

Recent ECHA and POP Restrictions on the Use of Substances from the PFAS Family

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ABSTRACT

This article reports the recent restrictions imposed by ECHA regarding the presence of undecafluorohexanoic acid (PFHxA), its salts and substances that degrade or transform into PFHxA, which can be emitted into the environment, particularly into water, by products on the market in Europe. Some of these compounds have been designed as substances POPs (persistent organic pollutants) and other have been recently proposed and therefore being restricted worldwide. Several perfluorating and polyfluorated alkylic substances (PFAS) have restrictions in their use in Europe, being present on the lists of substances under control by the ECHA, as part of the Reach directive. The article shown that will be the future of perfluoroalkylic acids from C2 to C16 carbon atoms, perfluoroalchilsolfonical acids from C4 to C8 carbon atoms and two complex perfluoroalkylic acids. Carbon-fluorine bonds are the strongest bonds in organic chemistry and for this reason PFAS substances do not degrade in the environment and are found, at the end of their life, in soil, water, food and in the bodies of humans and animals. Since many of them are also toxic, they are the subject of serious accusations by society and, fortunately, also of restrictions.

The ECHA lists where the different chemical products existing on the market in Europe are reported are the following: the "Candidate List", the "Authorization List", the "Restriction List", the list of "CoRAP" substances, the "Registration List" and the "Preregistration List". The type of toxicity of the substances considered here is taken from the CLP (Classification, Labeling and Packaging of Substances) regulation of Europe.

Keywords: ECHA List, EPA List, Per- And Poly-Fluorinated Alkyl Substances (PFAS), Perfluoroalkylsulfonic Acids.

INTRODUCTION

Several perfluorating and polyfluorinated alkyl substances (PFAS) have restrictions in their use in Europe, being present on the lists of substances under control by the ECHA, as part of the Reach directive. On this base, this article that will be the future of perfluoroalkyl acids from C2 to C16 carbon atoms, perfluoroalkylsulfonic acids from C4 to C8 carbon atoms and two complex perfluoro alkyl acids.

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In a previous paper [1] has analyzed the family of polyaromatic hydrocarbons (IPA), which are present on the Lists of the ECHA (European Chemical Agency), and therefore can be subject to restrictions on their use in Europe in the near future; the subject now is the analysis of some substances of the PFAS family (Polyfluoroalkyl substances) present on the Lists of the ECHA [2]. The PFAS substances are under accurate control by the Environmental Authorities in Italy [3] and are perfluoroalkylic and polyfluoroalkylic substances that have chains of carbon atoms completely (per) or partially (poly) fluorinated and connected to a functional group [2]. Following restrictions and bans on the production of traditional perfluorinated substances, in particular PFOA and PFOS, in recent years (since the 2000s) substitute perfluorinated substances have been introduced on the market: short-chain (PFBA and PFBS, n=4), GenX technology (HFPO-DA), ADONA, cC6O4[4].

These new compounds have been modified in structure compared to their PFAS counterparts, with the insertion of oxygen between the perfluorinated chains that make them more mobile and therefore with negative effects on the environment.

Even though alternative products to long-chain PFAS compounds have been used for some years, there is currently little information available on these substances and, in some cases, their chemical identity is not known.

The PFAS substances, which will be examined here, are only perfluoroalkylic acids and perfluoroalkyl sulfonic acids, included in the different lists of the ECHA, i.e. compounds produced or imported from the chemical industries in Europe and present in products that are found on the market.

Carbon-fluorine bonds are the strongest bonds in organic chemistry and for this reason PFAS substances do not degrade in the environment and are found, at the end of their life, in soil, water, food and in the bodies of humans and animals. Since many of them are also toxic, they are the subject of serious accusations by society and, fortunately, also of restrictions.

PFAS are present in various products used in everyday life (non-stick pans, water-repellent clothing, stain-resistant fabrics and carpets, some cosmetics, some fire-fighting foams and products resistant to grease, water and oil, etc.). The PFAS family, in addition to perfluoroalkyl acids and perfluoroalkylsulfonic acids that are analyzed here,

also includes alkylperfluoroethers, alkylperfluoroamides, alkylperfluorosulfonyls, alkylperfluoro polymers and other perfluorinated and perfluorides. The ECHA lists where the different chemical products existing on the market in Europe are reported are the following: the "Candidate List", the "Authorization List", the "Restriction List", the list of "CoRAP" substances, the "Registration List" and the "Preregistration List". The type of toxicity of the substances considered here is taken from the CLP (Classification, Labeling and Packaging of Substances) regulation of Europe.

