

Michał Kurtyka
Minister of Climate and the Environment

Mateusz Morawiecki
Minister of economic development and technology

Adam Niedzielski
Minister of Health

6th September 2021

Resorcinol vote at the REACH Committee meeting of 22-23 September: support the adequate SVHC identification of this known endocrine disruptor for health

Dear Minister Kurtyka,

Dear Minister Morawiecki,

Dear Minister Niedzielski,

We are writing to you on behalf of civil society organisations across Europe that work together to promote health and environmental protection. We monitor European chemical policies, including the flagship regulation REACH and the implementation of the recently agreed EU Chemicals Strategy for Sustainability.

With this letter, we would like to **alert you on an important upcoming milestone** in this context. At the **REACH Committee meeting** scheduled on 22-23 September, **Member States** will discuss and **possibly vote on a European Commission proposal to identify the substance Resorcinol as a substance of very high concern (SVHC) due to endocrine disrupting properties for health** under the REACH regulation (article 57(f)).

We call on you to support this proposed identification in order to ensure that public authorities, actors in the supply chain, workers, and citizens have adequate knowledge on the hazardous properties of the substance.

Resorcinol impacts the functioning of the thyroid system, which is essential for brain development, in particular for unborn children. Exposure to Resorcinol has been shown to affect thyroid hormone levels in experimental rodent studies and to lead to a series of **severe developmental effects related to such hormone level changes in humans** as documented by case reports, including **hypothyroidism**,

goiter, neurological impacts in the child. The latter effects can be considered **irreversible** because they strongly affect the wellbeing and quality of life of an individual over the long-term.

All such evidence is rigorously detailed in the SVHC identification document that supports the current discussion about Resorcinol's properties¹. Member States already rightly agreed that the substance meets the World Health Organization (WHO) definition of an endocrine disruptor. However, they could not reach unanimity as regards the criteria of equivalent level of concern (ELOC), which is necessary to identify a SVHC under REACH article 57(f). **In the annex** to this letter, you will find **detailed reasoning about why Resorcinol does meet such criteria, and why Poland should support the SVHC identification.**

Finally, it is important to stress that Resorcinol is a high-volume compound (registered at 1,000-10,000 tons/annum), which is used in multiple industrial and consumer applications. This includes but is not limited to cosmetics, hygiene products, pharmaceuticals, flame retardants, the manufacture of rubber products, adhesives, or resins. This means that **the exposure of both workers and the public (including vulnerable groups such as women of child-bearing age) to the substance is high. Adequate public information about the properties of the substance, which the SVHC identification process is meant to ensure, is therefore indispensable.**

Through the recently agreed **European Chemicals Strategy for Sustainability, European institutions and Member States have promised to ban the most harmful chemicals in consumer products, including endocrine disruptors, and to promote their substitution.** The current proposal to identify Resorcinol as a SVHC under REACH article 57(f) due to its endocrine properties for human health is an **important test case of Europe's credibility in the delivery of this strategy,** and a failure to do so would be incomprehensible from a scientific, regulatory and political point of view.

We call on you to support the SVHC identification of Resorcinol and to show leadership in the delivery of the commitments to increase health protection as set out by the Chemicals Strategy for Sustainability.

We thank you for considering our letter and we remain available for further exchanges with you on this important topic.

Yours sincerely,

A handwritten signature in black ink that reads "Genon Jensen". The signature is written in a cursive style with a large, sweeping flourish at the end.

Genon K. Jensen
Executive Director
Health and Environment Alliance (HEAL)

On behalf of the following signatories:

BUND – Friends of the Earth Germany

¹ For more information, see: Health and Environment Alliance, Comments in support of the SVHC identification of Resorcinol, April 2020, <https://www.env-health.org/wp-content/uploads/2020/06/HEAL-Resorcinol-corrected.pdf>

ChemTrust
Chemsec
Clientearth
Health and Environment Justice Support (HEJSupport)
The European Environmental Bureau (EEB)
Women Engage for a Common Future (WECF)

Contact:

Natacha Cingotti, Programme Lead, Health and Chemicals, Health and Environment Alliance (HEAL),
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In view of enhanced transparency on matters of public interest, we intend to make this letter publicly available.

Annex – Why Resorcinol fully meets the SVHC identification criteria

The current REACH Committee procedure follows a failed identification attempt at the ECHA Member State Committee 70 (MSC), which took place on 10-12 June 2020.² The MSC did not reach unanimity as regards the criteria of equivalent level of concern (ELOC), which is necessary to agree on a SVHC identification under REACH article 57(f). This situation is rare and unfortunate, as the delayed SVHC identification has allowed human exposure to an officially recognized endocrine disruptor to continue, without even information requirements being put in place.

