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# Effect thresholds and "adequate control" of risks: the fatal flaws in the Council position on Authorisation within REACH

# FATAL FLAWS

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# executive summary

Preparation of the REACH (Registration, Evaluation and Authorisation of CHemicals) regulation on chemicals has reached a critical stage in Europe. Depending on how key elements of the legislative proposal are finalised, especially that on the authorisation of uses of so-called 'substances of very high concern', REACH could either provide an effective measure to phase-out such chemicals by driving innovation towards cleaner and safer alternatives, or instead condemn the EU to decades more of inefficient and ineffective analysis and risk assessment while avoidable chemical exposures are allowed to continue. Given that some key indicators of the health of the reproductive system currently continue to decline in humans and wildlife in many parts of Europe, while incidences of many cancers continue to increase and evidence grows that exposure to man-made chemicals is at least partly to blame, it will clearly be vital to get the legislation right.

Whereas there is a consensus that uses of PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) substances should only be permitted when no safer alternatives are available, major differences remain between the European Parliament and Council of the European Union regarding the manner in which other 'substances of very high concern' (including substances which are carcinogenic, mutagenic or toxic to reproduction (CMRs) and endocrine disruptors) are addressed.

Using specific chemical examples, this paper examines those differences in more detail, critically evaluating the concepts of 'effect thresholds' (exposure levels below which adverse effects to human health or the environment are predicted not to occur) and 'adequate control' of risks, which underpin the Council's proposal for many CMRs and endocrine disruptors (chemicals which are capable of interfering at a fundamental level with the body's chemical signalling and development mechanisms).

In conclusion, the subjectivity and uncertainties inherent in the threshold approach proposed by the Council bring its ability to ensure a high level of protection for the environment and human health firmly into question;

* We may simply be looking for the wrong thing in the wrong place. Tests showing no observed effects for certain toxicological endpoints cannot be interpreted as demonstrating the absence of all adverse effects. The nature and extent of toxic effects recorded depend fundamentally on many different factors, including the type of test and conditions selected, the organisms exposed, the timing of exposure and precisely which effects are measured and over what timeframe.
* Toxicology has evolved and the detection of adverse impacts of chemicals at lower and lower doses has been a consistent trend. Levels previously thought safe have again and again been proven otherwise. Doses considerably below the so-called 'no effect level' for survival could nevertheless be causing significant impairment to health and/or reproductive success.
* Chemicals present in mixtures at levels below established thresholds for effects may, in combination, induce significant toxicological responses.

Despite this, under the Council's proposal, companies will be granted authorisations for some uses of chemicals which are carcinogenic, mutagenic, toxic to reproduction or endocrine disruptors, even if safer alternatives without these properties are already on the market. The consistency of the Council's proposal with the precautionary principle is therefore doubtful. The high level of evidence required for identification of e.g. endocrine disruptors as substances of equivalent concern, along with the fact that authorisations will be subject only to a flexible time-limited review period rather than a fixed lifetime, represent additional weaknesses in the Council approach.

Instead, a requirement (along the lines of the Parliament's proposals) to address the availability of alternatives in all cases, to use them when available and to initiate their development when not, represents a more robust, defensible and protective approach to the management of 'substances of very high concern'. Limited resources would be better targeted towards substitution than on costly and unnecessary assessment of thresholds. The possibility for authorisation of essential uses would remain, while all avoidable uses and exposures would progressively be prevented and sustainable innovation supported. In the long run, this can only lead to a more sustainable future for the chemical industry in Europe, as well as delivering benefits of increased protection for our environment and health for generations to come.

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# introduction

The European Commission's White Paper on a strategy for a future chemicals policy[1], born out of widespread recognition of the failure of existing legislation and published in February 2001, promised a groundbreaking new approach to the evaluation and control of hazardous chemicals:

***"We have decided on a step-by-step approach to phase out and substitute the most dangerous substances - the ones that cause cancer, accumulate in our bodies and in our environment and affect our ability to reproduce. This decision is crucial for future generations"[2]***

By the time of their publication in October 2003, the European Commission's formal REACH proposals[3] were already far less ambitious. Nevertheless, some of the foundations of a new system of chemicals management were emplaced, foundations which, if properly developed and implemented, could begin to provide the high level of protection for human health and the environment enshrined in the Treaty.

Aside from requirements for registration of chemicals and accompanying submission of basic data on properties and hazards (which have been drastically reduced), the key components of REACH designed to address and, as far as possible, prevent exposure to the 'most dangerous substances' are the Titles on Authorisation and Restrictions. Of these, Authorisation (the requirement that uses of so-called 'substances of very high concern' be permitted only if positively authorised) represents a substantially new approach to chemical regulation, intended to complement, rather than replace, the more traditional restrictions approach[4]. If applied rigorously, such that only those continued uses which are clearly justified and unavoidable receive authorisations, then this element of the legislation could contribute greatly to reducing and ultimately eliminating exposure to some of the most hazardous chemicals in commerce, ensuring they are replaced instead with safer alternative substances or technologies. In turn, this would encourage and drive forward innovation towards a more sustainable chemical industry for Europe, committed to providing less hazardous, and preferably non-hazardous, products to downstream users and retailers and, ultimately, to the public at large.

