EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Ecosystems I: Chemicals, Food, Retail
Bioeconomy, Chemicals & Cosmetics

Brussels,
GROW.F.2/BL

Working Group on Cosmetic Products

FRIDAY 17 MARCH 2023

09:30 – 13:00

MINUTES

1. ADOPTION OF THE AGENDA

The Working Group approved the agenda of the meeting.

2. ADOPTION OF MINUTES OF THE MEETING OF 8 NOVEMBER 2022

The Working Group adopted the minutes of the March Working Group meeting with a small correction from SE.

3. REGULATIONS TO BE VOTED IN THE COMMITTEE

The Commission informed the members of the WG that the draft Regulations concerning the fragrance allergens labelling and the Omnibus VI on CMR substances will be put on vote in the Standing Committee meeting that scheduled in the afternoon.

CE thanked COM for preparing the draft Regulation but requested additional exchanges in the future to cover some pending issues. COM explained that only minor corrections could be made following a positive vote on the draft Regulation.

CZ and SE signalled that there are translation errors in their respective versions.

NL requested from COM to provide a guidance document to address technical questions on the fragrance allergens labelling and CE and IFRA supported this approach especially in view of queries coming from SMEs.

COM requested from all interested parties to provide their comments and specific questions that may require a guidance document and to share their linguistic corrections in order to proceed swiftly with the respective changes.

4. FORTHCOMING REGULATIONS

a) **Draft Commission Regulation amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of 4-**

Methylbenzylidene Camphor, Kojic Acid, Genistein, Daidzein, Triclosan, Triclocarban, Alpha-Arbutin and Arbutin in cosmetic products.

The Commission informed the members of the WG that a draft Regulation is under preparation following the working document and the input received concerning six substances with potential ED activity including 4-MBC, Genistein, Daidzein, Triclosan and Triclocarban, as well the cosmetic ingredients Vitamin A and Arbutins. COM explained that except for 4-MBC that is proposed for prohibition, the rest of the substances will be restricted in the respective Annexes to the CPR. A vote is envisaged for June 2023.

CE explained that following the SCCS conclusions there are no safety issues for Vitamin A and that a simpler labelling would suffice. In addition, since such products are safe, they should not be destroyed just because they do not comply with the proposed labelling requirements, but instead a longer transitional period should be allowed.

DK reiterated their position on the approach followed by COM as regards ED and their use in consumer products especially in view of the CSS aims. As regards the Vitamin A labelling, DK considered that the labelling will not be informative for the average consumer and that this issue could be resolved with an allocation factor. DK expressed their interest in submitting in the future a proposal on this.

BEUC supported DK on this and stressed the importance of the assessment of the aggregate exposure to such substances.

FI pointed out that the systemic accumulation of Vitamin A in some population groups (e.g., pregnant women) may result in human health risks that should be taken under consideration.

NL explained that a labelling is important, but it should point to the concomitant exposure from food and food supplements.

BE supported DK comments as regards ED substances and its position on the labelling proposed for Vitamin A. BE considered that it is not clear for consumers.

CZ expressed their support on the prohibition of 4-MBC and for a short labelling for Vitamin A.

SMEUnited supported the CE comments on Vitamin A.

ES requested clarification from COM on Kojic Acid and the product types referred in CPNP. COM explained that this will be checked.

COM asked the members to reflect on the points raised and provide comments on the draft regulations following the meeting.

b) Draft Commission Regulation amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of nanomaterials in cosmetic products.

The Commission informed the members of the WG that the new version of the Omnibus on nanomaterials will cover the inconclusive SCCS opinions concerning Styrene/Acrylates copolymer (nano), Sodium Styrene/Acrylates copolymer (nano), Copper (nano), Colloidal Copper (nano), Gold (nano), Colloidal Gold (nano), Gold Thio-ethyl-amino Hyaluronic Acid (nano), Acetyl heptapeptide-9 Colloidal gold (nano), Platinum (nano), Colloidal

Platinum (nano), Acetyl tetrapeptide-17 Colloidal Platinum (nano) and Colloidal Silver (nano). In addition, the new version will not cover Silica (nano) in view of the commitment of industry to submit additional data prior to a new safety assessment by the SCCS, while it will restrict the use of Hydroxyapatite (nano) following the SCCS conclusions. A vote is envisaged for June 2023.

