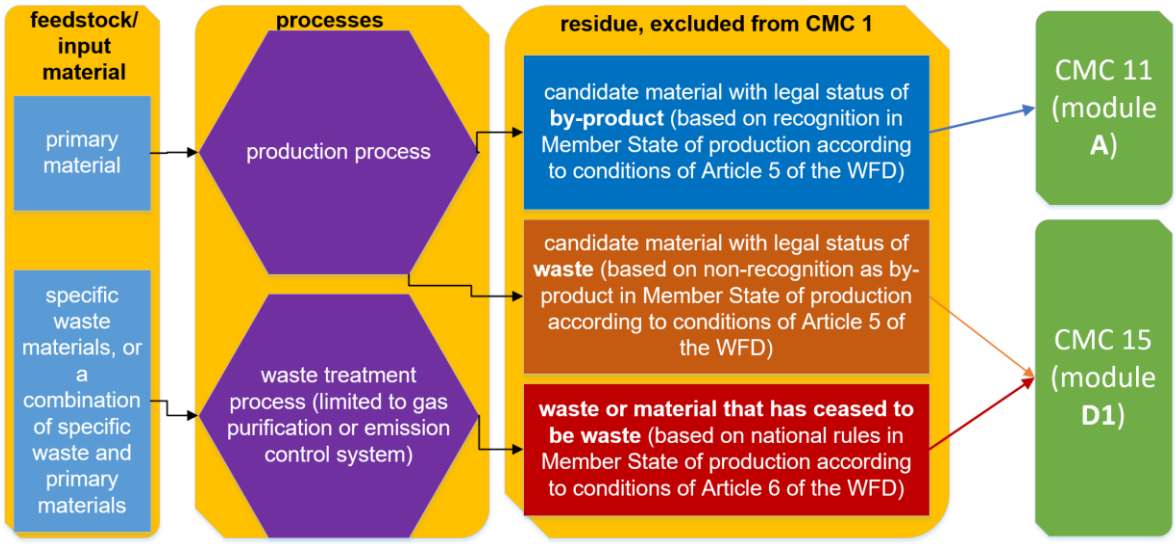
Annex 1

Additional explanations on the changes to the technical requirements in the JRC draft interim report

1 Classification of materials into CMC 11 and CMC 15[1]

COM: By-products of high purity are now included under Article 1, point (1) of CMC 11. The reason relates to the conformity assessment procedure. COM agrees with stakeholders that by-products within the meaning of Directive 2008/98/EC can be subject to conformity assessment module A. Annex IV, Part I, of the Fertilising Products Regulation (EU) 2019/1009 (FPR) indicates that module A can be applied to CMC 11 materials. For CMC 15, including high purity materials that are not recognised as by-products within the meaning of Directive 2008/98/EC, module D1 is then proposed (with requirements similar to other waste-derived CMCs, such as the STRUBIAS CMCs 12-14). This enables additional possibilities to place such materials on the market, even without a formal recognition as a by-product in the Member State of production, under a stricter conformity assessment regime.



In consideration of Article 42 of the FPR ('*Where the Commission adopts delegated acts in order to add or review component material categories so as to include materials that can be considered to be recovered waste or by-products within the meaning of Directive 2008/98/EC, those delegated acts shall explicitly exclude such materials from component material categories 1 and 11 of Annex II to this Regulation'),* an overlap between CMC 11 and CMC 15 is unwanted. After all, by-products that would meet the criteria of CMC 15, should in line with Article 42 be excluded from CMC 11, and thus be subject to the conformity assessment module D1 in line with the CMC 15 requirements.

[1] The CMC for high purity materials had in earlier drafts a working name CMC WW. Following recent progress on the file, it has been proposed to create an additional CMC (CMC 15: high purity materials) that will enable the placing on the market of EU fertilising products containing these component materials.

2 CMC 11

2.1 Scope

Taken into consideration the revised classification of materials into CMC 11 and CMC 15 (see above), CMC shall now include three different groups of materials:

- By-products of high purity (Article 1 – point 1);
- By-products used as technical additives, e.g. hardeners, binders (Article 1 – point 2);
- Designated other materials put on a positive list (Article 2)

2.2 Input materials - Article 1, point (1)

COM: Relative to the JRC Interim Report, point (a) has been rephrased by:

- including phosphate salts. While targeted phosphate salts (e.g. di-ammonium phosphate, magnesium ammonium phosphate) are also ammonium salts, these have been added to provide additional clarity to manufacturers;
- enabling mixtures of the different chemical compounds mentioned. In addition, some compounds, such as high-quality calcium sulphates from e.g. flue-gas desulphurisation systems, may also contain some impurities that do not cause adverse effects in the form of unreacted calcium carbonates. As such, also these compounds will be able to meet the proposed 95% threshold.