A number of recent declarations by scientists and doctors illustrate the urgency for action on the most problematic chemicals, highlighting deeply worrying trends in reproductive disorders and cancers in wildlife and humans across many parts of Europe, as well as the gathering evidence that exposures to carcinogens, chemicals toxic to reproduction and those with endocrine (hormone) disrupting properties are contributing to these trends. For example, the Paris Appeal issued in 7 May 2004 by a diverse group of nobel prized scientists, medical practitioners and jurists, among others, notes that:

***"infertility, and particularly male infertility - whether it be consecutive or not to congenital malformations or due to decline in sperm quality and/or sperm counts - is on the rise, especially in highly industrialized areas...in some European countries, up to 15% of couples are now infertile, chemical pollution being one of the causes of infertility"***

...and that...

***"incidence in pediatric cancers has been on the rise for the last 20 years in some industrialized countries"[5]***

Similarly, the Prague Declaration on Endocrine Disruptors, signed by more than 120 leading research scientists from across Europe in June 2005 notes that:

***"There is serious concern about the prevalence of reproductive disorders in European boys and young men and about the rise in cancers of reproductive organs, such as breast and testis."***

...and that...

***"Causality is well established for detrimental effects in wildlife as a direct consequence of exposure to endocrine disruptors. In some instances the severity of effects is likely to lead to population level impacts."***

...and finally stresses that, in addition to representing a protection target in its own right...

***"Wildlife provides early warnings of effects produced by endocrine disruptors which may as yet be unobserved in humans."[6]***

We therefore stand at a critical decision point not only for ourselves, but for the future of our environment and for the health and security of generations to come. For the EU to provide the high level of protection for human health and environment to which it aspires, it will be essential that the decisions made in finalizing REACH will render it capable of addressing and ultimately reversing these potentially devastating trends.

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# Parliament and Council positions on Authorisation

Following extensive discussions over the intervening two years, both the European Parliament[7] and the Council of the European Union[8] adopted their first formal positions on REACH in the latter part of 2005. There is now a clear agreement that the category 'substances of very high concern' (to be listed in Annex XIII in accordance with Article 54 of the REACH proposal) should include:

* substances which are classified as carcinogenic, mutagenic or toxic to reproduction category 1 or 2, in accordance with Directive 67/548 (so-called CMRs) (Article 54(a)-(c))
* substances which are persistent, bioaccumulative and toxic (so-called PBTs) (Article 54(d)) and
* substances which are very persistent and very bioaccumulative (so-called vPvBs) (Article 54(e)).

On the definition of the remaining group in this category, namely those substances which do not meet the criteria above but nevertheless give rise to equivalent concern (Article 54(f)), significant disagreement remains. The Council requires 'scientific evidence of probable serious effects to humans or the environment which give rise to an equivalent level of concern'[9] while the Parliament proposes the more generic and precautionary text 'giving rise to a similar level of concern'. This difference has serious implications for the regulation, for example, of endocrine (hormone) disrupting chemicals, and requires urgent resolution. This issue is addressed in detail elsewhere.[10]

Over and above this difference in proposed scope, however, lies a more fundamental disagreement between Parliament and Council regarding the purpose and mechanics of Authorisation, relating in particular to Article 57 of the REACH proposal and, more specifically, to the manner in which CMRs and substances of equivalent concern will be addressed.

The Parliament proposes that, for all 'substances of very high concern', including CMRs and substances of equivalent concern (Article 57):

**"2. An authorisation shall be granted *only* if:**

(a) suitable alternative substances or technologies do not exist, and measures are in place to minimise exposure, *and*

(b) it is demonstrated that the social and economic advantages outweigh the risks to human health or the environment which arise from the use of the substance, *and*

(c) the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIII(a) is adequately controlled in accordance with Annex I, section 6, and as documented in the applicant's chemical safety report."

In other words, for use of any such substances to be authorised, industry would need to provide a clear and sound justification in terms of benefits, measures in place to minimise exposure and ensure risks are adequately controlled and, most significantly, confirmation that no suitable alternatives are available. While allowing for authorisation of those uses which are essential, and establishing strict control conditions in such cases, this formulation provides a strong, objective and precautionary approach to ensure that exposures of humans or the environment to all 'substances of very high concern' are avoided wherever possible. By providing just one consistent route to authorisation, the approach is also clear and straightforward.

