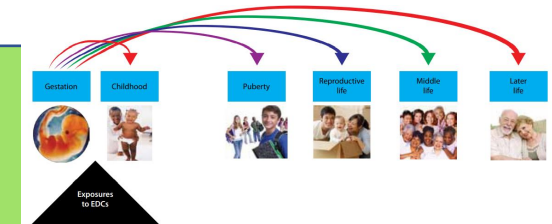
JEPA 2020年12月9日
JEPA 9 December 2020

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内容

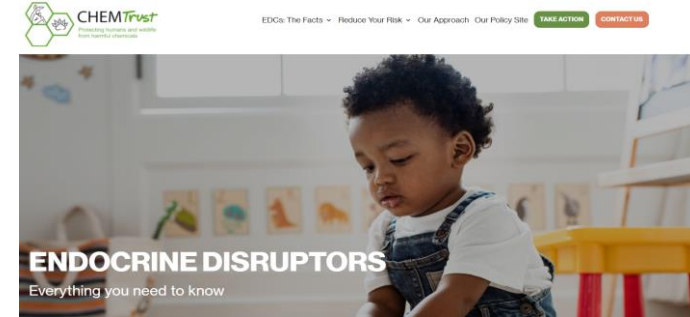
Contents

- EDCについての全体的な懸念
- Overall concerns about EDCs
- EDC（内分泌かく乱化学物質）に取り組むためにこれまでEUが取ってきた措置
- The steps EU has taken to address EDCs until now
- CHEM Trustの主要な要望と推奨事項
- CHEM Trust's main demands and recommendations
- 新しい「EUの持続可能性のための化学物質戦略」
－EDCに関して今後期待すべきこと
- The new EU Chemicals Strategy for Sustainability
－ what to expect in the future regarding EDCs
- EDCに関する日本のアクションをどのようにして求めるか
- How to push for Japanese action on EDCs



CHEM Trustとは？

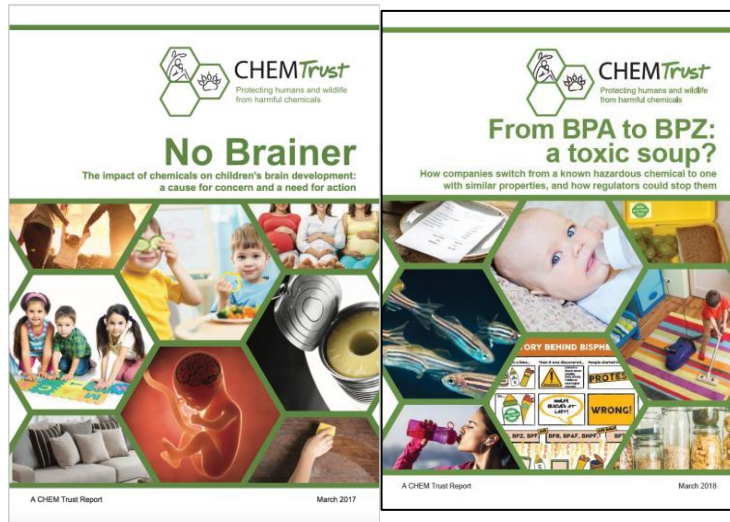
Who is CHEM Trust ?



<https://chemtrust.org>

CHEM Trustは、英国の慈善団体CHEM TrustとドイツのCHEM Trust Europeの共同NGOである
CHEM Trust is an NGO – a collaboration between UK charity CHEM Trust and CHEM Trust Europe in Germany

CHEM Trustの包括的目標：野生生物またはヒトに対して長期にわたって損傷を与える人工化学物質をより安全な代替品と置き換えることによって、そのような害を防ぐことである。
CHEM Trust's overarching aim: to prevent man-made chemicals from causing long term damage to wildlife or humans, by ensuring that chemicals which cause such harm are substituted with safer alternatives.



