

Follow-up REACH, CLP and BPR Regulations and autonomous adaptation of Swiss chemicals legislation

Up-dated on May 30, 2019

This document gives an overview of the planned or effective amendments of the EU REACH, CLP and BPR regulations not yet considered in the most recent revisions of the Swiss legislation on chemicals.

Only the modifications officially published by EU (TBT notification, official journal) or the restriction proposals published for consultation (ECHA) are considered.

If possible, an estimation of possible adaptation of the Swiss legislation is given.

Situation of the Swiss Chemicals legislation on May 30, 2019:

Chemicals Ordinance (OChem, SR 813.11): Status as of 01.12.2018, considering REACH as last amended by Regulation (EU) n° 2017/706 (Annex VII and VIII REACH) [see Annex 4] and CLP as last modified by Regulation (EU) n° 2018/669 (11th ATP) [see Annex 2]. Annex 3 OChem considering ECHA list of SVHC as last amended by ECHA decision ED/61/2018. Regulation (EU) 440/2008 as last modified by Regulation (EU) 2017/735 [see annex 2]

Chemical Risk Reduction Ordinance (ORRChem, SR 814.81): Status as of 26.02.2019, considering REACH as last amended by Regulation (EU) 2018/675 [see annex 1.10]

Ordinance on Biocidal Products (OBP, SR 813.12): Status as of 1.12.2018, based on Regulation (EU) 528/2012 as last modified by Regulation 334/2014.

Ordinance on Procedures for the Enforcement of the ordinance on Biocidal Products (SR 813.121): Status as of 1.03.2018, considering Implementing Regulation (EU) 2016/1802.

| What | Date | EU intention /decision | Date | CH intention / decision |
|--|------------|---|------|--|
| Harmonised classification and labelling (annex VI CLP) | | | | |
| 13. ATP to CLP | 4.10.2018 | Commission Regulation (EU) 2018/1480 . New entries for 16 substances and 18 updates of existing entries are introduced into Annex VI of CLP. | | Subject of an ongoing revision of Annex 2 ChemO (expected in force mid 2019) |
| SVHC: Candidate list and annex XIV REACH | | | | |
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| Addition of 6 SVHC in the candidate list | 15/01/2019 | <i>Candidate list contains 197 substances</i> ECHA Decision ED 88/2018 | | Is considered in the next revision annex 3 OChem (expected in force mid 2019) |
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| Addition of 12 substances in Annex XIV | 13.6.2017 | <i>Authorization list contains now 43 substances</i> Commission Regulation (EU) 2017/999 | | Under evaluation |
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| Restrictions (annex XVII REACH) published | | | | |
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| Nonylphenol, branched and linear and Nonylphenol, branched and linear, ethoxylated | 14.01.2016 | <i>Placing on the market of textile clothing, fabric accessories and interior textile articles containing NP or NPE that can be washed in water.</i> Commission Regulation (UE) 2016/26 | | Subject of the latest revision of ORRChem (Federal Council decision of 17.4. 2019; in force June 2019) |
| Ammonium salts | 23.06.2016 | <i>prohibition of manufacture, placing on the market, import, sale and distribution of cellulose insulation materials with inorganic ammonium salts adjuvants</i> Commission Regulation (EU) 2016/1017 | | Subject of the latest ongoing revision of ORRChem (Federal Council decision of 17.4. 2019; in force June 2019) |