In contrast, the Council retains two possible routes to authorisation, either by demonstrating simply that the risks from the use are 'adequately controlled' (according to Article 57 paragraph 2 of the Council text) or, if this is not possible, then on the basis of socio-economic benefits and the absence of alternatives (Article 57 paragraph 3). An additional clause under paragraph 2bis of the Council text specifies that, for certain groups of 'substances of very high concern', the 'adequate control' route to authorisation cannot be applied:

**"2bis. Paragraph 2 [the 'adequate control' route to authorisation][11] *shall not apply to:***

(i) substances meeting the criteria in Article 54 (a), (b), (c) [CMRs] and (f) [substances of equivalent concern] for which it is not possible to determine a threshold in accordance with Annex I, section 6.4; (emphasis added)

(ii) substances meeting the criteria in Article 54 (d) [PBTs] and (e) [vPvBs]."

Therefore, although paragraph 2bis effectively excludes PBTs, vPvBs and so-called 'non-threshold' CMRs from receiving authorisation through the 'adequate control' route, it nevertheless leaves this option open for CMRs and substances of equivalent concern providing it is possible to determine a 'threshold' of exposure to these chemicals below which adverse effects to human health or the environment are not expected.

In effect, under the Council's proposal, companies will be granted authorisations for some uses of chemicals which are carcinogenic, mutagenic, toxic to reproduction or capable of interfering at a fundamental level with the body's chemical signalling and development mechanisms, even if safer alternatives without these properties are already on the market, as long as the resulting exposures of humans and the environment to these chemicals are predicted to fall below certain predetermined thresholds for toxic effects (so-called Derived No Effect Levels, DNELs, or Predicted No Effect Concentrations, PNECs). In those cases the risks will be deemed to be 'adequately controlled'.

While at first sight this may seem to offer an attractive, prudent and entirely objective science-based approach, the setting of thresholds such as DNELs and PNECs depends unavoidably on a number of critical, and frequently untestable, assumptions regarding environmental fates, exposure routes, mechanisms of toxicity and the most sensitive indicators of adverse effects of chemicals.

So what are these thresholds and how will they be determined? And just how protective will they be? In short, how wise is it to use the threshold concept to allow any continued and avoidable exposure to carcinogens, mutagens, endocrine disruptors or substances toxic to reproduction?

As shown by the examples in the following sections, far from being an objective guarantee of safe chemical exposures, such thresholds are highly theoretical, based on a limited understanding of the potential for toxic effects at low doses and, therefore, may provide little more than a false sense of security.

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# Effect thresholds:
## an objective and reliable measure of safety?

According to the Council text, the manner in which thresholds will be determined is set out in Annex I, section 6.4. In turn, this section refers to two further sections of the same Annex, namely section 1 (addressing human health risks and, therefore, DNELs) and section 3 (addressing environmental risks and, therefore, PNECs).

In both cases, according to the Council proposals, evaluation of any individual substance starts with an assessment of all available information on the hazards presented and their 'dose-response' relationships (i.e. how the effects change with the level of exposure in standard toxicity tests). Normally, it is stated, "the study or studies giving rise to the highest concern shall be used to establish the Derived No-Effect Levels"; similarly for PNECs. Quite apart from the fact that this might not always be the case (see below), determining which of the toxicological endpoints measured to date represents 'the highest concern' relating to a chemical can be a complex and subjective process. The nature and extent of toxic effects recorded, and the concentrations or doses at which they occur, depend fundamentally on many different factors, including the type of test and conditions selected, the organisms exposed, the timing of exposure and precisely which effects are measured and over what timeframe. Extrapolating to predict effects in other organisms, including humans, adds a further layer of guesswork.

Take the example of the plasticiser (plastic softening agent) DEHP (bis(2-ethylhexyl) phthalate), classified as 'Toxic to Reproduction, category 2', banned in toys and childcare articles since 2005 but still used in a wide range of other consumer goods. The section of the human health risk assessment addressing the manner in which DEHP was distributed and broken down in the body (so-called 'toxicokinetics') concluded as follows:

***"The relative extent to which different metabolites are produced and excreted is very complex and may depend upon the species, the age of the animal, sex, inter-individual differences, state of health, nutrition state, prior exposure to DEHP, the amount of DEHP administered, the administration route etc."***

***"The available data on the toxicokinetics of DEHP cannot explain the species differences in the DEHP-induced toxic effects, and are consistently not adequate to support any conclusion on the relevance or irrelevance for humans of the DEHP-induced toxic effects in experimental animals."***[12]

Even assuming that it was possible to arrive at a defensible threshold value for the effects of highest concern in an 'average' human, chemical sensitivity and exposure scenarios can vary greatly from one person to another. Indeed, Annex 1 of the Council text proposal recognises this added complexity, noting that:

***"...it may be necessary to identify different DNELs for each relevant human population (e.g., workers, consumers and humans liable to exposure indirectly via the environment) and possibly for certain vulnerable sub-populations (e.g. children, pregnant women) and for different routes of exposure."*** [Annex 1, paragraph 1.4.1]

From the very outset, these needs entail very high data requirements, which are costly and time-consuming, and verifiable assumptions if the DNEL thresholds calculated are to be anything other than default values or an 'educated guess'. The situation is similar, if not more complex still, with respect to thresholds for environmental effects.[13]