Below, we provide detailed explanation that supports the identification of Resorcinol as SVHC under REACH article 57(f).

- **Legal considerations:**
 - The binding interpretation of the European Court of Justice points to Resorcinol being a perfect candidate for SVHC listing and must be taken into account.
 - The EU judges clarified that SVHC identification must be based purely on the intrinsic properties of the substance and that the real-life conditions of exposure are not relevant in this context (See for example T-519/18 §88, 89 and 116).
 - When it comes to the equivalent level of concern, the Court also stressed the importance of the nature of the effects – for example their seriousness, long-term nature, irreversibility – over the type or strength of the evidence (See T-207/18 §217-220).
- **Endocrine activity:**
 - Resorcinol has long been known to act on the endocrine system by strongly inhibiting thyroperoxidase (TPO), which is an essential enzyme in the synthesis of the thyroid hormone. The strength and consistency of such a mechanism across species is clearly documented in the SVHC dossier.
- **Adverse effects:**
 - Science has long established that any modulation in the thyroid function must be considered as adverse. Therefore, the observed impacts of TPO inhibition on the synthesis of the thyroid hormone must be considered as adverse.
 - This fully applies to Resorcinol. Available mechanistic data from in vivo animal studies shows significant changes in thyroid hormone levels after rodents' exposure that must be considered adverse. Moreover, case reports document severe effects related to such hormone level changes in humans, including hypothyroidism, goiter, neurological impacts in the child.

² ECHA, "Resorcinol not identified as a substance of very high concern", Press Release, 16 June 2020,

<https://echa.europa.eu/fr/-/resorcinol-not-identified-as-a-substance-of-very-high-concern>

ECHA, Minutes from MSC 70, Adopted on 7 September 2020,

https://echa.europa.eu/documents/10162/2200431/MinutesofMSC-70_adopted-1.pdf/2972d2e5-6a5b-67ce-efc8-1a67a8e025a9?t=1599732914263

- **Human relevance:**
 - It is established scientific knowledge that the thyroid systems are highly conserved across vertebrate species. This fully applies to the interpretation of the animal data available in the Resorcinol dossier. Especially because there is no indication or evidence disproving the relevance of such animal data in the dossier, the available evidence of Resorcinol's adverse effects in animals can be considered to have a high level of biological plausibility.
 - Moreover, the availability of human case reports strengthens the identification dossier by providing evidence that the same pathways lead to the same adverse effects in humans than in animals, when exposed to Resorcinol. It is important to stress that access to human data is a rare fact in the context of endocrine disruption evaluation. Although such data is by nature incomplete, in this case, it shows a high degree of consistency with the toxicological data and mechanisms described in animal studies.

- **Equivalent level of concern:**

Thyroid hormones play an extremely important role in the child prenatal brain development. Adverse developmental effects associated to changes in the levels of thyroid hormones – which are relevant in the case of Resorcinol and well described in the SVHC identification supporting dossier – include, but are not limited to, goiter, neurological impacts in the child, and hypothyroidism. All such conditions severely impact the development, health, and well-being of an individual over the lifetime and therefore cannot be considered easy to treat and reverse. For this reason, Resorcinol meets the criteria of equivalent level of concern, as described under REACH article 57(f).

- **Inadequacy of the minority opinion opposing the SVHC identification:**
 - The disagreement about the ELoC elements that are necessary for the SVHC identification is justified in a minority opinion report³ with the following reason: *“Resorcinol inhibits TPO activity in vitro. However, the available data suggests that the efficient and rapid metabolism by first pass metabolism in the liver, prevents resorcinol from reaching systemic concentrations which are toxic for the thyroid gland.”*
 - This uncertainty is however already well answered in the 124-page long SVHC identification supporting document⁴: *“Human cases have been identified under specific conditions and this may raise some questions on their relevance for actual conditions of human exposure. The effects induced by resorcinol in humans and in experimental animals are complementary in the demonstration that they cannot be considered as specific to exceptional conditions of exposure, in particular because some populations and periods of exposure can be associated with specific sensitivity. Besides, the possibility that resorcinol may induce effects in humans under common conditions of exposure cannot be excluded on a toxico-kinetic basis.”*
 - This minor uncertainty and disagreement relate to exposure to rather than the intrinsic hazard properties of Resorcinol. We are deeply concerned that it has stalled the entire process of SVHC identification of the substance, while the SVHC supporting

³ <https://echa.europa.eu/documents/10162/736eeb34-238e-a626-8217-4255adf92cba>

⁴ <https://echa.europa.eu/documents/10162/7d16c5c3-4fe7-21c4-462c-7ef8234c1c36>

document rigorously justifies why the substance meets each REACH criteria, including the equivalent level of concern.