5. SCCS ASSESSMENTS – UPDATE

a) INGREDIENTS

COM provided a status update on the safety assessment of various substances that are currently under assessment by the SCCS, including the last ED substances of Group A (Benzyl Salicylate) and Group B (Butylparaben, Methyl Paraben and Salicylic Acid) and other ingredients such as Sodium Bromothymol Blue, Aluminium, Citral, Titanium Dioxide, Silver Zinc Zeolite, the hair dyes hydroxyl propyl p-phenylene diamine and its dihydrochloride salt (A165) and HC blue 18, the CMR derogation request on Hexyl Salicylate and the scientific advice on Methyl Salicylate and its use in cosmetics intended for children. COM also informed the members about mandating the SCCS on the safety of Benzophenone-1, Benzophenone-4, OMC and Triphenyl phosphate in 2023.

BEUC inquired on how COM envisages to proceed with Aluminium in view of the SCCS concerns and the respective aggregate exposure. COM replied that industry has committed in submitting additional information and following this, COM will be mandating the SCCS to recalculate the respective MoS.

DK requested clarification from COM on the status of Silver Zinc Zeolite (SZZ). COM explained that SZZ is currently prohibited following its classification as a CMR substance. In view of the shrinking palette of preservatives in cosmetics and following a request to allow its use as a preservative, MS agreed to have SZZ assessed by the SCCS. After the completion of the SCCS assessment, COM will revert to the WG to explore a possible derogation for use in cosmetics.

b) NANOMATERIALS

COM provided a status update on the safety assessment of nanomaterials including Fullerenes/Hydroxylated Fullerenes and Hydroxyapatite (nano) for which the SCCS published the respective preliminary opinions.

6. TARGETED REVISION OF THE COSMETIC PRODUCTS REGULATION: STATE OF PLAY AND TIMELINES

COM provided a status update of the timelines for the targeted revision of the CPR. Following the negative opinion from the RSB in November 2022, COM is revising the draft impact assessment and in parallel is preparing a legislative proposal. COM envisages the resubmission to the RSB by end of spring 2023 and having a legislative proposal by early summer 2023. Following the negotiations in the Council and the EP a new CPR could be adopted in 2024-2025 and be applicable from 2026-2027.

In addition, COM informed the members of the WG on the content of the draft IA report and specifically the preferred policy options for the possible revision of the CPR, while stressing that some policy options are more controversial than others. In particular, COM explained that it aims to change the CPR provision for the most harmful substances including the application of Generic Risk Approach (GRA) to various hazard classes, the

mixture assessment factor (MAF) and the essential use concept. Furthermore, the preferred policy options also include introducing digital labelling, aligning the nanomaterial definition to the new COM Recommendation, reallocating the work of the SCCS, and linking the CPNP to the Single Window for Customs. Moreover, the CPR will be adapted to the Lisbon Treaty. Moreover, the Commission explained that the preferred policy options will be also part of an internal consultation process, which may result in further changes to what is currently proposed as preferred policy package.

SMEUnited asked for clarification on the SCCS reallocation. COM explained the various scenarios and the preferred option which was to keep SCCS as an independent committee under ECHA.

BEUC inquired when the CPR IA will be published and whether the study report on the essential use will be also available. COM explained that the IA will be published together with the legislative proposal (including the supporting study), while for the essential use study, COM clarified that it is part of the REACH IA, however, the information from this study has been considered for the CPR IA.

CZ inquired about the future application of the generic risk approach (GRA) within the CPR. COM explained that the idea is to extend the existing provisions of Article 15 to new hazard classes (i.e., implement an automatic ban of such substances with specific derogations). COM clarified that the existing provisions for CMR substances will be revised to improve the way the system work, especially in view of the strict timelines. BEUC requested clarification on whether the GRA will affect the new hazard classes of both category 1 and 2. COM clarified that only hazard classes relevant to human health will be considered under the CPR, but both categories will be covered.