Furthermore, it may be that the effect which should really give rise to the highest concern, because of the nature of the effect and/or the low level of exposure at which it occurs, has simply yet to be discovered or confirmed. Because of the complex nature of the endocrine (hormone) system in wildlife and humans and the fact that it is controlled by very low doses of natural hormones circulating in the body, the toxicology of endocrine disruptors has proven particularly difficult to predict, describe and quantify. Nevertheless, given the range of developmental and metabolic processes which are controlled by hormones, the significance of exposure to chemicals able to interfere with their natural signalling mechanisms cannot be overstated. As signatories to the Prague Declaration note:

***"Hormone action is important in the origin or progression of [reproductive disorders and cancers of reproductive organs in humans]. Therefore it is plausible that exposure to endocrine disruptors may be involved, but there are inherent difficulties in establishing such causal links in humans."***

...and furthermore...

***"There is a serious gap of knowledge regarding the effects of endocrine disruptive compounds on other serious human diseases such as obesity, neuronal disorders, stress, etc."*** [14]

As the science of toxicology has evolved, the detection of adverse impacts of chemicals at lower and lower doses has been a consistent trend. As illustrated by the examples below, levels previously thought safe have again and again been proven otherwise.

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# Thresholds depend on what you look for, and how

Classically, toxicology has focused heavily on lethal effects on test animals of high doses administered over short periods of time. Indeed, such tests (acute toxicity tests to determine lethal dose) still form part of the base set of data required for chemical assessment. Invariably, however, sub-lethal effects (i.e. adverse effects other than death) of acute exposure, as well as both lethal and sub-lethal effects of longer-term (chronic) exposure, are found to occur at doses well below the so-called $LD_{50}$ (the dose found to be lethal to 50% of the animals exposed in any one test).

Taking once again the example of the plasticiser DEHP, whereas the $LD_{50}$ for rats and mice reportedly lies somewhere above the range 10 000 - 20 000 mg/kg body weight, gross structural damage to the male reproductive tract and complete cessation of sperm production has been reported for the same animals at doses of only 375 mg/kg body weight/day. Moreover, more detailed examination of cells involved in the production of sperm in early development (the Sertoli cells) indicates that these can be damaged at doses at least 10 times lower again (with a No Observed Adverse Effect Level at 3.7 mg/kg bw/day)[15] while other studies have detected similar effects even at levels 100 times lower, such that a 'no effect level' simply could not be determined.[16]

Similar trends can be seen with respect to other chemicals which, though still in common use, may be considered to present a high level of concern.

For example, the brominated flame retardant decabromodiphenyl ether (BDE-209 or 'deca'), still used in a wide range of polymers, textiles and electronics goods across Europe, has long been characterised as having low acute toxicity (high $LD_{50}$ value, in excess of 2 000 - 5 000 mg/kg body weight)[17]. Chronic exposures generate toxic effects (especially non-cancer effects) in laboratory animals at lower doses, including reduced red blood cell counts (800 mg/kg bw), resorption of developing foetuses (100 mg/kg bw) and impacts on the liver, kidney and thyroid gland (80 mg/kg bw)[18]. More recently, other studies have shown that 'deca' can cause seemingly irreversible impacts on brain and behavioural development in mice following a single dose as low as 20 mg/kg body weight[19], around 100 times lower than the lowest recorded lethal dose and far below levels which cause any other clinical signs of toxicity. What is more, the scale of the effects observed depends critically on the precise timing of exposure, with the most severe impacts resulting from a single dose delivered on the third day after birth during a sensitive period for brain development.

The apparent ability of 'deca' to degrade in the environment to form less brominated but more bioaccumulative (and possibly even more toxic) BDEs[20/21], is an added concern, and one which is extremely difficult to address within the DNEL or PNEC threshold concept.

The case of another widely used chemical, the synthetic polycyclic musk fragrance additive HHCB (1,2,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta-y-2-benzopyran, otherwise known by its trade name Galaxolide), highlights similar concerns. Although the EU risk assessment for this substance (and for another common polycyclic musk, AHTN or Tonalide) is not yet completed, separate assessments have been carried out under the industry led programme HERA (Human and Environmental Risk Assessment)[22]. This assessment notes, once again, that the acute toxicity of HHCB is very low ($LD_{50}$ >3 000 mg/kg body weight). However, a potentially greater concern relating to HHCB, and the polycyclic musks in general, is their endocrine disrupting activity.

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# Thresholds depend on what you look for, and how *continued*

The HERA assessment concluded that, whereas HHCB does show some oestrogenicity (ability to mimic natural female steroid hormones) in human breast cancer cell lines (in vitro), the effects occur only at relatively high doses[23]. Furthermore, although weak oestrogenicity can be detected in vitro, such activity could not be detected using a commonly applied in vivo test, the so-called uterotrophic assay (measuring increase in the weight of the uterus), in mice[24]. On first assessment, this could therefore be taken as an assurance that any endocrine disrupting activity of HHCB would always be well below thresholds for concern.