CHEM Trustは、左記のメンバーである
CHEM Trust is member of:

内分泌かく乱物質に関する様々なEU専門家グループ
Various EU expert groups on endocrine disruptors

内分泌かく乱物質の試験・評価に関するOECD専門家グループ (EDTA AG)
OECD expert group on testing/assessment of endocrine disruptors (EDTA AG)

- **ED（内分泌かく乱物質）基準論議に最初から参加**
 - Involved in ED criteria debate since the beginning
- **2020年：CHEM Trust方針文書：EUのED規制の新たな道筋**
 - 2020: CHEM Trust policy paper: A new path for EU control of EDs

<http://www.chemtrust.org.uk/tag/endocrine-disruptors>

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CHEM Trustは、NGO連合のメンバーである

CHEM Trust is member of the NGO-coalition

- ヨーロッパでは70以上のNGO団体が連携してEDCの使用の段階的廃止に取り組んでいる
- Coalition of more than 70 NGO's in Europe working of phasing out the use of EDCs
- 2018年：EDC-Free Europeは、EUのED戦略のための8つの要求を提起
- 2018: EDC-Free Europe set up 8 demands for an EU ED strategy
- 2020年：EDC-Free Europeによる、EDCに関するヨーロッパの規制の枠組みの改正のための主要提言を含む方針書
- 2020: EDC-Free Europe position paper with key recommendations for a reformed European regulatory framework on EDCs



<https://www.edc-free-europe.org/articles/position-papers/eight-demands-edc-strategy>

<https://www.edc-free-europe.org/articles/position-papers/edc-free-europe-demands-for-a-protective-european-framework-on-endocrine-disrupting-chemicals>

EDC-Free coalition members



EDCについての全体的な懸念ーどのように始まったか

Overall concerns about EDCs – how did it start

90年代初期 :

Early 90's:

野生動物に生殖障害
Sex disturbances in wild
animals

男児の生殖器の形成異常
Malformation of boys'
genitals

ー仮説：エストロゲン様化学
物質への胎児曝露にが原因
(エストロゲン仮説)
– hypothesis: caused by fetal exposure
to estrogenic chemicals (estrogen
hypothesis)



国家主導事業
National initiatives

内分泌かく乱化学物質の科学の現状に
関する2つの国際的報告書が公開された
(2002年と2012年)

Two international reports published on the **state of the
science** of Endocrine Disrupting Chemicals
(2002 and 2012)

An **endocrine disruptor** is an exogenous substance or mixture
that alters function(s) of the endocrine system and conse-
quently causes adverse health effects in an intact organism, or
its progeny, or (sub)populations.

A **potential endocrine disruptor** is an exogenous substance or
mixture that possesses properties that might be expected to lead
to endocrine disruption in an intact organism, or its progeny,
or (sub)populations.

WHO/IPCS定義2002

WHO/IPCS definition 2002

EDに関する広範
囲におよぶ研究
Extensive
research on EDs

試験方法の開発
Development of
test methods



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[WHO | 内分泌かく乱化学物質の科学の現状ー2012年](#)

[WHO | State of the science of endocrine disrupting chemicals – 2012](#)

ー内分泌系の機能

- function of the endocrine system

ホルモン系が調節するもの： The hormonal system regulates:

- 成長と発達
- growth and development
- 代謝とエネルギーバランス
- metabolism and energy balance
- 食欲
- appetite
- 血糖バランス
- blood sugar balance
- 性機能と性的欲求
- sex function and sex drive
- 生殖
- reproduction
- 気分
- mood
- 睡眠
- sleep
- ストレス反応
- stress reaction

フィードバック機構を介して働く Works via feed-back mechanisms

多くの器官・機能は、適所、適時、および適量のホルモンに依存している
Many organs/functions are dependant of hormones at the **right place**, at the **right time**, and in the **right amount**