CZ requested clarification on the content of physical labelling that could be transposed to digital labelling. PT and IE agreed that the content to be transposed to digital format is important and needs to be discussed with Member States. IE has concerns over introduction of a digital label and how this would be managed. GR expressed concerns along the same line, while suggesting that the CPNP number should be included in the digital labelling. BEUC echoed the reservations for digital labelling stressing that this is an area that we need to be careful to avoid consumers being excluded from information. COM explained that currently two policy options were considered, mandatory and voluntary digital labelling, with different sub-options assessed in the IA. COM has not decided yet on the exact elements that will mandatorily need to be in digital format, this will be determined at later stage. COM also explained that the contractor has investigated a plethora of evidence including the input from the public and targeted stakeholder consultation, as well as the dedicated consumer interviews.

DK requested clarification on the preferred policy options on nanomaterials. COM explained that the preferred option is to align with the new COM Recommendation, with the possibility for additional provisions on safety. CE supported the horizontal definition but explained that this will be challenging without an adequate transition period for adaptation.

NL requested clarification on the MAF policy option. COM explained that there were two policy options, focusing on the possible application of a MAF in the risk characterisation either for all hazardous substance or only for the most harmful ones. The analysis performed in the context of the draft IA suggested that the cost from the application of a MAF in our sector is disproportionate, while the uncertainty around the possible human

health benefits from its application was too high. COM remarked that this will be subject to the RSB comments and, therefore, this approach might change.

PL and PT requested from COM to include the date of minimum durability in the forthcoming CPR revision, to improve market surveillance and protect further the consumers.

CZ inquired whether the RSB Opinion will cover the whole IA or specific sections. COM explained that the RSB opinion is inclusive.

BEUC inquired whether the WG will be involved in the process in terms of discussion on the legislative proposal. COM clarified that following a positive RSB opinion the Commission services must swiftly launch an interservice consultation with little opportunity for further discussion, remaking however, that there will be extensive discussions with MS at the Council level and afterwards with the European Parliament (EP).

SMEUnited expressed concerns that economic operators and especially SMEs will face great challenges from the simultaneous application of multiple changes concerning the GRA, nanomaterials and digital labelling. COM clarified that an optimistic scenario would entail the approval of a legislative proposal by the Council and EP in 2024, and the application of a transitional period of up to two years (subject to negotiations) to provide adequate time to economic operators and MS authorities to adapt to changes.

ES expressed their support in assisting the Commission in view of the forthcoming Spanish Presidency in the Council.

7. OUTCOME OF THE PEMSAC-MARKET SURVEILLANCE MEETING OF 29 NOVEMBER 2022

COM reported on the main issues discussed during the last meeting of PEMSAC-Market surveillance such as the establishment of the sub-group discussing the efficacy of sunscreen under the ES leadership, the possible participation of PEMSAC in Joint Action in 2024 and the finalisation of work on the Work Programme, which was distributed to the members via CIRCABC. In addition, COM mentioned that SE and FR shared the experience of the market surveillance authorities relating to the cosmetic products containing nanomaterials. COM informed that the next meeting of the group will take place on 1 June and will be followed by the meeting of the PEMSAC-Cosmetovigilance on 2 June, where the new features of the ICSMS will be presented.

Cosmetics Europe supported by ICADA expressed their readiness to engage with the work of the Cosmetovigilance group and attend the meeting on 2 June.

8. OUTCOME OF THE BORDERLINE PRODUCTS MEETING OF 2 MARCH 2023

COM informed about the conclusions of the last meeting of the Sub-group on Borderline Products: the group agreed to continue working on entries to the Borderline Manual on Do-It-Yourself products, glues for extended nails, false eyelashes, jewellery on teeth and facial stickers and magnetic eyeline. Discussions were carried out on the possible entry into the Manual of definitions relating to microbiome and on the qualification of products such as: teeth whitening products, self-tanning drops, self-administered tattoos, herbal medicines, products presented in a vial or ampoule and pain-relieving gels and creams. COM also inform that the Sub-group will develop guidelines according to which a product

can be considered as a cosmetic product to facilitate application of new paragraph 4 of the Cosmetics Regulation, introduced by the new Medical Device Regulation. The tentative date for the next meeting of the Sub-group is 28/09/2023.

SE enquired what procedure should be followed before the guidelines will be agreed upon. COM suggested that Member States could send their suggestions for the classification to GROW.F2 (*functional mailbox*) and the COM will initiate the discussion in the WG.

AT referred to the discussion on melatonin and asked whether the COM intends to follow the suggestion that the Cosmetics Regulation should be amended in light of the opinion of the SCCS. COM responded that it would consider this issue internally, also with other sectors as the SCCS Opinion was adopted several years ago and would come back to the WG.