More recent work, however, suggests a rather different conclusion. Although the ability of HHCB to mimic oestrogen may be relatively weak, it exhibits anti-oestrogenic properties (i.e. interfering with the normal signalling activity of oestrogen hormones) at doses up to 100 times lower.[25] Furthermore, this effect is not confined to in vitro tests but can be detected in vivo in zebrafish at similar exposure concentration ranges.[26]

This level of complexity of interaction with just one hormone communication system clearly causes major difficulties for chemical assessment in general, and threshold setting in particular. The possibility remains that polycyclic musks, along with a host of other chemicals in common use, may also mimic or interfere with other hormones in the body, including the male steroid hormones (androgens, such as testosterone) or thyroid hormone. A major EU research programme into androgenic and anti-androgenic activities of various man-made chemicals (under the COMPRENDO initiative)[27] has recently highlighted that these effects may be far more widespread than the oestrogenic activity, which has long been the focus of endocrine disruptor research and assessment protocols. They may even be of greater importance in terms of effects at environmentally-relevant concentrations and exposure-levels of chemicals. HHCB, along with the vast majority of other chemicals in use, has never been tested for possible effects on the androgen system, despite the fundamental role this system plays in controlling growth and development in wildlife and humans.

The potential for chemical interference with a diversity of non-reproductive processes which are also under hormonal control is even less well accounted for:

***"The current safety testing guidelines are based on reproductive effects, and thus do not take into account the deleterious effects of endocrine disruptors in other tissues."***[28]

Two important lessons can be drawn from the examples above. Firstly, the fact that no effect is observed in any particular toxicity test cannot be taken to imply that the chemical has no adverse effect of any kind on the test organism; it may simply be that the test conditions used do not allow us to observe the effects, either because they are not sensitive enough or because we are simply looking for the wrong type of effect.

Secondly, it follows that the effect thresholds determined from toxicity tests (be they DNELs or PNECs) will also depend on what we measure and how, and the assumption that this is the most sensitive and/or relevant indicator for chemical safety assessment. When we are dealing with chemicals which are carcinogenic, mutagenic, toxic to reproduction or capable of disturbing the endocrine system, this seems to be an unwise and unnecessary risk to take.

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# ‘There is no such thing as a single chemical exposure’[29]

Chemical risk assessments almost always consider the consequences of exposure to one chemical at a time. And yet, in reality, we are invariably exposed to complex mixtures of chemicals, from our food and water, in the air, even in the dusts in our homes and offices[30] and in our cars[31]. The possibility that chemicals could be interacting in causing adverse effects, which would not be predicted from the properties of the pure chemicals, is very real and yet rarely considered when determining thresholds of exposure and effect.

The presence of any particular chemical in a mixture may impact directly on overall toxicity or the toxicity of other chemicals present, or act to change adsorption or excretion rates, breakdown processes or the bioavailability of other contaminants[32]. In many cases, the resulting effect may be a simple additive one, though both synergistic (greater than additive) and antagonistic (less than additive) interactions are also possible. Even for relatively simple mixtures, effects remain very difficult, if not impossible, to predict with any confidence even where detailed knowledge of the properties of the individual chemicals is available.[33/34]

In the case of oestrogenic chemicals, for example, it has been noted that “hazard assessments that ignore the possibility of joint action of estrogenic chemicals will almost certainly lead to significant underestimations of risk”[35]. A common approach to the problem of mixtures for chemical assessment is the use of generic ‘safety factors’ to adjust threshold values calculated for individual components. But as other authors have stressed, “mixture effects are not generic”[36], and may be dependent not only on absolute doses but also on ratios of doses of chemicals in the mixture. In short, there is no way of knowing whether theoretical safety factors will be over- or under-protective in practice.

There are many examples of synergistic effects in chemical mixture toxicology, both in vertebrates[37] and invertebrates[38/39]. Nevertheless, even simple additive behaviour can result in significant effects being manifest when all chemicals in a mixture are present at levels which, if taken individually, would ordinarily be insufficient to cause observable effects. In other words, a mixture of chemicals at levels below individually determined effect thresholds can nevertheless show a substantial impact in combination:

***“Most chemicals are present in the field at concentrations far below their individual median effective concentration ($EC_{50}$), possibly also below their individual no observed effect concentration (NOEC), yet still they may contribute to substantial effects.”[40]***

***“Examination of new case studies, as well as those previously reported, shows that when the human body is exposed to mixtures of chemicals that include lipophilic and hydrophilic species, the lipophiles facilitate the absorption of the hydrophiles at enhanced levels and produce effects that are not expected from an individual chemical.”[41]***

In the case of endocrine disruptors, the activity of mixtures can be particularly striking. In vitro studies involving low concentration mixtures of bisphenol-A, PCBs and various other ‘weak’ oestrogens have revealed “something from ‘nothing’” in terms of oestrogenic activity[42], i.e.

