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## FEICA comments on the degradation of polyesters

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FEICA, the Association of the European Adhesive & Sealant Industry, is a multinational association representing the European adhesive and sealant industry. Today's membership stands at 15 National Association Members, 24 Direct Company Members and 19 Affiliate Company Members. The European market for adhesives and sealants is currently worth more than 17 billion euros. With the support of its national associations and several direct and affiliated members, FEICA coordinates, represents and advocates the common interests of our industry throughout Europe. In this regard, FEICA works with all relevant stakeholders to create a mutually beneficial economic and legislative environment.

### Introduction

Polymers of relevant toxicological or ecotoxicological properties will be subject to registration as foreseen under a new REACH amendment. Polymers without such hazards will be exempt from registration obligation (Polymers of Low Concern [PLC] concept). One such exemption is the so-called 'Polyester Exemption', under which certain polyesters manufactured from predefined monomers will not require registration. This paper intends to address the Polyester Exemption and will also provide some background on the degradation of polyesters.

### How do polyesters degrade?

Degradation of polyesters happens through their hydrolysis, that is, cleavage of chemical bonds by the addition of water.<sup>1</sup> This process will give back reactants, either as such or as smaller chains at first, that are then successively hydrolysed to the reactants as well. The reason for this is that polyester formation is a reversible chemical reaction; in the presence of water this reaction can be reversed.<sup>2</sup>

Whilst this process occurs easily in living organisms, there were doubts about the nature of degradation mechanisms of synthetic polyesters in the environment. Recent scientific work<sup>1</sup>, however, demonstrated that microorganisms present in the environment can hydrolyse polyesters under mild conditions. The hydrolysis rates are affected by the temperature, molecular structure, degree of crystallinity, molecular weight, and ester group density.<sup>1(d)</sup> Polyester degradation is further

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<sup>1</sup> (a) Müller, R.-J., Biological degradation of synthetic polyesters—Enzymes as potential catalysts for polyester recycling, *Process Biochemistry* 41 (2006) 2124–2128 - <https://doi.org/10.1016/j.procbio.2006.05.018>; (b) Müller, R.-J., Biodegradation behaviour of polymers in liquid environments, in: Catia Bastioli (ed.) *Handbook of Biodegradable Polymers*, De Gruyter 2020, 23–43; (c) Herzog, K., Müller, R.-J., Deckwer, W.-D., Mechanism and kinetics of the enzymatic hydrolysis of polyester nanoparticles by lipases, *Polymer Degradation and Stability* 91 (2006) 2486–2498; (d) Lindsay N. Woodard and Melissa A. Grunlan, Hydrolytic Degradation and Erosion of Polyester Biomaterials, *ACS Macro Lett.* 7(8) (2018) 976–982, DOI: 10.1021/acsmacrolett.8b00424; (e) Nakajima-Kambe, T., Ichihashi, F., Matsuzoe, R., Kato, S., Shintani, N., Degradation of aliphatic–aromatic copolyesters by bacteria that can degrade aliphatic polyesters, *Polymer Degradation and Stability* 94 (2009) 1901–1905

<sup>2</sup> Reversible Polymerization, in: *Polymer Properties Database*; [Reversible Polymerization \(polymerdatabase.com\)](https://polymerdatabase.com)

accelerated by an autocatalytic effect (one of the reaction products is also a catalyst for the same reaction) caused by the release of acidic protons due to hydrolysis.

In summary, hydrolysis of polyesters in the environments will give back the reactant building blocks. For polyesters that will qualify for the proposed polyester exemption, these building blocks will then be the monomers specified on a list of approved starting materials (e. g. the list of approved monomers for food contact materials)<sup>3</sup>. At the same time such monomers are already registered under EU-REACH.

## Cyclic Diesters

Common by-products of polyester synthesis are cyclic diesters which also hydrolyse back to the monomers. This has been demonstrated through in-vitro degradation studies using both simulants of stomach fluids and liver enzymes. A study, sponsored by FEICA, was able to demonstrate this and serves as an example of biodegradation of such esters in *in vitro* and *in vivo* conditions.<sup>4</sup> The study is a bibliographical review of toxicological studies conducted by FEICA members, peer reviewed and compiled by a certified European toxicologist. Further information is available from FEICA upon request.

## Other jurisdictions

Polyester Exemptions are foreseen in several other jurisdictions as well, such as Australia<sup>5</sup>, China<sup>6</sup>, Taiwan<sup>7</sup>, Canada<sup>8</sup> and United States<sup>9</sup>. The US EPA comments on the exemption by saying that it 'has had sufficient experience in reviewing polymer exemption notices for polyester polymers' and 'does not believe such polymers present an unreasonable risk of injury to human health or the environment. Accordingly, these polyester polymers continue to be eligible for exemption'<sup>10</sup>. Moreover, a provision for polymers permissible for use in food-contact materials manufactured from a positive list of monomers can also be found in the EU Food Contact Regulation.<sup>11</sup> The rationale behind these exemptions is that polyesters without reactive functional groups are considered non-hazardous.

## Conclusions

FEICA proposes to keep the Polyester Exemption as an EU PLC criterion, considering that polyesters hydrolyse, as discussed above, back to the initial building blocks from an approved list of monomers, e. g. that of the EU Food Contact Regulation<sup>11</sup>. This is also in line with the objective stated by the Commission of 'aligning PLC criteria with other global frameworks'<sup>12</sup>.

## Contact

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<sup>3</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011R0010>

<sup>4</sup> [https://wall.feica.eu/#/group/4810/file/10151?mc\\_phishing\\_protection\\_id=28396-c691aa4na38luuus3pbq](https://wall.feica.eu/#/group/4810/file/10151?mc_phishing_protection_id=28396-c691aa4na38luuus3pbq)

<sup>5</sup> <https://www.legislation.gov.au/Details/F2019L01543>

<sup>6</sup> [https://www.cirs-reach.com/China\\_Chemical\\_Regulation/New\\_Polymer\\_Notification\\_China\\_REACH.html](https://www.cirs-reach.com/China_Chemical_Regulation/New_Polymer_Notification_China_REACH.html)

<sup>7</sup> <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=00060043>

<sup>8</sup> <https://laws-lois.justice.gc.ca/eng/regulations/SOR-2005-247/>

<sup>9</sup> <https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act>

<sup>10</sup> <https://www.federalregister.gov/documents/1995/03/29/95-7712/premanufacture-notification-exemptions-revisions-of-exemptions-for-polymers-final-rule>

<sup>11</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011R0010>

<sup>12</sup> E. g. 42<sup>nd</sup> Meeting of Competent Authorities for REACH and CLP, 17 November 2021

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