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Persistant Organic Pollutants (POP) / REACH C9-C14

## Chemicals Restrictions will Make Production of Protective Masks in EU Impossible EU Regulation Urgently Needs Further Review

Chemicals are essential for the textiles industry – e.g. as flame or infection protection for clothing, or as functionalisation of medical devices. The same goes for other industries like electronics, automotive and aerospace.

Under REACH, since 2018 only registered chemicals may be produced or imported into the EU.

- In the **EU**, only 13,500<sup>1</sup> single chemical substances and unregistered polymers are currently available – compared to 160 million<sup>2</sup> CAS number registered substances, polymers and DNA-sequences worldwide.

The administrative effort and the expenses for the required studies of registration under REACH and the Biocidal Products Regulation (BPR) are disproportionally high compared e.g. to the US and China. As a matter of fact, to date only 12 percent of the 145,000 substances pre-registered under REACH have been finally registered in the EU. As further result, only 7,500 registrations out of 53,000 in 2018 came from SMEs, almost all of which were specialised in chemicals. This created a bias in the EU market towards other players in the market.

The REACH registration process, together with the acceleration of multiple fundamental restrictions and bans of chemicals, unscientific CLP re-classifications by ECHA etc. may be operable for some larger chemical companies but pushes many of the small and medium-sized businesses — which the European Union has so often promised to support - to their very limits. In the existing framework under REACH, these SMEs are losing their capacity to innovate; production needs increasingly to be outsourced to countries outside Europe. For a wide range of essential products like protective textiles, infection prevention, pharmaceuticals, antibiotics, etc., Europe is already dependent on suppliers outside the EU. As there is hardly any product without chemistry, there is hardly any sector unaffected by REACH and BPR - the harm inflicted by the EU's chemicals regulations cascades down across all downstream sectors.

<sup>&</sup>lt;sup>1</sup> Rounded

<sup>&</sup>lt;sup>2</sup> Rounded



## Persistant Organic Pollutants (POP) / REACH C9-C14

Also in the field of fluorinated polymers, the EU chemicals policy - if further pursued - will not only lead to an increase in global PFOA / PFC emissions but also drive a considerable number of SMEs at the edge of bankruptcy soon. The German textile and fashion industry has already called for a general moratorium<sup>3</sup> on REACH and other chemical and environmental legislation. As decisionmakers in Helsinki and Brussels remain unimpressed by the sector's contributions - despite all the adverse consequences these policies might trigger - textil+mode wishes to come back with the present paper on a selected number of the most worrying specific amendments that need to be addressed even at this advanced stage of the legislative process in order to avoid major harm to the industry:

C8, so far regulated in REACH annex XVII, entry 68, are currently subject to a review of the Commission Delegated Regulation<sup>4</sup> amending Annex I to Regulation (EU) 2019/1021 as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds - C(2020) 1973 final (POP Regulation).

Other REACH restrictions like into the alternative to C8 - perfluorohexanoic acids / PFHxA (= C6) and, as already announced, into general per- and polyfluoroalcyl substances (PFAS), will drastically weaken the textile industry's ability to produce urgently needed medical and protective masks in Europe and other items in high demand as it would simply deny companies the indispensable market approval required by EU chemicals regulation.

The same goes for the present initiative to restrict C9-C14: Where a specific derogation exists under the POP Regulation for C8, the exemptions shall also apply to C9-C14 and their related substances.

Amendments urgently needed for the Commission Delegated Regulation<sup>5</sup> amending Annex I to Regulation (EU) 2019/1021 as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds - C(2020) 1973 final (POP Regulation):

To prevent such scenario from arising the German textile and fashion industry urgently calls for four decisive amendments for:

- 1. Restoring the 12-year transition period<sup>6</sup> (until 2032) foreseen in REACH for the derogation applied to medical devices other than implantable within the scope of Directive 93/42/EC. At the very least, a transition period of 5 years (until 2025) followed by a subsequent review would be required by economic operators.
  - REACH annex XVII, entry 68 granted this derogation until 4 July 2032. Under the draft POP Regulation, it would expire already on 3 December 2020.
  - Companies cannot be reasonably expected to adapt their production at such short notice. If PFOA (perfluorohexanoic acid), its salts and/or PFOA precursors may no longer be used after only six months advance notice, the production of the respective medical equipment will be forced to a hard stop with severe consequences for the manufacturer and healthcare providers alike.