Some stakeholders have requested to further lower the 95% threshold and increasing the organic carbon limit (point (c)) indicating that it remains unclear if also materials for which no information could be collected are able to meet the threshold/limit. JRC can, however, base its analysis only on information received in response to its multiple data requests and publically available techno-scientific information. The JRC information base and technical assessment have been built with materials that meet these quality requirements, and further lowering quality standards would therefore involve a risk of overseeing certain contaminants. JRC found for instance, based on ECHA data, that some materials of lower purity may contain greater amounts of impurities (e.g. caprolactam in ammonium sulphate, up to 4.8%). Therefore, it is proposed to maintain the current 95% purity threshold as well as the 0.5% limit on organic carbon.

Point (b) clarifies that by-products under CMC 11 can only be derived from susbtances and mixtures, other than animal by-products and derived materials. The wording substances and mixtures also excludes waste materials. Some waste-derived and animal by-product derived materials will be covered under CMC 15.

2.3 Input materials - Article 1, point (2)

COM: This point refers to by-products used as technical additives (e.g. binders, hardeners) that do not provide nutrients to plants or mushrooms or improve their nutrition efficiency. These materials should not comply with minimum purity requirements or maximum organic carbon contents. However, they shall not be present in quantities greater than 5% by mass in the EU fertilising product. In addition, PAH and PCDD/F contents - two contaminants of main concern due to their persistence, bioaccumulative potential in the food chain, and toxicity – shall be limited (see section 2.5).

2.4 Input materials - Article 2, point (b)

COM: Relative to the JRC Interim Report, the text has been rephrased as follows:

- The reference to "containing exclusively biodegradable processing residues" has been excluded as the current text of CMC 11 in the Regulation already excludes non-biodegradable polymers;
- Magnesium oxide and phosphate salts have been added, as these may be formed as by-products from magnesium ore pressing and e.g. present-day state-of-the art ore processing techniques[2], respectively.

2.5 Criteria for persistent organic pollutants (Article 1, point 1(d)(e); point 2(c)(d))

COM: In the JRC Interim Report, criteria had been proposed for three different classes of persistent organic compounds (POPs): polyaromatic hydrocarbons (PAHs), summed polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (PCDD/Fs + dl-PCBs), and particular perfluorinated compounds (perfluorooctane sulfonic acid and its derivatives (PFOS) and Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds).

The general principle applied for POPs for CMC 11 is based on the fact that the FPR, Regulation (EU) 2019/1021 on persistent organic pollutants and the REACH Regulation apply in parallel. Therefore, requirements on POPs are only required for CMC 11 when no criteria apply to a specific POP present as an unintentional trace contaminant in a substance or mixtures.

Regulation (EU) 2019/1021 on persistent organic pollutants includes prohibitions for the manufacturing, placing on the market and use of intentionally produced substances (PFAS, PCBs). For PFAS, the prohibitions also apply to substances, mixtures and articles that have PFOS and PFOA present as an unintentional trace contaminant above a threshold value of 10 mg kg^{-1} and 0.025 mg kg^{-1}, respectively. In addition, a phased restriction on a broader subset of around 200 linear and branched perfluorocarboxylic acids (PFCAs) substances, a PFAS sub-group, containing 9-14 carbon atoms, their salts and related substances, has been adopted in August 2021 (Regulation (EU) 2021/1297 amending Annex XVII to Regulation (EC) No

[2] See https://www.phosphorusplatform.eu/espp-members/1579-easy-mining

1907/2006). The latter Regulation limits C9-C14 PFCAs in substances and mixtures to concentrations below 0.025 mg kg^{-1}. Restrictions will begin to take affect as of February 2023 under Annex XVII of REACH. Finally, the new European Chemicals Strategy has announced the EU's ambitious plans to ban all non-essential uses of PFAS.