The "Candidate List" [5] reports the "Substances of Very High Concern" (SVHC), present in concentrations >0.1% by weight in products on the market, of whose presence consumers must be immediately informed, via the labels placed on the products. They are "candidates" to be placed in the "Authorization List" and therefore could be eliminated from the market. For now, only perfluoroalkyl acids, perfluoroalkylsulfonic acids, their salts and derivatives are the only PFAS present in the "Candidate List". It is very likely that "SVHC" substances could be included in the "Authorization List" [6] in the future and, to remain on the market, they will need an authorization by ECHA; however, currently, there is no PFAS substance in this list.

Interestingly the perfluorooctanoic acid family initially was included in the ECHA Restriction List in position 68, now it is no longer present and has been replaced by the PFCAs family (C9-C14), because since 14 July 2020 the perfluorooctanoic acid family has been officially considered a POP substance for the Stockholm Convention II, following Reg. (EU) 2020/784 and therefore subject to similar restrictions and for this reason it was not necessary to keep it included in the ECHA Restriction List, but it was precisely the restrictions on PFOA that had led to their replacement with the C9-C14 PFCAs family that pushed to introduce the latter in the Restriction List. The substances of the C4-C19 PFCAs family in Europe are mainly present as by-products released inadvertently during the manufacturing of perfluorinated and polyfluorinated substances.

Recently, the two types of restrictions present in position 68 in the ECHA Restriction List are reported: for Restriction 1, the production or placing on the market individually of the previous substances of the C9-C14 PFCAs family has not been allowed starting from 25 February 2023; for Restriction 2, the placing on the market and use of the components of the

PFCAs- C9-C14 family as constituents of another substance, their presence in a mixture and their presence in an article starting from 25 February 2023 is not allowed. unless the level of concentration in the substance, in the mixture or in the article is less than 25 ppb for the sum of the C9-C14 PFCAs and their salts or 260 ppb for the sum of the substances related to the PFCAs C9-C1. Restriction 2 ia applied without modifications and verifications according to the product type. In the “Restriction List” [7] for now there is only one PFAS, a C8 perchloroacid, but it is planned to also include perfluoroalkyl and perfluoroalkylsulfonic acids and their salts and derivatives [8]. Perfluoroalkyl acids and perfluoroalkylsulfonic acids, in addition to being restricted on the market by ECHA within the Reach convention, are also restricted by the Stockholm Convention on POP (Persistent Organic Pollutant) substances and by the European Commission on POPs.

There is also the list of substances present in the CoRAP document [9] (Community Rolling Action Plan), which includes those that have low toxicity or are only suspected to be toxic, but used in large quantities and with dispersive uses and, for this reason, under analysis by one of the European States, to verify their dangerousness and possible placement in the lists or definitively declare their non-dangerousness. In the list of CoRAP substances there are various PFAS substances, different from perfluoroalkyl acids, such as alkylperfluoroethers and an alkylperfluoroamide.

The “Registration List” [10] includes all the substances used in Europe, even the non-toxic ones, not present in the previous lists.

The “Preregistration List” [11] includes substances registered by a single company that are waiting for the interest of other companies to proceed with the official registration; these substances are not produced or imported into Europe or are produced in low quantities. This list includes several PFAS substances, as well as some perfluoroalkyl acids.

This article also includes two alkylperfluoroacids that are not present in the ECHA documents, but which could be inside products of extra-European origin, and therefore dispersed in the environment in Italy, which is why they are under investigation by the Italian Environmental Authorities.