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| Chrysotile | 22.06.2016 | time-limited derogation for diaphragms containing chrysotile Commission Regulation (EU) 2016/1005 | | Subject of the latest revision of ORRChem (Federal Council decision of 17.4. 2019; in force June 2019) |
| Bisphenol A | 13.12.2016 | <i>restriction in thermal paper</i> Commission Regulation (EU) 2016/2235 | | Subject of the latest revision of ORRChem (Federal Council decision of 17.4. 2019; in force June 2019). Includes also a restriction for Bisphenol S in thermal paper. |
| Bis (pentabromophenyl)ether DecaBDE | 10.2.2017 | <i>Manufacture, use and placing on the market of DecaBDE and of mixtures and articles containing it.</i> Commission Regulation (EU) 2016/227 | | Subject of the latest revision of ORRChem (Federal Council decision of 17.4. 2019; in force June 2019) |
| PFOA and derivatives | 13.6.2017 | <i>Shall not be manufactured, used or placed on the market as substances on their own, as constituents of other substances, in a mixture or in articles.</i> Commission Regulation (EU) 2017/1000 | | Subject of the latest revision of ORRChem (Federal Council decision of 17.4. 2019; in force June 2019) |
| Methanol | 18.04.2018 | <i>Shall not be placed on the market to the general public in windscreen washing or defrosting fluids, in conc. $\geq 0,6\%$</i> COMMISSION REGULATION (EU) 2018/589 | | Subject of the latest revision of ORRChem (Federal Council decision of 17.4. 2019; in force June 2019) |
| Octamethylcyclotetrasiloxane (D4),Decamethylcyclopentasiloxane (D5) | 11.1.2018 | <i>Wash-off personal care products shall not contain more than 0.1% of D4, nor more than 0.1% of D5</i> Commission Regulation (EU) 2018/35 | | Subject of the latest revision of ORRChem (Federal Council decision of 17.4. 2019; in force June 2019) |
| Diisobutyl phthalate (DIBP), Dibutyl phthalate (DBP), Benzyl butyl phthalate (BBP), Bis(2-ethylhexyl) phthalate (DEHP) | 17.12.2018 | Restriction of the 4 phthalates in articles for used by the general public. Commission Regulation (EU) 2018/2005 | | Subject of the latest revision of ORRChem (Federal Council decision of 17.4. 2019; in force June 2019) |
| TDFAs: (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives | | Restriction covering use of a combination of perfluorinated silanes and one or more organic solvents in sprays used for the general public. Publication pending. | | Subject of the latest revision of ORRChem (Federal Council decision of 17.4. 2019; in force June 2019) |

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| Hazardous substances (CMR 1A and 1B) in textile articles and clothing for consumer use | 10.10.2018 | Restriction of certain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A or 1B Commission Regulation (EU) 2018/1513 | | Subject of a next revision of the Verordnung über Gegenstände für den Humankontakt (BLV) |
| 1-methyl-2-pyrrolidone (NMP) | 18.04.2018 | <i>Manufacturing, and all industrial and professional uses of the substance, where workers' exposure exceeds a level specified in the restriction.</i> COMMISSION REGULATION (EU) 2018/588 | | under evaluation |
| Restrictions under consideration | | | | |
| C9-C14 Perfluorocarboxylic acids(PFCAS), their salts and related substances (precursors) | 21.12.2018 | Restriction on the manufacturing of C9-C14 PFCAs, their salts and related substances and on their use, placing on the market and import as substances on their own, in mixtures or in articles. COM decision pending | | |
| Diisocyanates | 13.2.2019 | <i>Restriction concerning placing on the market or professional and industrial uses</i> COM decision pending | | |
| Lead compounds PVC | 21.12.2018 | <i>Restriction on the use of lead compounds to stabilise PVC and on the placing on the market of PVC articles stabilised with lead compounds</i> COM decision pending | | |
| Lead compounds Shot | 21.12.2018 | <i>Restriction on the use of lead and its compounds in shot (containing lead in concentrations greater than 1% by weight) within wetland</i> COM decision pending | | |
| Substances used in tattoo inks and permanent make-up | 21.12.2018 | Restricting the placing on the market of certain chemicals in tattoo inks and permanent make-up. on-going process by ECHA | | |
| Polycyclic-aromatic hydrocarbons (PAH) | 25.3.2019 | Restricting placing on the market of plastic, rubber and other granules containing PAHs above a set concentration limit for use as infill material on synthetic turf pitches or for use as loose granules or mulch on playgrounds and sport applications. on-going process by ECHA | | |