***“The combined additive effect of the 11 xenoestrogens led to a dramatic enhancement of the hormone’s action, even when each single agent was present below its NOEC.”[43]***

In conclusion, even if it were possible to arrive at robust, reliable and sufficiently protective threshold values for individual chemical exposures, it is unlikely that these would provide effective protection in the real world, given that we are constantly exposed to complex and ever-changing mixtures in practice.

***“Europeans are exposed to low levels of a large number of endocrine disruptors which can act in concert…Testing does not account for the effects of simultaneous exposure to many chemicals and may lead to serious underestimations of risk.”[44]***

***“It is difficult to overstate the complexity of assessing risks from chemical mixtures. For every valid reason to do so, there appears to be an equally valid question as to whether it is possible to do so in a scientifically rigorous and relevant manner.”[45]***

The fact that we are exposed constantly to chemical mixtures adds an additional layer of complexity and uncertainty to that already arising from the difficulties of setting thresholds for individual chemical exposure. Taken together with the Council’s recognition (noted above) that thresholds may also differ depending on the nature and route of exposure, we are left with a seemingly unmanageable situation. Certainly it is one in which reliance on Derived No Effect Levels (DNELs) and Predicted No Effect Concentrations (PNECs) to confer protection is an incautious and highly questionable approach.

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# There is another way:
## precaution and substitution

Taking into account all the inherent problems and uncertainties discussed above, it must surely be a more prudent, precautionary and defensible approach to avoid the use of and, therefore, exposure to all CMRs or chemicals of equivalent concern (including endocrine disruptors) wherever and whenever possible. This is not to say that all proposed uses should automatically be prohibited from authorisation under REACH, but rather that such uses should only be permitted where no safer alternatives are currently available, the benefits are unquestionable and the risks can be properly controlled.

In essence, this is the approach adopted by the Parliament in its first reading (see above). It provides for essential and irreplaceable uses of 'substances of very high concern', be they PBTs, vPvBs, CMRs or chemicals of equivalent concern, to be authorised through one logical and consistent route rather than placing reliance on complex, time- and resource-consuming and potentially subjective estimations of effect thresholds and exposures. Under the Parliament's proposals, the existence of a suitable safer alternative, be it a different chemical, material, technology or other alternative, would be sufficient in itself for an authorisation for that use to be refused (recognising that, in certain cases, temporary authorisation may nevertheless be necessary in order to give time for such substitutes to be put fully into place).

Furthermore, the approach adopted by the Parliament takes far greater account of the propensity for new, safer and more sustainable solutions to emerge over time. Indeed, by requiring that all authorisations issued are subject not only to a strict time limit (not exceeding 5 years) but also to "review periods and the presentation of substitution plans"[46], the Parliament's approach would ensure that REACH would act as a strong driver for substitution of the most hazardous chemicals currently in use with safer alternatives. Current absence of a workable alternative would become an incentive to develop one rather than a justification for 'business as usual' and thus a strong driver for sustainable innovation, one of the key elements of the EU's Lisbon Agenda. This approach would also be consistent with the direction given to the EU by the Ministerial Meeting of the OSPAR Commission in 2003 and, indeed, consistent with the objective of OSPAR's Hazardous Substances Strategy to stop releases of all hazardous substances to the marine environment by the year 2020 (the 'one generation' goal).[47]

In contrast to the Parliament's approach, however, the proposals from Council open the possibility that some uses of 'substances of very high concern' may be granted authorisations on the assumption that any risks they may pose are capable of being identified and 'adequately controlled'.

Taking some of the specific chemical examples referred to above[48], it is clear that the manner in which they would be addressed under the Parliament and Council proposals, and the consequences for protection of the environment and human health, could differ quite markedly. Whether for the category 2 reproductive toxicant DEHP, the possible neurotoxin decabromodiphenyl ether ('deca') or the potential endocrine disruptor HHCB, alternatives have been available and on the market for some time. Case study examples of substitution in action, and the companies which are leading the way in innovation, are provided in the Greenpeace report 'Substitution within REACH'[49]. There are may be circumstances in which substitution is difficult or complex but these challenges should not prevent the research and development of suitable alternatives.

It may be that the most suitable alternative is not a simple 'drop-in' chemical replacement and, in such cases that it is, it will remain vital to ensure that one problem chemical is not simply replaced with another. Hence replacing DEHP with other toxic phthalates or poorly assessed alternative plasticisers, replacing decabromodiphenyl ether with decabromodiphenyl ethane[50] or other brominated or chlorinated flame retardants, or even replacing polycyclic musks like HHCB with largely unassessed macrocyclic musks before their greater safety is proven would all be unwise decisions. Fortunately they are also all entirely avoidable decisions.

* Alternatives to continued widespread use of DEHP, for example, include use of alternative polymers or other materials which confer flexibility on the product without the need for mobile and leachable chemical additives.
* For most current uses of 'deca' in polymers and textiles, non-halogenated and chemically safer alternative flame retardants have long been available[51], albeit often at some additional cost to manufacturers, and are capable of meeting all necessary fire safety standards. Once again, alternative, non-combustible materials and novel product designs undoubtedly also have a role to play.[52]
* In the case of polycyclic musks, while there are many natural fragrances which could provide replacements, it is also important to reconsider the need for, and benefits of, such widespread fragrance use in a diversity of consumer products. It is common sense that any unnecessary use of chemicals, and the exposure it entails, should be avoided.

