

**ENVIRONMENT DIRECTORATE
CHEMICALS AND BIOTECHNOLOGY COMMITTEE**

Proposal for updating the OECD Guidance on Polymers of Low Concern

Meeting of the Chemicals and Biotechnology Committee

5-7 July 2023, starting at 14h00 on 5 July
2 rue André Pascal, Paris, France

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In 1993, the OECD developed considerations for polymers of low concern. These were used by many countries to develop criteria for reduced registration or notification requirements. These considerations may be outdated due to new scientific knowledge and new regulatory objectives in countries. It is therefore worthwhile to reflect on whether the OECD considerations should be updated or not.

Action required : ***The Chemicals and Biotechnology Committee is invited to decide on a way forward, choosing among the three options outlined in paragraph 11, or proposing other options.***

Background

1. Work on polymers was undertaken at the OECD starting in the early 1990s. The First Meeting of the Expert Group on Polymer Definition held in Toronto, Canada (January 1990), developed the polymer definition. This was reconfirmed at the Second Meeting of the Expert Group on Polymer Definition held in Paris, France (October 1991), and in the Second Meeting of the OECD Expert Group on Polymer Definition: Chairman's Report [ENV /MC/ CHEM (91)18], it is stated in paragraph 5:

In considering the report and subsequent comments the Group reconfirmed the agreed definition on polymers for use in new chemicals notification procedures i.e.":

An OECD definition developed to distinguish discrete substances from polymers:

A 'POLYMER' means a substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition a 'MONOMER UNIT' means the reacted form of a monomer in a polymer."

2. A Third Meeting of OECD Experts on Polymers, held in Tokyo, Japan (April 1993), further clarified some of the terms of the definition to avoid ambiguity and set criteria for identifying polymers of low concern [ENV/ MC/ CHEM /RD(93)4].

3. The document states in paragraph 8:

The Working Group recommended the following addition to the polymer definition

Sequence: means that the monomer units under consideration are covalently bound to one another and form a continuous string within the molecule, uninterrupted by units other than monomer units.

Monomer: means a molecule which is capable of forming covalent bonds with two or more like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process.

Other reactant: means a molecule linked to one or more sequences of monomer units but which, under the relevant reaction conditions used for the particular process, cannot become a repeating unit in the polymer structure.

4. The meeting of this working group also discussed criteria for decision-making regarding low concern for polymers. Seven main criteria were discussed, although others were mentioned, but particular parameters were not agreed for each criterion. From the same report:

The Working Group, as asked, discussed criteria.

(1) Concerning MW: the range of 1,000 - 10,000 Mn was agreed as a range within which the concern value was likely to lie.

(2) Concerning MW of low MW compounds giving rise to concern: the agreement was MW below 1,000.

(3) Concerning percentage of low MW compounds of concern: no agreement

(4) Concerning functional groups: only one value, applicable to epoxy and anhydride groups was mentioned (it was 1 reactive group in 20 monomer units); no general conclusion was reached.

(5) Metal content: no value agreed.

(6) Extractivity in water: 10mg/l was seen as acceptable, provided that test conditions were standardized

(7) Cationic charge density: the 5,000 equivalent weight value was accepted (as defined by EPA: not more than one cationic charge in 5000 monomer units).

5. Several countries implemented criteria for reduced regulatory requirements for polymers that depended on the nature of their regulatory systems. In March 2007, the then OECD Task Force on New Chemicals Notification and Assessment organised an Expert Group Meeting on polymers. The meeting was organised to (i) share information on national legislative schemes; (ii) review commonalities and differences in criteria, approaches and methodologies with a focus on low concern polymers; (iii) consider the merits of various approaches; and (iv) investigate the potential for a common approach [[ENV/JM/NWCH\(2007\)1](#)] [[ENV/JM/MONO\(2009\)1](#)].