PFAS are widely used in industrial processes and consumer goods, but the production processes that give rise to the known CMC 11 candidate materials do not use PFAS in their production process. This knowledge base of candidate materials that will be placed on the market in large tonnages is well developed. Hence, only certain by-products produced in low tonnages (e.g. a limited set of high purity materials and by-products added for technical reasons at low concentrations in EU Fertilising Products, as per Article 1, point (1) and (2)) could theoretically contain minor amounts of PFAS. For PFOA – a main PFAS compound of regulatory interest - the abovementioned limits in recent EU Regulation (Regulation (EU) 2021/115 and Regulation (EU) 2021/1297) are more restrictive than legislations for fertilising products in EU Member States (0.1 mg/kg dw for the sum of PFOS and PFOA in AT and 0.5 mg/kg dw for PFAS in general in DE). PFOS has been restricted in the EU since 2006, for which present-day use of PFOS in the EU as well as its presence in by-products is not expected.

Altogether, PFAS is already effectively dealt with in other EU legislations, and therefore imposing additional requirements for these intentionally produced chemicals under the FPR without a detailed risk assessment seems not pertinent due to risks of introducing non-aligned legislations on PFAS restrictions. Therefore, no criteria on PFAS, additional to the ones already taken up in the abovementioned Regulations, are proposed in the revised criteria proposals.

PCBs had widespread use in numerous industrial applications, but were banned since long in most countries. It is thus improbable that PCBs may end up in by-products. As a matter of fact, the POPs Regulation (Annex I) excludes the presence of PCBs in products. Therefore, no criteria have been proposed for the (out-phased) intentionally produced chemicals.

Regulation (EU) 2019/1021 encompasses release reductions for PAH and PCDD/Fs as unintentionally produced substances during manufacturing and combustion processes. However, no limit values applies to products that are placed on the market as part of Annex I of that Regulation. PAH and PCDD/F could, however be present in various CMC 11 materials. Therefore, and in the absence of a more detailed risk assessment, it is proposed to maintain the limit values for PAH and PCDD/F as applicable to other CMCs of the FPR, more specifically CMC 13 (thermal oxidation materials or derivates):

- 6 mg kg^{-1} dry matter of polyaromatic hydrocarbons (PAH_{16})[3];
- 20 ng WHO toxicity equivalents kg^{-1} dry matter of the summed polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) (PCDD/Fs)[4]

[3]Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.

[4] Sum of 2,3,7,8-TCDD, 1,2,3,7,8-PeCDD; 1,2,3,4,7,8-HxCDD; 1,2,3,6,7,8-HxCDD; 1,2,3,7,8,9-HxCDD; 1,2,3,4,6,7,8-HpCDD; OCDD; 2,3,7,8-TCDF; 1,2,3,7,8-PeCDF; 2,3,4,7,8-PeCDF; 1,2,3,4,7,8-

2.6 Metals – selenium and chromium

COM: Requirements were proposed for selenium, total chromium, vanadium and thallium in the JRC draft interim report.

With respect to selenium, stakeholders indicated its importance as a micronutrient, as well as the low limit value proposed. Many crops grown in the EU show relatively low Se concentrations possibly leading to dietary Se deficiencies (Haug et al., 2007). Therefore, it is proposed to remove the limit value from the compliance scheme, and to introduce a labelling requirement for certain by-products with a Se content higher than 10 mg kg^{-1} dry matter (Article 4).

Some stakeholders also requested a review of the criteria for other metals, mostly on total chromium, for steel slags (see Article 2, point (f)). The JRC has revisited the assessment, without further changes to the criteria proposed.

We have analysed a scenario of continuous application of 5 tonnes ha-1 yr-1 of slags during a long-term period, at the proposed limit value of 400 mg kg^{-1} for Cr (100 years). Based on EUSES modelling calculations (REACH R.16, 2016), this would result in an additional Cr accumulation in soils of 57-59 mg kg^{-1} of soil, depending on the soil pH and related soil-water adsorption coefficient. This value is about two times higher than current median soil Cr(total) concentrations of 33 mg kg^{-1}, and further increase the soil concentrations up to 92 mg kg^{-1} of soil. The projected increase in total Cr content is in line with observations that indicated the accumulation of Cr in soils following long-term applications of steel slags (e.g. Algermissen et al., 2016).

Firstly, it is indicated that several EU Member states have soil quality standards (in the form of so-called soil screening values, thresholds that are considered as being of concern to Member States for differing reasons) (Carlon, 2007). AT, BE (Wallonia), FI, DK, and LT have established soil screening values for Cr(total) in between 50 (AT, DK) and 125 (BE) that may be reached or exceeded following long-term application of materials containing 400 mg kg^{-1} total Cr. Enabling higher concentrations could therefore lead to Cr accumulation in soils that is beyond the desirable levels by some Member States.