9. EXCHANGE OF VIEWS ON THE STATUS OF HEMP AND CANNABIS-DERIVED INGREDIENTS IN COSMETICS

COM explained the main changes to the Discussion Paper which followed the comments received from the Member States and aimed to clarify the impact of the judgement of the CJEU in Case C-663/18 on the interpretation of the Cosmetic Products Regulation. The revised version of this document will be prepared for an *ad hoc* meeting of WG in April/May 2023. The launching of a Call for data followed by a mandate to the SCCS to assess the safety of CBD with THC as impurity seemed the preferable action at this stage. COM announced that it will proceed with drafting of such Call so that it can be published in June.

ES considered that the document gained on clarity but its approach to CBD as a non-controlled substance clashes with the national Spanish legislation which implements correctly the 1961 Single Convention (SC) and is in line with the INCB position. ES suggested that COM contacts the INCB so that both organisations can work on a shared interpretation of the SC. ES added that in case the conclusions of the Discussion Paper were to be followed, the sectoral rules on cosmetics would be contrary to the horizontal legislation on drugs. ES stressed that the THC level of 0.3% cannot be considered as a safe level in cosmetics but as a maximum THC level in a cannabis plant. ES welcomed the suggestion to request the SCCS for its opinion on the safety of CBD.

SE indicated that the Discussion Paper draws conclusions which are too far away from the Court judgement which relates to the free movement of goods. The Court did not pronounce itself on the THC content or on other cannabinoids. SE stressed that several conclusions in the Discussion Paper conflict with the Swedish narcotic legislation, which complies with the 1961 Single Convention, and therefore SE has to object to such conclusions. SE noticed that if the document was not to change, the surveillance authorities would have to receive a specific authorisation to assess the presence of narcotic drugs. It would also be impossible to assess from which parts of the cannabis plant the CBD is taken. Also, CBD, in some conditions, can produce more THC and clients will be using such products not being aware of the amount of THC consumed. SE also explained that oils with different CBD concentration are present on the market and even if the Borderline Sub-group concludes that such products, used orally, are not cosmetics, they still will be marketed under e.g. skin conditioning products and used orally. SE plead that this group makes it more difficult for companies to use the Cosmetics Regulation as a vehicle to bring their products on the market with CBD content with possible THC. SE also asked COM to prepare the next revision of the document with track changes. For those reasons SE could

not support this document in its current form and doubted that it will be possible to reach consensus by June.

AT enquired about the approach to cannabis leaves as the commentary to the Single Convention mentions that leaves can contain some resin with THC and other cannabinoids which can have psychotropic effects.

Cosmetics Europe (CE) asked about the intended final status of the Discussion Paper.

COM stressed that the Court judgement in Case C-663/18 clearly departed from the literal interpretation of the 1961 Single Convention in favour of its teleological interpretation which takes into account the object and purpose of the Convention. The Court ruled that if the *cannabis sativa* plant has THC level smaller than 0.2%, and the plant is legally cultivated in a Member State, the CBD, which according to the current state of scientific knowledge does not have a psychotropic effect, taken from the whole plant, cannot be considered as a drug. COM reminded that Member States and the Commission are bound to observe the Court rulings. Consequently, the national legislation enacted before this ruling will have to be adapted. COM confirmed that the 0.3% of THC content relates to the plant itself and not to the final product and that the paper will be redrafted to clarify this. Any references in this paper to THC should not be interpreted as acceptance of THC, but acknowledgement that a trace of this substance may be present in a cosmetic containing CBD. COM indicated that the problems faced by the market surveillance authorities in relation to cosmetics with CBD can be discussed in the PEMSAC group. As regards the presence of resin in leaves, the COM indicated that the conclusions of the commentary to the Single Convention did not go as far as to consider leaves as a drug, but recommended Parties to the Convention to put in place relevant control measures. COM clarified that this paper does not represent the official position of the Commission. Once the discussion is concluded, the paper will be attached to the minutes of the meeting. COM summed up that all Member of the WG seemed to agree on the Call for data. The Chair asked for written comments to the draft document by 14 April.