6. At the meeting, the Expert Group recommended that a scientific examination of the polymer of low concern concept be performed, through an analysis of polymer data submitted by OECD regulatory authorities. This work was carried out in 2007 and 2008, and published in 2009 [[ENV/JM/MONO\(2009\)1](#)]. The initial analysis supported the contention that polymers meeting low concern criteria have insignificant human health or environmental impacts, which in turn, supports reduced regulatory requirements for these polymers. However, gaps in data to support the analysis were also noted. Further work has not been carried out at the OECD.

Recent developments

7. A number of countries including Australia, Canada, Japan, Korea, New Zealand and the United States have introduced reduced regulatory requirements for some polymers based on criteria. A summary of the history and criteria applied in these approaches can be found in recent reports such as Groh et al. (2023)¹ and Wood (2020)².

8. Criteria for polymers of low concern have received increased attention in recent years, mainly for two reasons. First, the EU is discussing the introduction of reporting requirements for polymers under the EU REACH regulation. Many of the elements under consideration for identifying polymers requiring registration under REACH draw from the application of criteria in other countries. This discussion has also highlighted new information, data and considerations since many of the polymer of low concern criteria were established in the early 1990s.

9. Second, many countries are planning to regulate PFAS and will need to decide on how to deal with fluoropolymers. Criteria for polymers of low concern have recently been applied to justify low concern for some fluoropolymers (Henry et al. (2018)³). While not focused on fluoropolymers, since 2010, the US EPA excludes from exemption rules polymers containing as an integral part of their composition, except as impurities, certain perfluoroalkyl moieties consisting of a CF₃- or longer chain length⁴. Initial EU discussions on criteria for registration of polymers under REACH would require all fluorinated polymers to be registered.

10. Third, at the international level, countries have started negotiations to develop an international legally binding instrument to end plastic pollution⁵. In that context, agreed criteria for polymers of low concern may be particularly relevant.

¹ Ksenia J. Groh, Hans Peter H. Arp, Matthew MacLeod and Zhanyun Wang (2023). Assessing and managing environmental hazards of polymers: historical development, science advances and policy options. *Environ. Sci.: Processes Impacts*, 2023,25, 10-25 <https://doi.org/10.1039/D2EM00386D> (see in particular supporting documentation for detailed information of criteria applied in countries)

² Wood (2020). European Commission, ENV.B.2 – Sustainable Chemicals - Scientific and technical support for the development of criteria to identify and group polymers for Registration/ Evaluation under REACH and their impact assessment - Final Report <https://op.europa.eu/s/yyJv>

³ Henry B J, Carlin J P, Hammerschmidt J A, Buck R C, Buxton L W, Fiedler H, Seed J and Hernandez O, 2018. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. *Integrated Environmental Assessment and Management*, 2018, 316–334 <https://doi.org/10.1002/ieam.4035>

⁴ <https://www.regulations.gov/docket/EPA-HQ-OPPT-2002-0051>

⁵

<https://wedocs.unep.org/bitstream/handle/20.500.11822/39764/END%20PLASTIC%20POLLUTION%20-%20TOWARDS%20AN%20INTERNATIONAL%20LEGALLY%20BINDING%20INSTRUMENT%20-%20English.pdf?sequence=1&isAllowed=y>

Should the OECD criteria for polymers of low concern be revisited?

11. While explicitly agreed criteria for polymers of low concern were not harmonised between countries in the 1990s and 2000s, many regulatory approaches have leveraged the initial OECD discussions, which are still frequently cited.

12. Given the years of experience in many countries in applying criteria to identify polymers of low concern and more recent discussions in some countries, the CBC could consider several possible options:

- Option 1: No further work is needed at this time.
- Option 2: Communication could be developed outlining the past criteria discussions and the more recent scientific advances in this area to be posted on an OECD website, with guidance that the regulatory schemes of individual countries should be consulted.
- Option 3: The CBC could launch a project to update the criteria for polymers of low concern/reduced regulatory requirements.

13. In case Option 3 is preferred, it would be necessary for a country or organisation to volunteer to lead the project or for a country or organisation to provide a voluntary financial contribution, as this project would be in addition to the current Programme of Work and Budget.