Secondly, a predicted no-effect concentration (PNEC) for chromium (III) of 3.2 mg Cr/kg dry soil has been indicated (EU RAR, 2005). It should be noted that the PNEC for chromium (III) is derived from experiments where a highly soluble (and hence bio-available) form of chromium (III) has been tested. In natural soils, the majority of chromium will be present as low solubility chromium (III) complexes (in either soil or slag residues), with a limited bioavailability. The bio-available fraction of Cr(total) in soils has been estimated at around 0.02-3.1% of the total soil Cr content, depending on the sample and extractant applied to estimate the "bio-available" fraction (Agrelli et al., 2020; Leśniewska et al., 2017). In case a maximum value of 3.1% would be applied, the estimated bio-available Cr fraction (2.9 mg

HxCDF; 1,2,3,6,7,8-HxCDF; 1,2,3,7,8,9-HxCDF; 2,3,4,6,7,8-HxCDF; 1,2,3,4,6,7,8-HpCDF; 1,2,3,4,7,8,9-HpCDF; and OCDF.

Cr/kg dry soil) would be close to the PNEC value (risk ratio of 0.89). Risks for aquatic organisms are much smaller, mostly due to the high Cr absorption in soil and the low bio-available Cr fraction in the slags. Under normal soil conditions, the transformation of Cr (III) into Cr (VI) also appears to be highly unlikely, indicating overall low risk for humans from toxic Cr(VI).

In conclusion, evidence indicates that long-term application of steel slags might lead to accumulation in soils above or close to levels that have been identified by Member States as being of concern. In addition, soil organisms might be at risk when a small amount (3.1%) of the Cr(III) in soils and/or steel slags becomes available to them. Hence, the JRC proposes a limit value of 400 mg kg^{-1} for steel slags to ensure that EU fertilising products that are placed on the market are safe and not subject to Member State concerns.

Alternative options for criteria setting proposed by the COM expert group have been evaluated. On the one hand, some organisations have challenged the setting of limit values for Cr(total), dominantly including Cr(III). Nonetheless, based on the establishment of soil quality indicators by Member States, it was judged that confidence in EU fertilising materials is critical. We understand the argument from specific Member States that reject the use of Cr-rich fertilising materials that may jeopardise the quality of their soils. Moreover, it is noted that the optional harmonisation principle enables Member States to enable the use of materials with higher Cr concentrations on their territory based on national rules. On the other hand, different organisations and Member States have called for stricter limit values (e.g. 100 mg Cr(total) kg^{-1}), in line with their existing regulatory standards. The JRC has not followed their proposals because the material-specific properties of steel slags. For these materials, Cr is strongly bound in a matrix and the Cr bio-availability is therefore lower compared to other Cr-containing materials, such as sewage sludge. Therefore, and already accounting for a 3.1% bioavailability as a worst case scenario, the JRC proposes a higher limit value of 400 mg kg^{-1}, specific for these materials.

2.7 Chloride ions (Article 4(b))

COM: A limit value for chloride ions was proposed in the JRC Interim Report with a view to limit the build-up of soil salinity, and in more extreme cases, chloride toxicity. The basis for this proposed criterion was that some by-products could contain chloride as an impurity. This was mainly the case for the post-distillation liquid from Solvay process (estimated Cl^- content of 1-10%), whereas other by-products (e.g. humic/fulvic acids from drinking water production, mineral processing residues, flue-gas desulphurisation gypsum) contain lower levels of chloride (estimated Cl^- content of less than 3%).

In addition, the most common fertiliser containing chloride is KCl (muriate of potash), which contains 47% chloride and is a fertiliser that applied in large volumes (> 2-3 million tonnes in the EU). These amounts of KCl fertilisers thus largely outweigh any production volumes of the above-mentioned tonnage of by-products that will be placed on the market as EU fertilising products. Moreover, the ions responsible for soil salination are not only Cl^-, but also Na^+, K^+, Ca^{2+}, Mg^{2+} and Cl^-. Actually, Cl^- will leach more easily in soils compared to the positively

charged cations. These observations suggest that Cl- toxicity is under most conditions not problematic and/or toxic.

It is proposed to set a labelling provision instead of a limit value for Cl^- to control for soil salination and Cl^- plant toxicity.