<sup>&</sup>lt;sup>3</sup> Statement published on 15 May 2020 (in German)

<sup>4 8</sup> April 2020

<sup>&</sup>lt;sup>5</sup> 8 April 2020

<sup>&</sup>lt;sup>6</sup> Regulation (EU) 2019/1021, annex I, part A, specific exemption 9a



- 2. Restoring the <u>3-year transition period</u><sup>7</sup> (until 2023) foreseen in REACH for the derogation applied to Personal Protective Equipment (**PPE**).
  - The products concerned here stand for significantly lower total emissions than C6 and for the **highest protection level for the EU population**, highest washfastness, longevity, etc.
  - The European textile companies would be deprived of the indispensable critical mass of predictability following the drastic shortening of the implementation periods to zero and, as a result, could now no longer produce e.g. first-class corona-protective textiles, as compared to other countries like e.g. China. With the new circumstances imposed by Covid-19, the EU should value the availability of these textiles in the EU's domestic market.
- 3. Allowing for a <u>review position</u><sup>8</sup> for all **textile-related C8 derogations**, similar to those granted to the chemical industry in two cases.
  - This would <u>not</u> enhance the transitional period for textiles, but well give the Europeans a relapse position which will be crucially needed if essentially needed textiles are soon to be banned under REACH, by the already initiated C6 restriction and the already announced substantial PFAS restriction.
- 4. <u>Clarifying both textile-related derogations</u><sup>9</sup> ("medical" and "production processes") with regard to membranes.
  - The new wording replacing the previously foreseen provisions in REACH annex XVII, entry 68, has sparked confusion and legal questions. A better (clearer) alternative wording would be "membranes/textiles".

Unless the necessary re-orientations and corrections take place, there is a risk that the current REACH policy, aimed at protecting people, will lead to the creation of monopolies, the disappearance of essential chemicals, competitive disadvantages and, ultimately, de-industrialisation in the EU.

As the industry faces unprecedented challenges posed by the corona crisis, **the EU cannot pursue its pre-corona chemicals policy as if nothing had happened**. Larger companies in some sectors might be able to cope for some months, in some cases probably also for the next few years, but SMEs in the textile and fashion sector are reaching their limits already now.

In times of instability and uncertainty, economic operators need a stable, predictable and reliable policy framework. The new POP Regulation, on the contrary, makes orderly business planning impossible. Items like first-class corona-protective textiles and other could no longer be produced in the European Union.

textil+mode stands ready to explain the need for the above amendments in more detail and to explore viable solutions with the competent EU decision-makers.

The German textile and fashion industry is the second largest consumer goods industry with around 1,400 companies and more than 132,000 employees in Germany. German textile and fashion companies generate an annual turnover of around 32 billion Euro (60% of which are textiles, 40% of clothing) and are thus leading in Europe. Textile companies are important suppliers for industries such as automotive, aerospace, medicine, geotechnology etc. The Confederation of the German Textile and Fashion Industry (textil+mode) is the umbrella organisation of the sector in Germany. textil+mode represents the interests of the industry in the area of economic, social, collective bargaining and education policy. <a href="https://www.textil-mode.de">www.textil-mode.de</a>

 $<sup>^{7}</sup>$  Regulation (EU) 2019/1021, annex I, part A, specific exemption 5c

<sup>&</sup>lt;sup>8</sup> Regulation (EU) 2019/1021, annex I, part A, specific exemptions 5c, 5d, 5e, 9a, 9c

<sup>&</sup>lt;sup>9</sup> Regulation (EU) 2019/1021, annex I, part A, specific exemptions 5c, 5d