適正なホルモンが私たちの健康を維持する Hormone precision keeps us healthy

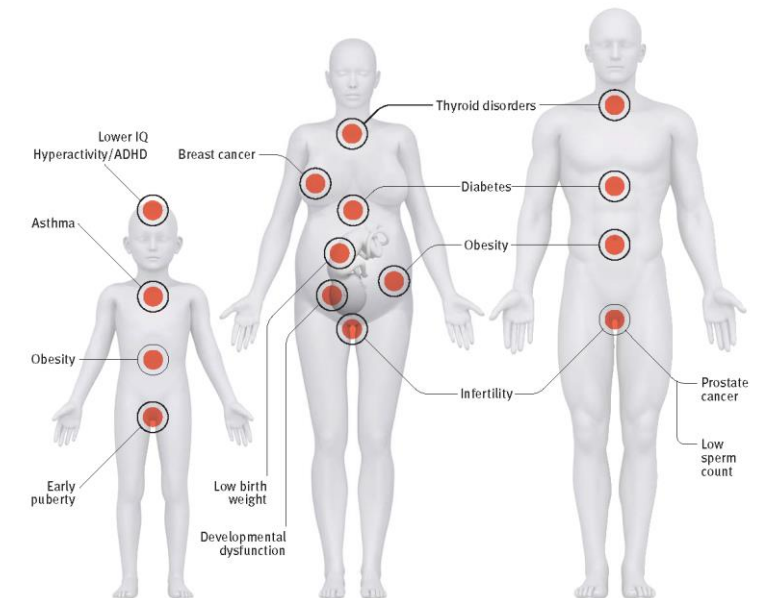
EDCが問題を生じる得る原因： EDCs can create problems by:

- 自然ホルモンの生成を妨害
- **Disturbing** natural hormone **production**
- 自然ホルモンを擬態
- **Mimicking** natural hormones
- 自然ホルモンを阻止
- **Blocking** natural hormones
- ホルモンの輸送および自然ホルモンの劣化への影響
- **Affecting** hormone **transport** and natural hormone **degradation**

Endocrine
Disrupting
Chemicals

Low Doses Matter

Everyday exposures to EDCs contribute to modern health epidemics.



How are people exposed?

Children's toys (phthalates)	Fragrances (phthalates)
Plastic drinking bottles (BPA, BPS, BPF)	Food (pesticides like chlorpyrifos)
Cleaning products (phthalates, triclosan)	Food packaging (BPA, PFAS, phthalates)
House dust (flame retardants, pesticides)	Thermal cash register receipts (BPA, BPS)
Home furniture/electronics (flame retardants, PFAS)	Drinking water (arsenic, lead, perchlorate)
Building materials (flame retardants, phthalates, PFAS)	Personal care products (parabens, phthalates, triclosan)