PERFLUOROALKYL AND PERFLUOROALKYL SULFONIC ACIDS OF THE PFAS FAMILY

Together with perfluoroalkyl acids, some of their salts and related substances that must be considered equally toxic to the single acid are reported in the ECHA lists. These are those that present PFAS components within their structure that, when degraded, can emit perfluoroalkyl acids or perfluoroalkylsulfonic acids into the environment during their use and, above all, in their waste, therefore the family of toxic PFAS to be kept under control is greatly expanding [12]. This note mentions perfluoroalkyl acids (PFCAs) with carbon atoms from C2 to C16, perfluoroalkylsulfonic acids (PFSAs) with carbon atoms from C4 to C8 and two other acids with a more complex structure. For each substance, the acronym used in the various articles, the atomic composition and the name in Italian will be indicated first, then the name in English present in the ECHA documents, which most of the time is not a simple translation of the Italian one, to make it easier for readers to find other information on ECHA documents, by writing the English name of the individual PFAS on the web followed by “substance information ECHA”.

PERFLUOROALKYL ACIDS

PFEA (C₂F₃HO₂). Perfluoroacetic acid (trifluoroacetic acid) is not toxic, it is only present in the “Registration List” and is used as an intermediate.

PFPA (C₃HF₅O₂). Perfluoropropionic acid (pentafluoropropionic acid) is not toxic and is present only in the “Preregistration List”.

PFBA (C₄HF₇O₂). Perfluorobutanoic acid (heptafluorobutyric acid) is non-toxic and is only present in the “Preregistration List”.

PFPeA (C₅HF₉O₂). Perfluoropentanoic acid (perfluorovaleric acid) is non-toxic and is only present in the “Preregistration List”.

PFHxA (C₆HF₁₁O₂). Perfluorohexanoic acid (undecafluorohexanoic acid) is reported in the “Candidate List” together with its ammonium salt (PFHxA) and is considered a SVHC substance because it has toxicity equivalent to those toxic to humans CMR (cat. 1A and cat. 1B) and those equivalent to PBT substances toxic to the environment. Furthermore, on

12/06/2020, the Committee for European Socio-Economic Analysis (SEAC) proposed to include PFHxA and related substances in the “Restriction List”, therefore they can no longer be present in products on the market [13].

PFHpA (C₇HF₁₃O₂). Perfluoroheptanoic acid is toxic for reproduction of cat. 1B and is only present in the “Preregistration List”, for this reason it has not yet been considered a SVHC substance.

PFOA (C₈HF₁₅O₂). Perfluorooctanoic acid (pentadecafluorooctanoic acid), its salts and related substances are SVHC substances because they are toxic for reproduction of cat. 1B and PBT (and also carcinogenic of cat. 2). PFOA is also reported in the “Restriction List”, together with its salts and related substances, and is the only PFAS currently present in this list, with the name of “perfluorooctanoic acid”.

According to ECHA, the restrictions on the use of this PFAS and related substances are as follows: from 04/08/2020 they have been removed from the European market alone or as salts and cannot be present in products in concentrations >20 ppb, while substances related to PFOA cannot be present in products in concentrations >1000 ppb; from 04/07/2022 they cannot be present in equipment for the production of semiconductors and inks; from 04/07/2023 they cannot be present in products in concentrations >1000 ppb; from 04/07/2022 they cannot be present in equipment for the production of semiconductors and inks; from 04/07/2023 they cannot be present in products in concentrations >1000 ppb. ppb; from 04/07/2022 they cannot be present in equipment for the production of semiconductors and inks; from 04/07/2023 they cannot be introduced in medical textiles used for worker safety and in membranes for water filtration. Since July 2020, PFOA and related substances have also been included in the list of POP (Persistent Organic Pollutant) substances, under control by the Stockholm Convention and the European regulation for POP substances [14,15].

APFO (C₈H₄F₁₅NO₂). The ammonium salt of perfluorooctanoic acid (ammonium pentadecafluorooctanoate) is included in the Candidate List, separate from the acid, and is a SVHC substance because it is toxic for reproduction of cat. 1B and PBT and subject to restrictions like PFOA.

PFNA (C₉HF₁₇O₂). Perfluorononanoic acid (perfluorononanoic acid) and its sodium and ammonium salts are SVHC substances because they are toxic for reproduction of cat. 1B and PBT (also carcinogenic of cat. 2).

PFDA (C₁₀HF₁₉O₂). Perfluorodecanoic acid (nonadecafluorodecanoic acid) and its sodium and ammonium salts are SVHC substances because they are toxic for reproduction of cat. 1B and PBT (also carcinogenic of cat. 2).