2.8 Other contaminants

COM: Apart from the contaminants indicated in the paragraphs above, a wider set of organic (mineral oil hydrocarbons, methyl mercaptan, acrylamide, acrylonitrile, acetaldehyde, crotonaldehyde, methacrylamide, dimethyl disulphide, carbon disulphide, and solvent such as benzene, toluene, and others) and inorganic (free cyanides) contaminants was proposed in the initial draft criteria proposals. After a more thorough review, and based on comments from the stakeholders of the Commission Expert Group, following issues are noted:

- Whereas most of these substances had been identified as intermediates in production processes, there is no factual evidence that indicates their presence in the by-product that will be placed on the market, neither in scientific literature nor in data collected from the stakeholders. A main reason is that the overall share of the materials where these substances could be present are materials of high-purity that have undergone chemical processing and purification steps to remove these substances form the final materials. The criterion on a maximum organic carbon content (<0.5%) in by-products is an additional criterion that leverages the use of such advanced processing techniques that limit organic substances in the by-products. In addition, these identified pollutants are typically highly volatile for which reason they will likely be removed from the by-product prior to application on land. The draft criteria were thus proposed based solely on the precautionary principle;
- Even if these substances were present in EU fertilising products, substance concentrations are expected to quickly decline to the natural background levels. Low residence times observed in soils have e.g. been indicated for volatile organic compounds used as solvents, acrylonitrile, free cyanide, methyl mercaptan, and carbon disulphide (ATSDR, 1992; EFSA, 2014; EFSA et al., 2019; EFSA Panel on Contaminants in the Food Chain, 2012; EU RAR, 2004; Koster, 2001; WHO, 2002);
- Other compounds (e.g. acetaldehyde, dimethyl disulphide) are naturally contained in food in concentrations that exceed the limit values proposed in the draft criteria (EFSA et al., 2019; Uebelacker and Lachenmeier, 2011);
- A preliminary JRC screening risk assessment and available risk information (i) did not indicate any risks to human health, and/or (ii) showed that other pathways of human intake are much more relevant relative to fertilisers (Eder et al., 1999; EFSA, 2014; EFSA et al., 2019; Koster, 2001; WHO, 2002). Particularly, this was the case for acrylamide, cyanides, dimethyl disulphide, acetaldehyde, crotonaldehyde, and carbon disulphide.
- Available information on the sensitivity of soil organisms to most of these compounds is limited, and mostly estimated using data for aquatic organisms. In order to establish

limit values for these compounds, a more extensive ecological risk assessment would be required to ensure that no unnecessary requirements are set on by-products that can be used in agriculture, and how alternative use routes compare in terms of environmental and socio-economic impacts. This holds particularly true given the lack of persistence of these susbtances in soils.

- The main objective of this work is focused on harmonising requirements for by-products that are currently placed on the market using the outgoing (EC) 2003/2003 framework and/or national rules. With the exception of volatile monocyclic aromatic hydrocarbons (BE) and mineral oil hydrocarbons (BE, NL), EU Member States have not introduced limit values for these identified substances. Rather than harmonising criteria, the Regulation would thus introduce new requirements.
- International standards to measure these susbtances in different types (solid, liquids) of EU fertilising products are mostly unavailable.

It is indicated that insufficient evidence is available to include these substances in the compliance scheme. Therefore, it is proposed not to include any criteria on the substances in the compliance scheme for CMC 11.

2.9 Nanomaterials

COM: a criterion on nanomaterials was introduced to limit certain substances that could be present as nanomaterials (diiron trioxide, titanium dioxide, silica). After a more thorough review, the JRC proposes the remove this requirement because the Commission Communication on the Second Regulatory Review on Nanomaterials[5] concluded that Regulation (EC) No 1907/2006 sets the best possible framework for the risk management of nanomaterials when they occur as forms of substances or mixtures. Hence, Commission Regulation (EU) 2018/1881 was published to address nanomaterials and nanoforms of substances falling under REACH, and more specifically with the purpose to clarify registration duties for nanomaterials under REACH. In addition, national legislation in EU Member States also does not focus on nanomaterials in fertilising products. Overall, and to avoid conflicting requirements within EU Regulations, no additional criteria on nanomaterials in the FPR are proposed.

2.10 Storage time and conditions

COM: In its Interim Report, the JRC included criteria to ensure good management during material storage as well as a maximum storage time. The criterion on maximum storage time is mainly related to the Waste Framework Directive conditions on “certainty of further use” for by-products (Article 5). Such conditions that may not be compatible with an unlimited storage time. Limiting storage to a maximum time would also evade that certain materials of low market demand (e.g. because regionally supply exceeds agricultural demand) are stacked as EU Fertilising “Products”.