According to the Parliament's formulation, it would seem reasonable, therefore, that few if any continued uses of these potential 'substances of very high concern' would receive authorisations.

In contrast, it is feasible under the Council's proposals that all three chemicals - DEHP, 'deca' and HHCB - would be regulated according to a series of exposure scenario-specific effect thresholds, such that their widespread use and release to the environment, though entirely avoidable, would nevertheless be allowed to continue. In the long run, this cannot be a sustainable or precautionary approach.

Moreover, faced with the inevitable limitations to time, technical expertise and financial resources, it will be far better to invest in the identification, development and implementation of safer and more sustainable alternatives, including clear and timed substitution plans where necessary, than to commit yet more resources to the assessment of risks, definition of thresholds and determination and monitoring of 'safe levels of exposure' for substances which already present 'very high concerns' and which could be readily replaced.

**If drafted correctly, incorporating a single route to authorisation and a requirement for substitution, wherever possible, for 'substances of very high concern', REACH could act not only to protect our health and environment for the future but also as a driver for innovation and positive change within the European chemical industry with benefits to all levels of society.**

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# Abbreviations

| | |
|---|---|
| **AHTN** | 6-Acetyl-1,1,2,4,4,7-hexamethyltetraline, also known by trade name Tonalide |
| **BDEs** | brominated diphenyl ethers, also referred to as PBDEs or polybrominated diphenyl ethers |
| **CMRs** | substances which are carcinogenic, mutagenic or toxic to reproduction |
| **'deca'** | commonly used shorthand for decabromodiphenyl ether, or BDE-209 |
| **DEHP** | bis(2-ethylhexyl) phthalate |
| **DNELs** | Derived No Effect Levels |
| **EU** | European Union |
| **EP** | European Parliament |
| **HERA** | Human and Environmental Risk Assessment project of CEFIC and AISE |
| **HHCB** | 1,2,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta-y-2-benzopyran, also known by trade name Galaxolide |
| **$LD_{50}$** | the dose of a substance found to be lethal to 50% of the animals exposed in any one test |
| **OSPAR** | Convention for the Protection of the Marine Environment of the North-East Atlantic |
| **PBT** | substances which are persistent, bioaccumulative and toxic |
| **PCBs** | polychlorinated biphenyls |
| **PNECs** | Predicted No Effect Concentrations |
| **REACH** | Registration, Evaluation and Authorisation of Chemicals |
| **vPvB** | substances which are very persistent and very bioaccumulative |

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# **Table:** Comparison of the Parliament and Council positions regarding authorisation within REACH

| GRANTING OF AUTHORISATION ARTICLE 57 PARAGRAPH 2 | EUROPEAN PARLIAMENT 1ST READING POSITION | COUNCIL POLITICAL AGREEMENT | GREENPEACE'S COMMENTS |
|---|---|---|---|
| | **2. An authorisation shall be granted only if:**<br><br>**(a) suitable alternative substances or technologies do not exist, and measures are in place to minimise exposure, and**<br><br>(b) it is demonstrated that the social and economic advantages outweigh the risks to human health or the environment which arise from the use of the substance, and<br><br>(c) the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIII(a) is adequately controlled in accordance with Annex I, section 6, and as documented in the applicant's chemical safety report. | **2. Without prejudice to paragraph 2bis, an authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIII is adequately controlled** in accordance with Annex I, section 6.4, and as documented in the applicant's chemical safety report. The Commission shall take into account all discharges, emissions and losses known at the time of decision.<br><br>The Commission shall not consider the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC, Council Directive 93/42/EEC or Directive 98/79/EC of the European Parliament and of the Council.<br><br>2bis. **Paragraph 2 shall not apply to:**<br><br>**(i) substances meeting the criteria in Article 54 (a), (b), (c) and (f) for which it is not possible to determine a threshold in accordance with Annex I, section 6.4;**<br><br>**(ii) substances meeting the criteria in Article 54 (d) and (e).** | Greenpeace welcomes the Council clarification that PBT and vPvB substances cannot be 'controlled' and therefore should not be granted an authorisation if there are suitable safer alternatives. However, under the same decision, companies will be granted authorisations for some uses of chemicals which are carcinogenic, mutagenic, toxic to reproduction (CMRs) or capable of interfering at a fundamental level with the body's chemical signalling and development mechanisms, even if safer alternatives without these harmful properties are already on the market, if an 'effect threshold' can be established. Greenpeace believes that the Parliament's proposal is a far more robust, defensible and protective approach to the management of the most harmful chemicals currently on the market. Authorisations could be authorised through one logical and consistent route rather than placing reliance on complex, time- and resource-consuming and potentially subjective estimations of effect thresholds and exposures. |