PFUnDA (C₁₁HF₂₁O₂). Perfluoroundecanoic acid (hencosafluoroundecanoic acid) is a SVHC substance because it is vPvB.

PFDoDA (C₁₂HF₂₃O₂). Perfluorododecanoic acid (tricosafuorododecanoic acid) is a SVHC substance because it is vPvB.

PFTrDA (C₁₃HF₂₅O₂). Perfluorotridecanoic acid (pentacosafuorotridecanoic acid) is a SVHC substance because it is vPvB.

PFTDA (C₁₄HF₂₇O₂). Perfluorotetradecanoic acid (heptacosafuorotetradecanoic acid) is a SVHC substance because it is a vPvB.

PFPeDA (C₁₅HF₂₉O₂). Perfluoropentadecanoic acid (nonacosafuoropentadecanoic acid) is only toxic for reproduction cat. 2, it is not in the ECHA lists, therefore it is not present on the market in Europe.

PFHxDA (C₁₆HF₃₁O₂). Perfluorohexadecanoic acid (perfluoropalmitic acid) is not toxic and is only present in the “Preregistration List”.

PERFLUOROALKYLSULFONIC ACIDS

PFBS (C₄HF₉O₃S). Perfluorobutanesulphonic acid, its salts and related substances are all SVHC because they have toxicity equivalent to those toxic to humans CMR (cat. 1A and cat. 1B) and those equivalent to PBT substances harmful to the environment. Together with this acid, the “Candidate List” includes three other products: perfluorobutanesulfonyl fluoride (C₄F₁₀O₂S), perfluorobutane sulfonamide (C₇H₈F₉NO₃S) and triethylammonium perfluorobutanesulfonate (C₁₂H₂₀F₉NO₃S).

PFHxS (C₆HF₁₃O₃S). perfluorohexanesulfonyl acid (perfluorohexane-1-sulphonic acid) its salts and related substances are SVHC because they are vPvB. In the “Candidate List”, together with PFHxS, the following substances are also included: the ammonium salt, the potassium salt and the reaction product with an iminodiethanol. In addition, in the same ECHA list, 37 other related substances are reported together with PFHxS. It has recently been proposed to include PFHxS both in the list of POP substances [16] and in the “Restriction List” [17], with its salts and related substances, so their presence in products on the market should soon be eliminated.

PFHpS (C₇HF₁₅O₃S). Perfluoroheptanesulfonic acid (hepta-decafluorooctane-1-sulfonic acid) is not present in the list ECHA therefore it is not present on the market in Europe.

PFOS (C₈HF₁₇O₃S) is toxic for reproduction cat. 1B (also carcinogenic cat. 2 and toxic to the aquatic system cat. 2). Since 2010 it has been in the list of POP substances [15] and for this reason, although it is toxic, it has not been included in the "Candidate List" or in the "Restriction List" but is only present in the "Preregistration List". PFOS is included in the list of POPs together with its derivatives, i.e. **PFOSX (C₈F₁₇SO₂X; X= OH)**, salts, metals, halides, amides, polymers and other derivatives). The restrictions on PFOS and related substances are as follows: they must be present in products on the market in concentrations <0.001%; in textiles and paints in quantities <1 µg/m²; they may only be used in photographic material. Furthermore, the use of PFOS is prohibited by European legislation on cosmetics. In 2020, however, it was decided that PFOS can be used for metal plating in closed circuits [18].

OTHER PERFLUOROACIDS

HFPO-DA (C₆H F₁₁O₃). This PFAS is the reaction product between perfluoropropylene epoxide and a fluorinated alcohol [2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propionic acid], with its K⁺ and NH₄⁺ salts and acyl halides, because it has a toxicity equivalent to CMR substances (cat. 1A and cat. 1B) and toxicity equivalent to PBT substances.

cC6O4 (C₆HF₉O₆). Difluoro ([2,2,4,5-tetrafluoro-5-(trifluoromethoxy)-1,3-dioxolan-4-yl-oxy) acetic acid] is a substance that causes eye damage of cat. 1, STOT (Specific Target Organic Toxicity) cat. 2 and is currently only present in the "Registration List". Recently doubts have arisen about its low toxicity and in Spinetta Marengo, where it is produced in Italy, it is expected that it will soon be included by ECHA in the "Candidate List" [19].