[5] COM(2012) 572 final.

On the one hand, stakeholders argue that a legislation that regulates the placing on the market should not focus on storage conditions. On the other hand, the maximum storage time was considered unpractical and redundant for many materials.

The JRC follows the arguments related to criteria that focus on storage conditions and adverse environmental effects thereof. Other regulatory instruments (e.g. Industrial Emissions Directive 2010/75/EU and best available techniques) may be more suitable. In addition, the criterion on maximum storage time may be redundant for this CMC as all by-products ought to be recognised within their Member State of production, and should thus comply with conditions of Article 5 of the Waste Framework Directive. Therefore, these criteria have been removed from the criteria proposals.

3 CMC 15

3.1 Minimum purity – point (1)

The purity requirements are aligned to these of high purity byproducts. It is referred to section 2.2 for the rationale of this criterion.

3.2 Input materials – point (2)(b)

COM: In comparison to the JRC Interim Report, the text has been slightly reformulated based on stakeholder comments. The revised formulation focusses on the process and its intention of nutrient recovery, rather than to make an explicit reference to "capturing off-gases". It could then further be clarified in the FAQ that aqueous droplets and unintentionally present dust particles are considered part of the off-gases. The formulation also makes clear that the focus is on off-gases, and not on fly ash, dust filter/cyclone systems, etc.

In sub-point (iii)

COM: The criteria proposals of the interim report excluded waste waters that display hazardous properties as per Annex III of Directive 2008/98/EC. However, waste waters would not be subject to waste classification according to Annex III of the WFD. Therefore, the reference to hazardous properties has been deleted. To limit potentially more contaminated waste waters from industrial facilities, the reference to "industrial wastewaters" has been removed. Based on stakeholder input, it is understood that recovery of high purity materials is envisaged at municipal waste water treatment plants, but not at dedicated industrial waste water treatment plants that do not treat urban or domestic waste waters.

Sub-point (v)

COM: this point has been rephrased in response to stakeholder comments. The intention is to include e.g. materials recovered from desulphurisation systems of co-incineration plants that take in some non-hazardous waste.

3.3 Persistent organic pollutants – Point (4)

COM: Criteria were only proposed for PAH and PCDD/F, but not for PCBs and PFAS.

Similar as for CMC 15, the general principle applied for POPs is based on the fact that the FPR, Regulation (EU) 2019/102 on persistent organic pollutants (POPs Regulation) and the REACH Regulation apply in parallel. Therefore, requirements on POPs are only required for CMC 15 when no criteria apply to a specific POP present as an unintentional trace contaminant in a substance or mixtures.

PAH: The POPs Regulation encompasses release reductions for PAH as unintentionally produced substances during manufacturing and combustion processes. However, no limit values applies to products that are placed on the market as part of Annex I of that Regulation. PAH could, however be present in various CMC 15 materials. Therefore, and in the absence

of a more detailed risk assessment, it is proposed to maintain the limit values for PAH as applicable to other CMCs of the FPR (6 mg kg^{-1}).

PCDD/F: Article 7(4) of the POPs Regulation indicates that waste containing or containing or contaminated by PCDD/F listed in Annex IV may be otherwise disposed of or recovered in accordance with the relevant Union legislation, provided that the content of the listed substances in the waste is below the given concentration limits specified in Annex IV. Whereas thus in principle the POPs Regulation should control for PCDD/Fs in waste (including CMC 15), it remains debatable as to whether the limit value indicated in Annex IV of the POPs Regulation (15 µg/kg) is protective enough. Therefore, COM introduce the criteria of 20 ng TEQ PCDD/F kg-1 (aligned to CMC 11) in the criteria.

The POPs Regulation (Annex I) already excludes the presence of PCBs in products. Therefore, no criteria have been proposed for the (out-phased) intentionally produced chemicals.

PFAS could be present in waste materials used as input materials, but most hazardous long-chain PFAS, and especially perfluoroalkyl carboxylic acids such as PFOS, are hardy volatile (Prevedouros et al., 2006). This suggests the low potential for PFAS to be removed from aqueous media by air stripping. Together with the existing legislation on PFAS (POPs and REACH Regulation), and particularly perfluoroalkyl carboxylic acids such PFOA (outlined in section 2.5), this indicates that risks from PFAS for CMC 15 materials are well controlled. In line with criteria on persistent organic pollutants for CMC 11 (section 2.5), the abovementioned requirements are therefore proposed.