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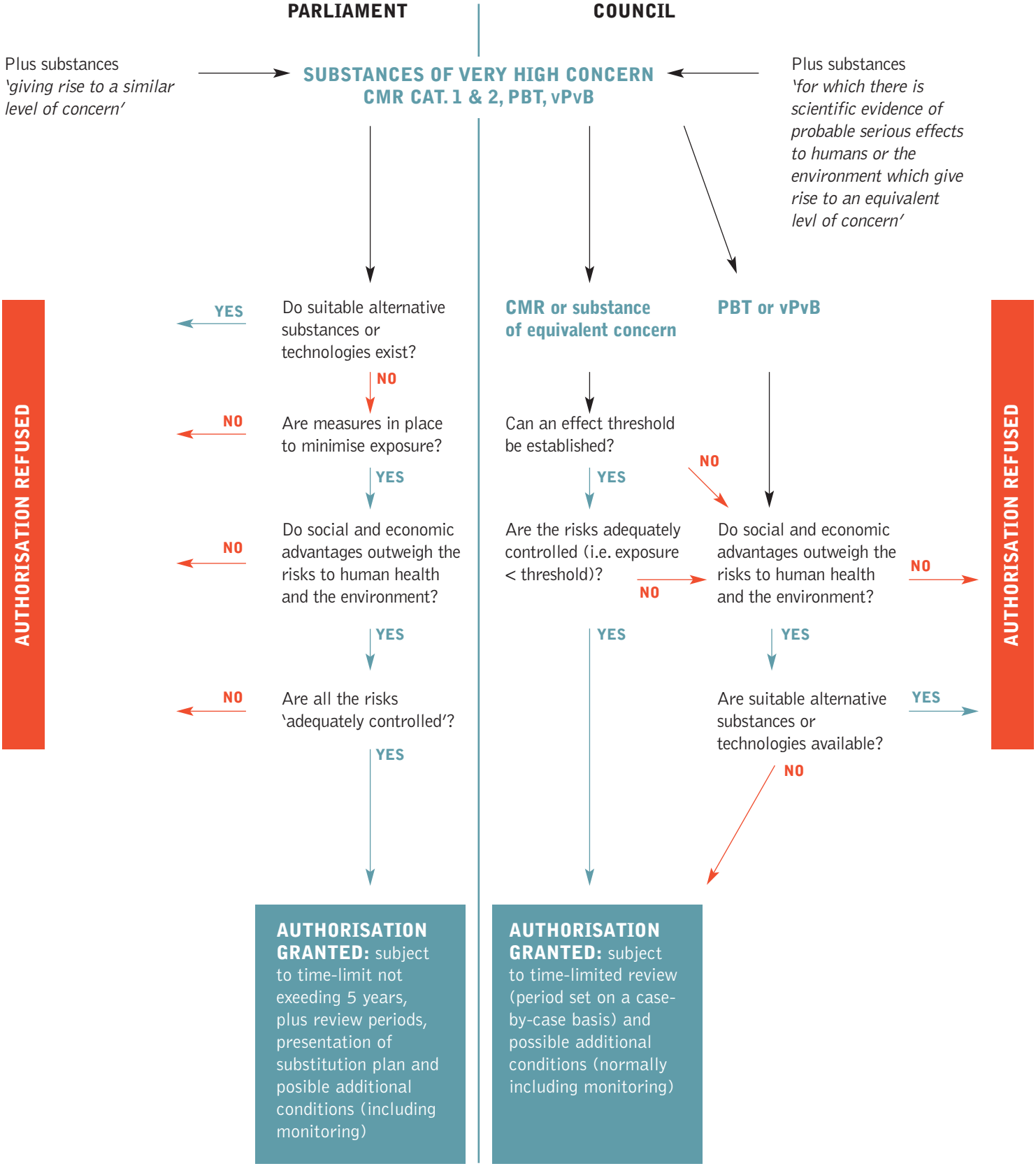
# **Flowchart:** Comparison of the Parliament and Council positions regarding authorisation within REACH



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**4.** In the first instance, the Restrictions component of REACH represented by Annex XVI, will largely be transcribed from the equivalent annex of the existing marketing and use Directive 76/769

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**11.** The text in the square brackets is inserted for better understanding of the context

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a. to take full account of the need to protect the marine environment;

b. to take account of our commitments to move towards the cessation of emission, discharges and losses of hazardous substances;

c. to promote the substitution of hazardous substances with safer alternatives, including promoting and facilitating the development of such alternatives where they do not currently exist

d. to ensure that purchasers and consumers are provided with information on hazardous substances in goods, to help reduce the risks from them."

**48.** The specific cases of these three chemicals are highlighted here as an illustration of a wider concern. Until it becomes clear precisely which 'substances of very high concern' will ultimately fall into the category for which the Council envisages that thresholds may be set (and, therefore, the 'adequate control' route applied), a more exhaustive analysis of the potential consequences is not possible.

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# FATAL FLAWS

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INNOVATION THROUGH SUBSTITUTION

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