—EDCの特異性

- what is special for EDCs

- EDCは大部分の他の化学物質と異なる
- EDCs different from most other chemicals

- 低用量影響

- low dose effects

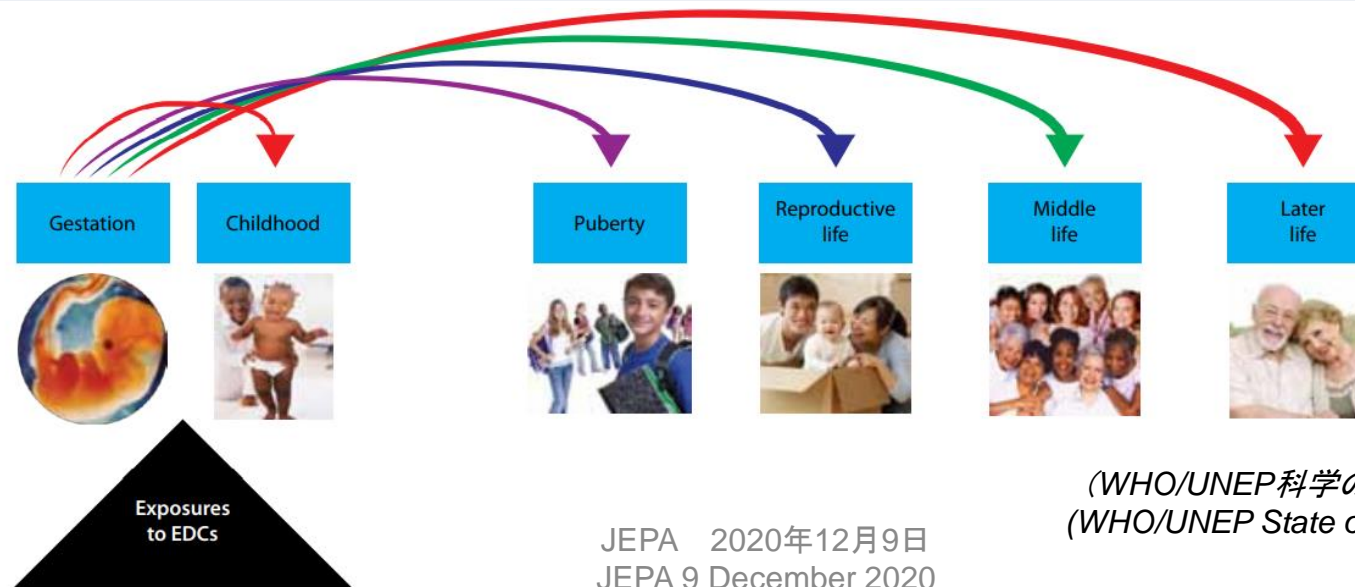
- 一定時間のホルモンのアンバランスが重要であり、用量は必ずしも重要でない

- hormonal imbalance at a certain time important, and not necessarily the dose

- 感受性の高い時機の曝露は、高齢期または次世代における不可逆的影響につながる

- exposure during sensitive windows leading to irreversible effects later in life
or in the next generation(s)

例：
フタル酸塩
ビスフェノール
パラベン
PFAS
難燃剤
殺虫剤
農薬
e.g.
Phthalates
Bisphenols
Parabens
PFAS
Flame retardants
Pesticides
Biocides



(WHO/UNEP 科学の現状報告、Bergman ら、2012 年)
(WHO/UNEP State of the Science report, Bergman et al. 2012)

- なぜ懸念すべきなのか？

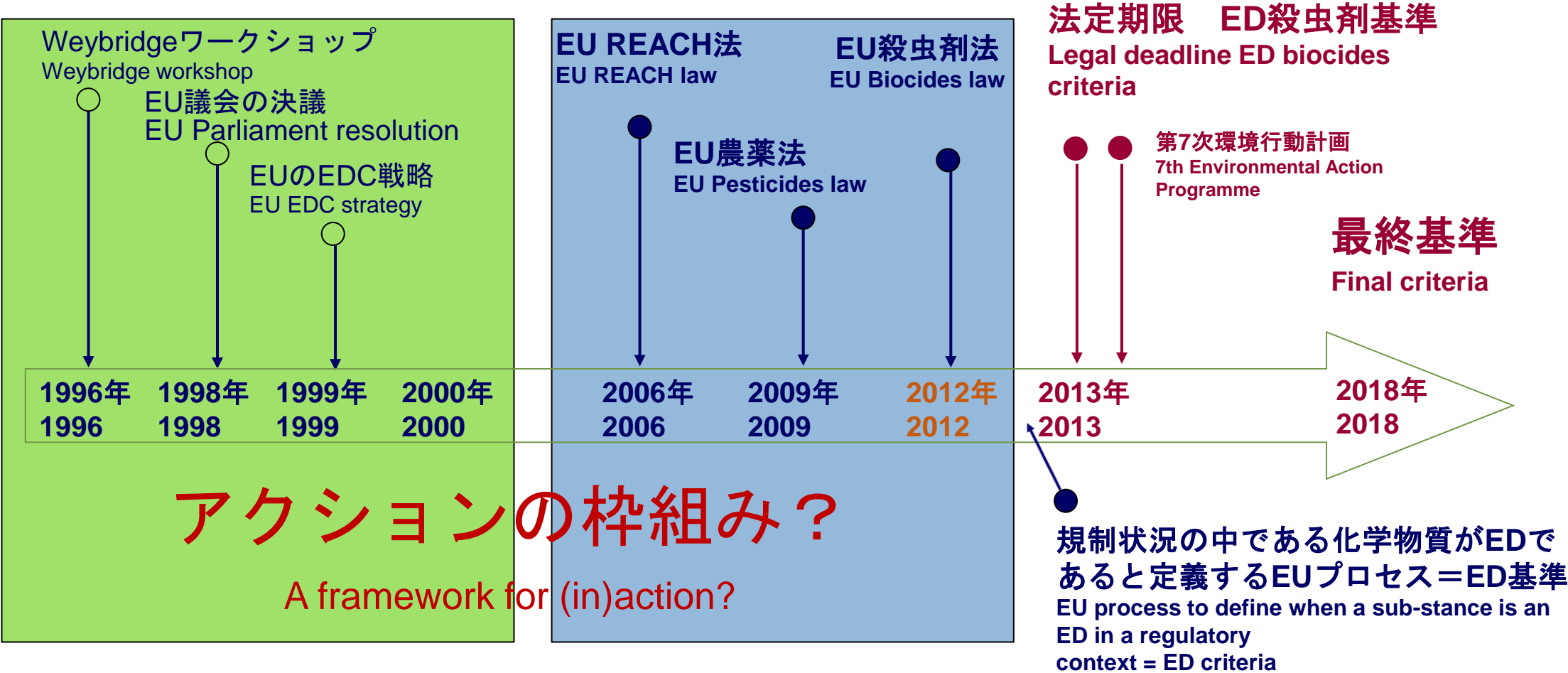
- why should we be concerned?