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| Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5); dodecamethylcyclohexasiloxane (D6) | 26.3.2019 | Leave on personal care products and other consumer/professional products (e.g. dry cleaning, waxes and polishes, washing and cleaning products) containing D4/D5/D6 in concentrations > 0.1% shall not be placed on the market. In addition, wash off and rinse off cosmetic products containing D6 in concentrations > 0.1% shall not be placed on the market. on-going process by ECHA | | |
| microplastics | 3.4.2019 | Restricting the use of intentionally added microplastic particles to consumer or professional use products of any kind. on-going process by ECHA | | |
| formaldehyde and formaldehyde releasers | 5.4.2019 | Restriction of formaldehyde and formaldehyde releasers in mixtures and articles for consumer uses on-going process by ECHA | | |
| cobalt carbonate; cobalt di(acetate); cobalt dichloride; cobalt dinitrate; cobalt sulphate | 7.3.2019 | Restricting the placing on the market of certain chemicals and use of professional and industrial use of the 5 cobalt salts where adequate control cannot be demonstrated. The restriction may also be implemented by imposing operational conditions and risk management measures. on-going process by ECHA | | |
| N,N-dimethylformamide | 10.4.2019 | Risk reduction for the general worker population on-going process by ECHA | | |
| Other adaptations to REACH | | | | |
| Commission regulation amending Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances | 4.12.2018 | Nanoforms are specifically addressed in the REACH annexes. OJ L 308/1 of 4.12.2018 | | deferred for the time being |
| Other adaptations to CLP | | | | |
| New Annex VIII CLP | 22.03.2017 | Commission Regulation (EU) 2017/542 of 22 March 2017 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on | | Only the UFI will be introduced into the OChem. |

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| | | classification, labelling and packaging of substances and mixtures by adding an Annex on harmonised information relating to emergency health response OJ L 78/1 of 23.3.2017 | | For mixture for private use with the Revision of 2018. The professional and industrial use is planned to be introduced in the OChem with the revision of OBP (foreseen date of entry into force 1.10.2020). |
| 12. ATP to CLP | 27.3.2019 | Commission Regulation (EU) 2019/521 . Introduces mainly the changes resulting from the 6. Rev. Ed. UN GHS 2015 and the 7. Rev. Ed. UN GHS 2017. | | Subject of an ongoing revision of Annex 2 ChemO (expected in force mid 2019). |
| Biocidal active substances | | | | |
| Approval and renewals of active substances | | All Commission Implementing Regulations approving and renewing active substances published in the European Union within August 2018 and February 2019. | | Adaptation of annex 2 OBP ongoing (expected in force mid 2019) |
| Amendment of the Reviewprogramme for notified active substances | | COMMISSION DELEGATED REGULATION (EU) 2019/157 of 6 November 2018 amending Annex II to Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council | | Adaptation of the list of notified active substances according to art. 9 (1) letter c OBP ongoing (expected in force mid 2019) |
| Amendment of the Reviewprogramme for notified active substances due to Brexit | | COMMISSION DELEGATED REGULATION (EU) 2019/227 of 6 November 2018 amending Delegated Regulation (EU) No 1062/2014 as regards certain active substances/product-type combinations for which the competent authority of the United Kingdom has been designated as the evaluating competent authority | | Adaptation of the list of notified active substances according to art. 9 (1) letter c OBP ongoing (expected in force mid 2019) |
| Non approval of active substances | 2018 | Commission Implementing Decision (EU) 2018/619 of 20 April 2018 not approving PHMB (1415; 4.7) as an existing active substance for use in biocidal products for product-type 1, 5 and 6 | | Non approval decisions are not adapted in Swiss law. The swiss notification authority will inform concerned Z _N /Z _B authorisation holders about the non approval decision. |

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| | | <p>Commission Implementing Decision (EU) 2018/622 of 20 April 2018 not approving Chlorophene as an existing active substance for use in biocidal products of product-type 3</p> <p>Commission Implementing Decision (EU) 2018/1251 of 18 Septembre 2018 not approving Empenthrine as an existing active substance for use in biocidal products of product-type 18</p> <p>Commission Implementing Decision (EU) 2018/1622 of 29 Octobre 2018 on the non approval of certain active substances in biocidal products</p> <p>Commission Implementing Decision (EU) 2018/1985 of 13 Decembre 2018 not approving <i>Willaertia magna c2c maky</i> as an existing active substance for use in biocidal products of product-type 11</p> | | |
| Commission Decisions according to article 3 (3) BPR | | | | |
| no decisions published up to May 2019 | | | | |
| Other adaption to BPR | | | | |
| no adaption up to May 2019 | | | | |