USES OF SUBSTANCES FROM THE PFHxA FAMILY

The PFHxA family is used in the following products, which have been considered by ECHA due to the high risk of emissions to the environment: cleaning products, polishes for flooring, clothing and home textiles, cardboard food packaging, footwear and cosmetics, fire-fighting foam mixtures used in public places and in civil aviation [20]. In addition, the PFHxA family is also used in other products, not yet restricted by ECHA [17], including semiconductors, batteries and fuel cells

for green hydrogen, coatings of electronic devices, coatings of optical fibres, anti-fog visors, filtration and separation media, photographic coatings, medical devices (such as hearing aids, eye drops), personal protective equipment, fire-fighting foams used in industry, technical textiles and fabrics used in the engine compartment in the automotive and aerospace industries, as well as filtration and separation media for high-performance applications in air and liquids. Substances of the PFHxA family are also used in the production of fluorinated or perfluorinated polymers, both as monomers and as supporting additives in polymerization processes, as well as in fluoroelastomers, mainly used in petrol and diesel engines to increase heat and chemical resistance.

RECENT RESTRICTIONS IN THE ECHA AND EPA RESTRICTION LIST

The restrictions established by ECHA on the production, distribution and use of molecules of the PFHxA family are reported in the Restriction List [20,21]. The following members of the PFHxA family are listed separately at position 79 of the list [22]: undecafluorohexanoic acid, its salts and related substances, sodiumundecafluorohexanoate and undecafluorohexanoic acid in its ammonium salts.

The PFHxA family includes molecules that contain a linear or branched perfluoropentyl group (formula C₅F₁₁-) directly bonded to another carbon atom, or a linear or branched perfluorohexyl group (formula C₆F₁₃-). List 1 lists some molecules of the PFHxA family [17].

List 1 - Some molecules of the PFHxA family

- (Fluorohexyl) phenylphosphine
- Alkyl iodides, C6-18, perfluoro
- Ammonium undecafluorohexanoate
- Methyl undecafluorohexanoate
- Perfluorohexanoyl chloride
- Perfluorohexanoic anhydride
- 1-(Perfluorohexyl)docosane
- Trimethyl(tridecafluorohexyl)silane

The above denomination excludes molecules containing the following groups: C₆F₁₄, C₆F₁₃-C(=O)OH, C₆F₁₃-C(=O)O-X or C₆F₁₃-CF₂-X' (where X is any group, including salts); substances containing a perfluoroalkyl group C₆F₁₃- bonded to an oxygen

atom or to a non-terminal carbon atom, since, during their decomposition, they do not produce PFHxA; substances with a perfluoroalkyl group C_6F_{13} - bound to a sulphur atom, which are already prohibited in Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council.

More recently nine PFAS, List 2, were automatically added for reporting year 2025 due to US Environmental Protection Protection (EPA) [23] having finalized a toxicity value during 2024:

List 2 - Some molecules PFHxA for reporting year 2025 to EPA.

- Ammonium perfluorodecanoate (PFDA NH₄)
- Sodium perfluorodecanoate (PFDA-Na)
- Perfluoro-3-methoxypropanoic acid
- 6:2 Fluorotelomer sulfonate acid
- 6:2 Fluorotelomer sulfonate anion
- 6:2 Fluorotelomer sulfonate potassium salt
- 6:2 Fluorotelomer sulfonate ammonium salt
- 6:2 Fluorotelomer sulfonate sodium salt
- Acetic acid, [(γ - ω -perfluoro-C8-10-alkyl) thio] derivs., Bu esters.

The concentration limit values of substances of the PFHxA family present in products are uniform for all restrictions: the sum of PFHxA and its salts cannot exceed a concentration of 25 ppb, while the sum of PFHxA-related substances, measured in homogeneous materials, cannot exceed 1000 ppb.

From 10 October 2026, restrictions on the concentrations of substances from the PFHxA family will be introduced in the following sectors intended for sale to the general public: textiles, leather, fur (including clothing and rain jackets), waterproof accessories, consumer mixtures, such as waterproofing sprays, footwear, paper and cardboard in contact with food (e.g. pizza boxes), and in cosmetic products for leather. These restrictions do not apply to articles and mixtures placed on the market before 10 October 2026.

