Annex 2 Substitution of hazardous substances

Sykehusinnkjøp focuses on substituting and reducing hazardous substances in products that are invasive, come into contact with patients, or substances that may be dangerous to the people who work with them, or make them.

Products as mentioned above shall meet all the requirements regarding chemicals of concern, as mentioned below[1]:

Homogenous materials[2] contained in a product must not contain more than 0,1 % by weigth of the following substances:

1. LATEX

2. SUBSTANCES ON THE EUROPEAN UNION CANDIDATE LIST* OF SUBSTANCES OF VERY HIGH CONCERN FOR AUTHORIZATION
   The Candidate List can be found at https://echa.europa.eu/candidate-list-table.

3. BISPHENOLS*
   **Bisphenol A and bisphenols with structural/functional analogues include bisphenol AP, bisphenol AF, bisphenol B (BPB), bisphenol C, bisphenol C2, bisphenol E (BPE), bisphenol F (BPF), bisphenol G, bisphenol M, bisphenol S (BPS), bisphenol P, bisphenol PH, bisphenol TMC, bisphenol Z, and 4-cumylphenol (HPP) or Bisphenol A derived chemicals. Bisphenol A is on the Candidate List.*

4. PVC (POLYVINYL CHLORIDE)

5. PHTHALATES listed on the Candidate List* or in Annex XVII** to REACH entry 51 and 52
   **The Candidate List can be found at https://echa.europa.eu/candidate-list-table.*
   ***Annex XVII to REACH entry 51 and 52 can be found at https://echa.europa.eu/substances-restricted-under-reach.*
   Phtalates that are included in REACH annex XVII, but that are not included in the candidate list are DINP, DIDP and DNOP.

6. ANTIMICROBIAL AGENTS
   Microbes are viruses, bacteria, mycobacteria, yeast, fungi and bacterial spores etc. Antimicrobial agents include aldehydes, including OPA, quaternary ammonium compounds, biguanide (PHMB) and chlorhexidine. The list is not exhaustive.

[1] Any exemptions from the requirements will be detailed in the tender document for the relevant procurement. Exemptions may apply if the substance is included in a product for medical reasons, and in cases where market research indicates that there are no available products without these substances.

[2] *Homogeneous material* means one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes, as defined in RoHS-2: Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (see article 3 (20)) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0065&from=EN