- 野生生物において深刻かつ不可逆的な生殖影響が見られる
- Serious and irreversible reproductive effects seen in wildlife.
- 世界中でホルモン病の発生が増加
- Increase in the incidence of hormonal diseases globally
 - 因果関係を証明するのは難しいが、
 - difficult to prove causality, but
 - 環境要因に関係しているにちがいない、
 - must be related to environmental factors, and
 - EDCに曝露した実験動物で同じ影響が見られる
 - same effects seen in experimental animals exposed to EDCs.
- 私たちは誰もが、様々な発生源から多くのEDCに日々曝されている
— 最新の研究によると、EDCで汚染された赤ん坊が生まれている。
- We are all daily exposed to multiple EDCs from many different sources – latest research shows that babies are born polluted with EDCs.
- 次世代に及ぼし得る不可逆的影響
- Irreversible effects that may affect the next generation(s).



EDC問題に対するEUの対応

EU response to EDC concern



EDC基準の策定ー複数幕のドラマ

EDC criteria development - a drama in several acts

科学的報告 (EU、WHO)
Scientific reports
(EU, WHO)



論戦
Editorial battles



市民の動員
Public mobilisation



2012年 2013年 2014年 2015年 2016年 2017年 2020年



EU影響評価
EU impact
assessment



EU裁判所：
EU COM法律違反
EU Court of Justice:
EU COM breached the law



EU COMがED殺虫剤・
農薬の基準を公表
EU COM published criteria
for ED biocides/pesticides



EU COMが持続可能
性のための化学物質
戦略を公表
EU COM published Chemicals
Strategy for Sustainability

EUのED取組み状況

Status of the EU ED work



- EUは、世界で初めて**ED戦略**およびEDCに対する**法的拘束力のある基準**を導入した地域である
- EU was the **first** region in the world to introduce an **ED strategy** and **legally binding criteria** for EDCs.
- これは偉大な業績であるが、EDCから健康および生態系を**適切に保護するにはまだ長い道のりがある**
- This is a great achievement but there is **still a long way to go before we achieve adequate protection** of health and ecosystems against EDCs.
- 化学物質の内分泌かく乱特性に関するデータはまだかなり不足している
- There is still a **huge lack of data** on the endocrine disrupting properties of chemicals.
- これまで、EDCを規制する**アプローチは小刻みに行われてきた**
- So far, a **piecemeal approach** to controlling EDCs.

