EUROPEAN
COMMISSION

Brussels, XXX
SANTE/2561/2022 ANNEX
(POOL/E4/2022/2561/2561-EN
ANNEX.docx)
[…](2023) XXX draft

ANNEX

ANNEX

to the

COMMISSION IMPLEMENTING REGULATION (EU) .../...

approving ozone generated from oxygen as an active substance for use in biocidal products of product-types 2, 4, 5 and 11 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance[1]	Date of approval	Expiry date of approval	Product type	Specific conditions
Ozone generated from oxygen	IUPAC name: Ozone EC No: not applicable CAS No: not applicable	For ozone generated from the precursor oxygen supplied in containers, the following specifications apply: The purity of oxygen shall be at least 90% by volume fraction and the hydrocarbons content reported as methane equivalents (methane index) shall not exceed a volume fraction of 50 ppm. Depending on the production route of oxygen, oxygen may contain quantities of the following impurities: water, nitrogen, argon, carbon dioxide and other rare gases.	1 July 2024	30 June 2034	2	The authorisation of biocidal products is subject to the following conditions: (a) the product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance; (b) the product assessment shall pay particular attention to: (i) professional users; (ii) non-professional users; (iii) the secondary exposure of the general public.
					4	The authorisation of biocidal products is subject to the following conditions: (a) the product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance; (b) the product assessment shall pay particular attention to: (i) professional users; (ii) the secondary exposure of the general public; (c) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels (MRLs) need to be set or the existing MRLs

[1] The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

						need to be amended in accordance with Regulation (EC) No 396/2005[2] or Regulation (EC) No 470/2009[3] of the European Parliament and of the Council, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
					5	The authorisation of biocidal products is subject to the following conditions: (a) the product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance; (b) the product assessment shall pay particular attention to: (i) professional users; (ii) the secondary exposure of the general public; (c) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels (MRLs) need to be set or the existing MRLs need to be amended in accordance with Regulation (EC) No 396/2005 or Regulation (EC) No 470/2009 of the European Parliament and of the Council, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
					11	The authorisation of biocidal products is subject to the following conditions:

[2] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

[3] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

						(a) the product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance; (b) the product assessment shall pay particular attention to: (i) professional users; (ii) surface water following direct discharge of treated cooling water.