From 10 October 2027, restrictions on substances from the PFHxA family will also extend to textiles, leather, fur and hides, other than those intended for clothing and accessories for the general public. Again, the restrictions do not apply to articles placed on the market before that date. Furthermore, these restrictions do not apply to certain categories of use for

which there are currently no alternatives, such as personal protective equipment intended to protect against risks, medical and diagnostic devices made of glass, textile products used in construction (e.g. tents, stadium and pavilion roofing), reinforcements for road and bridge pavements, and thermal insulation or agricultural roofing materials.

From 10 April 2026, further restrictions are foreseen for substances of the PFHxA family on the use of fire-fighting foams and fire-fighting foam concentrates, used for training and testing, where safety is not compromised, with the exception of functional testing of fire-fighting systems, when all emissions are contained.

Finally, from 10 October 2029, further restrictions will be introduced on the use of fire-fighting foams and fire-fighting foam concentrates in the aviation sector and at civil airports.

CONCLUSIONS

All the PFAS that were reported in a document by ARPA Veneto on 19 November 2020 [3] and that were searched for in the Po area and Italian river basins [4], are precisely the perfluoroalkyl acids and perfluoroalkylsulfonic acids, mentioned in this note. However, only the perfluoroalkyl acids from C2 to C5 and from C15 and C16, described in this note, were not examined by ARPA Veneto, because, in addition to being not very toxic, they are little or not used in Europe. The Environmental Agency of the Veneto commemorates (World Water Day is celebrated on March 22nd) the day by remembering the great commitment made for the study and monitoring of the pollution caused by the perfluoroalchilic substances in the waters of the Veneto. At the end of 2020, the agency laboratories performed over 100 thousand PFAS analyzes

The perfluoroalkyl acids from C6 to C14 and PFHxA are all very toxic and are subjected to restrictions on their use in Europe [2], in the Reach Restrictions while PFOA that have been restricted in Reach regulation now are restricted as POP substances like PFOS. While PFHXS and PFHXA have been proposed to be considered POP substances.

The restrictions on undecafluorohexanoic acid (PFHxA), its salts and related substances (i.e. those which, due to their molecular structure, degrade or transform into PFHxA), were published on 19 September 2024 in a document of the European Parliament and of the Council [21] and on 20 September 2024 in the ECHA Restriction List [20], where they were inserted at position 79, the last one, at least until

13 November 2024, immediately after synthetic polymer microparticles. PFHxA is not registered or used in Europe, but its salts and several PFHxA-related substances are registered in quantities ranging from 1 to over 100 t/year.

The molecules of this family are dangerous because they are resistant to hydrolysis, photolysis and biodegradation; they are persistent in the environment and mobile in water, the latter being the main concern. Their use in certain products poses an unacceptable risk to human health and the environment. The current ECHA restrictions were proposed for products where these emissions cannot be adequately controlled, and where cost-effective alternatives exist. Substances in the PFHxA family are part of the PFAS (perfluoroalkyl and polyfluoroalkyl substances) family, which were already restricted a few years ago [22]. In this context, the reduction of PFHxA emissions represents a further step towards controlling PFAS. The PFHxA family has often been used as a substitute for other PFAS that are already banned, such as perfluorooctanoic acid.

PFHxA has been found to accumulate in agricultural crops and has been detected in house dust, soil, food products, and surface, ground and drinking water. Therefore, exposure is possible through inhalation of indoor and outdoor air, ingestion of drinking water and food, and skin contact with products containing PFHxA.

The restrictions imposed by ECHA on substances of the PFHxA family concern only uses for which the risk cannot be adequately controlled, and where alternatives are available with acceptable socio-economic costs compared to the benefits for public health and the environment. The high persistence of these chemicals contributes to the growing environmental pollution, particularly in water, and can lead to contamination even over long distances, exposing people to risks through drinking water, food and, in infants, also through breast milk. Interestingly, before the restrictions, some studies suggested that as an alternative to the use of fluorinated polymers [24], polymers based on itaconic, stearic or succinic acid could be used. Furthermore, recent research has highlighted the negative effects on fish health resulting from the presence of PFHxA in water [25].

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CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest.

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