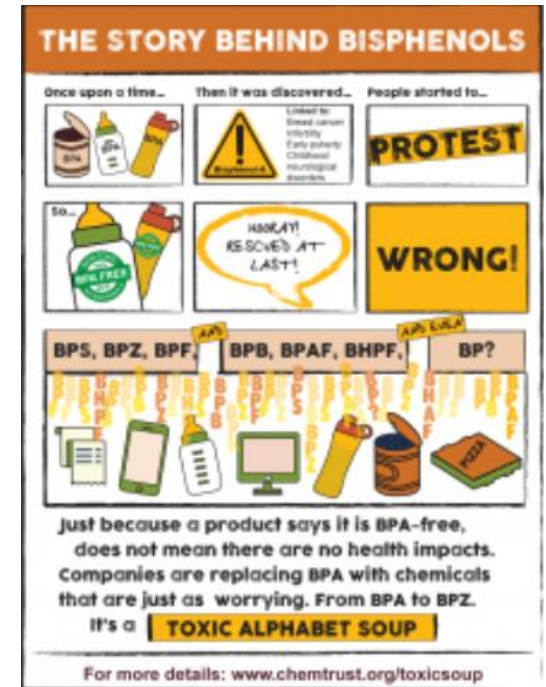
首尾一貫したED規制の必要性

Need for coherent ED regulation

残念な代替

Regrettable
substitution

- BPA（ビスフェノールA）：生殖毒性および内分泌かく乱物質
- BPA: reprotoxic & endocrine disruptor
- 感熱紙へのBPAの禁止、2020年1月
- Ban of BPA in thermal paper, Jan. 2020
- 「有毒スープ報告」2018年—他の類似ビスフェノールへの代替許可
- “Toxic soup report” 2018 - substitution with other similar bisphenols allowed
- 2年後：他のビスフェノールの使用増加＋ヒトの摂取量の増加
- 2 years after: increase in use of other bisphenols + increasing human levels
- BPS（ビスフェノールS）：新しい研究でEDの特性を確認（BPAF、BPBもEDである）
- BPS: new studies confirm ED properties (BPAF, BPB also ED)



https://chemtrust.org/bisphenol_group/

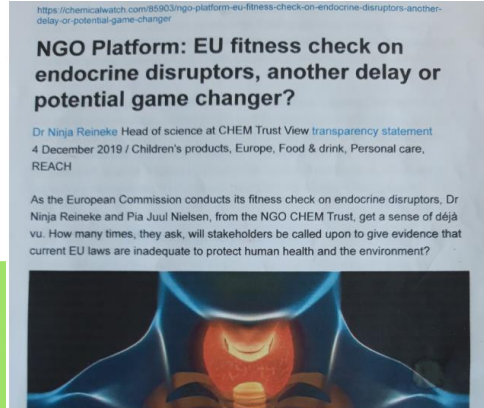
これからの方法....

The way forward....

EDCへの曝露を最小限にするために確実にすること Minimize exposure to EDCs by ensuring

- **EDCの段階的廃止に焦点をあて、すべてのEUの関連立法において保護規定を組み入れる**
- Inclusion of **protective rules** in all relevant EU legislation with **focus on phase out of EDCs**
- **EDCの迅速な同定**
- **Swift identification** of EDCs
 - 広範な情報・データ要求事項
 - extended information/data requirements
 - **移行期間**
 - a transition period
- **2つのカテゴリーにおける同定：EDおよび疑わしいED**
- Identification in two categories: **EDs and Suspected EDs**
- **透明性の向上—EDおよび疑わしいEDのリストの公開**
- More **transparency** - publication of lists of EDs and Suspected EDs
- **消費者製品におけるEDCの禁止**
- **Ban of EDCs in consumer products**

<https://chemtrust.org/eu-fitness-check-on-edcs/>



これからの方法....

The way forward....

A new approach to protect people and wildlife from endocrine disruptors

July 15, 2020 By Anna Watson

Policy paper
July 2020

A new path for EU control of Endocrine Disruptors

1 Executive Summary

The harmful impact that Endocrine Disruptors (EDs) have on health and environment has been known for more than 20 years. Despite the adoption of a Community Strategy for Endocrine Disruptors in 1999¹ and the 7th Environment Action Programme² (7th EAP) in 2013 envisaging protective measures, very little progress has been made to protect European citizens and the environment from exposure to EDs.

Instead of adopting immediate measures to minimize exposures to EDs, the outgoing European Commission in 2019 started yet another review of the chemicals legislation as regards EDs – a 'fitness check'. CHEM Trust provided an analysis of the existing gaps as part of the ED Fitness Check consultation³ and submitted some first ideas for a way forward on ED regulation in our comments to the CARACAL ED subgroup work⁴.

Over the years CHEM Trust and the NGO coalition EDC-Free Europe have continuously called for preventive measures to protect against EDs. In this policy briefing, CHEM Trust maintains the call by proposing a new path for EU control of EDs focused on a horizontal approach for identification across regulatory sectors and strict control of these substances to protect citizens and the environment, and to facilitate innovation and ensure predictability for commercial operators.