3.4 Metals – Point (5)

COM: Scrubbing slurries and calcium sulphates from flue-gas desulphurisation system may contain high levels of Cr(total) and Tl, and were therefore retained in the criteria for CMC 15.

3.5 Storage time and conditions – Point (8)

COM: Certain CMC 15 materials that are produced in quantities exceeding market demands may be stored without a clear final use (e.g. calcium sulphates). The criterion on maximum storage time is mainly related to the Waste Framework Directive conditions the “existence of a market or demand” (end-of-waste; Article 6); unlimited storage time may not be compatible with these legal demands. Limiting storage to a maximum time would evade that certain materials of low market demand (e.g. because regionally supply exceeds agricultural demand) are stacked as EU Fertilising “Products”. Compared to the proposals of the Interim Report, the JRC has modified this criterion by focusing solely on materials that are stockpiled outdoors and increased the maximum storage time from 18 to 36 months.

The criterion of good storage conditions has been removed as JRC agrees with the stakeholders that other regulatory instruments (e.g. Industrial Emissions Directive 2010/75/EU and best available techniques) may be more suitable to regulate proper storage conditions.

3.6 Labelling: Chloride and selenium - Annex II

COM: Based on the evaluation and arguments of chloride and selenium limits for CMC 11 materials (see section 2.6 and 2.7), it is similarly proposed to rely on labelling requirements (instead of limit values as proposed in the JRC Interim Report) for selenium and chloride.

3.7 Other contaminants

COM: A wider set of organic and inorganic contaminants was proposed in the initial draft criteria proposals. Most of these contaminants have been assessed during a more thorough review for CMC 11, taking into consideration the comments from the stakeholders (see section 2.8). Since the same arguments of that assessment are also valid for CMC 15, no limit values for these substances are proposed in the revised criteria for this CMC.

In addition, three additional substances were identified that are only relevant for CMC 15: limonene, p-cymene, and siloxanes.

Following application, limonene and p-cymene and d-limonene residues are expected to quickly decline to the natural background levels and setting of maximum residue levels in materials applied to land was therefore considered unnecessary (EFSA, 2014). Therefore, no criteria were proposed to limit such substances in CMC 15.

Siloxanes are volatile and have somewhat larger residence time in soils (Panagopoulos and MacLeod, 2018), flagging them as potentially relevant for this CMC. Risk assessment reports identified, however, no ecological or health risks to humans exposed via the environment from the use of D4 and D5, although uncertainties remain (Brooke et al., 2009a, 2009b; Fairbrother et al., 2015). In addition, some uses of the three siloxanes (D4, D5, D6), formerly ingredients in personal care and cleaning items, are already restricted in consumer products in the European Union (e.g. wash-off cosmetics since 2020). Given that some commercial applications of these substances remain, including use in leave-on cosmetics, ECHA has further proposed in the year 2019 a broader restriction, which would ban the use of D4, D5 and D6 in consumer and professional products and in dry cleaning solvents that contain them in concentrations of more than 0.1% weight-by-weight. In June 2020, the agency published the consolidated opinion of its Committees for Risk Assessment and Socio-Economic Analysis, supporting the proposal. This provides possibilities for the addition of the three substances to the REACH authorisation list (Annex XIV), if supported by the Commission, Parliament and Council. Based on the risk assessment and further actions undertaken in the current regulatory context, no criterion is proposed for siloxanes for CMC 15.

References

Agrelli, D., Caporale, A.G., Adamo, P., 2020. Assessment of the Bioavailability and Speciation of Heavy Metal(loid)s and Hydrocarbons for Risk-Based Soil Remediation. Agronomy . doi:10.3390/agronomy10091440

Algermissen, D., A. Morillon, K.-J. Arlt, N. Wolsfeld, M. Rex, M. Mauhart, H. Spiegel, T. Lehtinen, A., T., Branca, V. Colla, G. Ragaglini, C. Pistocchi, S. Tuo-Mikoski, S., 2016. Impact of long-term application of blast furnace and steel slags as liming materials on soil fertility, crop yields and plant health (SLAGFERTILISER). European Commission,

Research Programme of the Research Fund for Coal and Steel, TG9, 1. Juli 2011 - 30.

ATSDR, 1992. Toxicological profile for methyl marcaptan.