The proposal includes the following elements:

- **New overarching ED legislation*** for a **horizontal approach** on EDs across sectors
- **'One' ED identification** system including a **new category for Suspected EDs**
- **Improved identification** of EDs through **extended information/data requirements and screening**
- **Changes to existing legislation** to ensure **strict controls for sensitive uses** of EDs
- **A transition period** with specific measures to ensure **immediate protection** from EDs
- **Full transparency** of ED assessments to **facilitate substitution and informed choices**

This proposal should lead to:

- **Rapid and improved identification** of substances with ED properties
- **Strict control** of substances with ED properties to avoid/**minimize exposure**
- **Full transparency** and easily accessible public information on EDs

* or clear political mandate ensuring equivalent control of EDs

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:51999DC0706&from=EN>

² <https://ec.europa.eu/environment/action-programme/>

³ <https://chemtrust.org/wp-content/uploads/CHEM-Trust-Submission-ED-Fitness-Check-Jan-2020.pdf>

⁴ <https://chemtrust.org/wp-content/uploads/First-CHEM-Trust-submission-to-CARACAL-ED-subgroup-work.pdf>

[EUの内分泌かく乱物質規制の新たな道筋 \(chemtrust.org\)](https://chemtrust.org/)
[A new path for EU regulation of Endocrine Disruptors \(chemtrust.org\)](https://chemtrust.org/)



EUの持続可能性内分泌かく乱物質のための 化学物質戦略

14.10.20

EU Chemicals Strategy for Sustainability Endocrine Disruptors 14.10.20

機運は今
Momentum now

内分泌
かく乱物質
Endocrine Disruptors

EDの法的拘束力のある危険性の同定を確立し、すべての立法に適用する

Establish legally binding hazard identification of EDs and apply it across all legislation

消費者製品におけるEDの禁止

Ban of EDs in consumer products

EDCからの労働者の保護を強化する

Strengthen worker's protection against EDCs

関係当局が十分かつ適切な情報を利用できるように徹底する

Ensure sufficient and appropriate information is available for authorities

EDCに関する情報を生成するための方法の開発および取込みを加速させる

Accelerate the development and uptake of methods to generate information on EDCs



[Chemicals strategy \(europa.eu\)](https://european-council.europa.eu/media/en/press-room/image/asset-detail/Chemicals-strategy-for-sustainability)

すべてのコミットメントの実現

To make all commitments a reality

課題

Challenges

疑わしいEDの同定は不可欠
即座の保護策無し

Crucial to identify Suspected EDs
No immediate protection

EDCに関する日本のアクションを どのようにして求めるか

How to push for Japanese action on EDCs

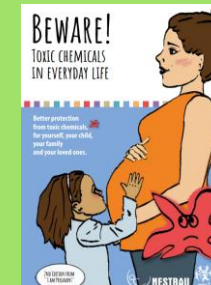


- EDCに取り組んでいる日本の科学者と連携
- Engage with Japanese **scientists** working on EDCs.

- 関係当局にEDCに対する保護措置を求める
- Demand protective actions towards EDCs from **authorities**.

- 産業・企業に対して、消費者製品における有害物質の使用を代替品に変更することを推進する—公的圧力が効果的であり、ゲームチェンジャーになり得る
- Push on **industry/companies** to substitute hazardous substances from consumer products - public pressure can be powerful and a game changer.

- 市民社会団体が国民意識を高めるキャンペーンを行うことができる
- Civil society organisations can run **public awareness campaigns**.



[EDC-FREE Europe \(edc-free-europe.org\)](http://edc-free-europe.org/)
www.wecf.org



目標は、私たちの生態系と、
現世代および将来世代を守ること

Aim is to protect our ecosystems and current and future
generations

結論

Conclusion

今が行動すべきとき！

High time to act now!

国民意識が重要

Public awareness important

- 公的行動が必要

- public action needed

- 代替の推進

- push for substitution

- 規制の推進

- push for regulation

<https://chemtrust.org/>