Brooke, D.N., Crookes, M.J., Gray, D., Robertson, S., 2009a. Environmental Risk Assessment Report: Decamethylcyclopentasiloxane.

Brooke, D.N., Crookes, M.J., Gray, D., Robertson, S., 2009b. Environmental Risk Assessment Report: Octamethylcyclotetrasiloxane.

Carlon, C., 2007. Derivation methods of soil screening values in Europe - a review and evaluation of national procedures towards harmonisation. European Commission, Joint Research Centre, Ispra, EUR 22805-EN, 306 pp.

Eder, E., Schuler, D., Budiawan, 1999. Cancer risk assessment for crotonaldehyde and 2-hexenal: an approach. IARC Science Publications 150, 219–232.

EFSA, 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance terpenoid blend QRD-460. EFSA Journal 12, 3816. doi:https://doi.org/10.2903/j.efsa.2014.3816

EFSA, Anastassiadou, M., Arena, M., Auteri, D., Barmaz, S., Brancato, A., Bura, L., Carrasco Cabrera, L., Chaideftou, E., Chiusolo, A., Court Marques, D., Crivellente, F., De Lentdecker, C., Egsmose, M., Fait, G., Ferreira, L., Greco, L., Ippolito, A., Istace, F., Jarrah, S., Kardassi, D., Leuschner, R., Lostia, A., Lythgo, C., Mangas, I., Miron, I., Molnar, T., Padovani, L., Parra Morte, J.M., Pedersen, R., Reich, H., Santos, M., Serafimova, R., Sharp, R., Stanek, A., Streissl, F., Sturma, J., Szentes, C., Terron, A., Tiramani, M., Vagenende, B., Villamar-Bouza, L., 2019. Peer review of the pesticide risk assessment of the active substance dimethyl disulfide. EFSA Journal 17, e05905. doi:https://doi.org/10.2903/j.efsa.2019.5905

EFSA Panel on Contaminants in the Food Chain, 2012. Scientific Opinion on Mineral Oil Hydrocarbons in Food. EFSA Journal 10, 2704. doi:https://doi.org/10.2903/j.efsa.2012.2704

EU RAR, 2005. chromium trioxide, sodium chromate, sodium dichromate, ammonium dichromate, potassium dichromate - Risk assessment.

EU RAR, 2004. Acrylonitrile. Risk assessment - final report.

Fairbrother, A., Burton, G.A., Klaine, S.J., Powell, D.E., Staples, C.A., Mihaich, E.M., Woodburn, K.B., Gobas, F.A.P.C., 2015. Characterization of ecological risks from environmental releases of decamethylcyclopentasiloxane (D5). Environmental Toxicology and Chemistry 34, 2715–2722. doi:https://doi.org/10.1002/etc.3041

Haug, A., Graham, R.D., Christophersen, O.A., Lyons, G.H., 2007. How to use the world's scarce selenium resources efficiently to increase the selenium concentration in food. Microbial Ecology in Health and Disease 19, 209–228. doi:10.1080/08910600701698986

Koster, H.W., 2001. Risk assessment of historical soil contamination with cyanides: origina, potential humna exposure and evaluation of intervention values. RIVM report 711701019.

Leśniewska, B., Gontarska, M., Godlewska-Żyłkiewicz, B., 2017. Selective Separation of Chromium Species from Soils by Single-Step Extraction Methods: a Critical Appraisal. Water, Air, & Soil Pollution 228, 274. doi:10.1007/s11270-017-3459-5

Panagopoulos, D., MacLeod, M., 2018. A critical assessment of the environmental fate of

linear and cyclic volatile methylsiloxanes using multimedia fugacity models. Environmental Science: Processes & Impacts 20, 183–194. doi:10.1039/C7EM00524E

Prevedouros, K., Cousins, I.T., Buck, R.C., Korzeniowski, S.H., 2006. Sources, Fate and Transport of Perfluorocarboxylates. Environmental Science & Technology 40, 32–44. doi:10.1021/es0512475

REACH R.16, 2016. Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation, February 2016.

Uebelacker, M., Lachenmeier, D.W., 2011. Quantitative determination of acetaldehyde in foods using automated digestion with simulated gastric fluid followed by headspace gas chromatography. Journal of Automated Methods & Management in Chemistry 2011, 907317. doi:10.1155/2011/907317

WHO, 2002. Carbon disulfide - Concise International Chemical Assessment Document 46.