10. UVA PROTECTION – POSSIBLE UPDATE OF COMMISSION RECOMMENDATION 2006/647/EC

The NL requested to add this point on the agenda as a follow up to the presentation made at the meeting on 8 November 2022 on sunscreens, SPF and UVA and noted that several Member States were supportive and required the Commission to look into the possible revision of Recommendation 2006/647/EC. As the COM asked which elements should be redrafted the NL volunteered to make a proposal and for this purpose enquired about the interest among Member States to participate in a focus group which could discuss and draft the possible updates to Recommendation 2006/647/EC.

Cosmetics Europe (CE), supported by the NL, agreed that after 20 years the revision of the Recommendation would need to be looked at, especially the testing methods which are currently evolving. CE reminded that currently ISO is looking into the new methodology for SPF testing which would need to be included in such a revision, e.g. question about primary and secondary sunscreen or UVA protection. As ISO will come up with a standard in 2025, CE suggested to put the discussion on hold in 2023 but work on this issue throughout 2024 (reconvene a group which exists since 2006) so that, by the time ISO is ready with its methodologies, this WG would be ready with the revision of the Recommendation.

ICADA enquired whether it would be possible to have a report on the direction which ISO takes in its group. CE committed to ask the Chair of ISO Working Group 7 to give a short presentation at the one of the next meetings of the WG.

BEUC supported the update to the Recommendation and asked for a report from discussions in PEMSAC on how to ensure uniform approach to enforcement of the SPF claims. This is an issue that BEUC members have been raising for several years. The Member States' approach to enforcement of a situation where a claimed SPV factor and the measured SPF factor is not uniform. BEUC suggested that this issue should be also taken up in the future recommendation.

IE declared its interest in the work on the revision of the Recommendation and was not in favour of delaying it and awaiting the ISO standards.

COM supported the idea of the creation of the sub-group and extended the invitation, via CE, to the Chair of ISO Working Group 7 to give a presentation to the WG on Cosmetic Products. The composition of the sub-group will be decided at the November meeting based on volunteers, so that the sub-group can start meeting 1Q 2024 and conclude towards the end of 2024. COM stressed the importance of good preparation: a list of topics for the revision, the timeline and the commitment of the members of the sib-group to invest sufficient time for the meetings.

11. AOB – CPNP testing phase

COM reminded about the call for volunteers to test the portal.

12. Next meeting

The next meeting is tentatively scheduled for 29 June 2023 (to be confirmed).

13. LIST OF PARTICIPANTS

• Agency for Health and Food Safety (AGES) • Federal Ministry of Health and Women	AT
• Federal Public Service Health, Food Chain Safety and Environment • Ministry of Health	BE
• Ministry of Economy • Ministry of Health • National Center of Public Health and Analyses	BG
• Ministry of Health	CY
• National Institute of Public Health	CZ
• Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection • Chemisches und Veterinäruntersuchungsamt Karlsruhe • German Federal Institute for Risk Assessment	DE
• Ministry of Environment	DK
• Health Board • Ministry of Social Affairs	EE
• National Organisation for Medicines	EL
• Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)	ES
• Ministry of Social Affairs and Health	FI

• Finnish Safety and Chemicals Agency	
• Direction générale de la concurrence, de la consommation et de la répression des fraudes • Ministère des Solidarités et de la Santé	FR
• Ministry of Health	HR
• The National Institute for Food and Nutrition Science (NIFNS)	HU
• Health Products Regulatory Authority (HPRA) • Department of Health	IE
• Ministry of Health	IT
• Ministry of Health – National Public Health Center	LT
• Ministry of Health	LU
• Department of Public Health, State Sanitary Inspectorate • Health Inspectorate	LV
• The Malta Competition and Consumer Affairs Authority (MCCAA)	MT
• Rijksinstituut voor Volksgezondheid en Milieu • Ministry of Health, Welfare and Sport	NL
• Chief Sanitary Inspectorate • Ministry of Development and Technology	PL
• National Authority of Medicines – Infarmed	PT
• Institute of Public Health	RO
• Medical Products Agency	SE
• Ministry of Health	SI
• Public Health Authority	SK
• Norwegian Food Safety Authority	NO
• Cosmetics Inspection Department	TR
• The Environment Agency	IS
• European Parliament – IMCO Secretariat	EP
• BEUC	
• Cosmetics Consultants Europe	
• Cosmetics Europe	
• EFEO	
• EffCI	
• ERPA	
• IFRA	
• NATRUE	
• SMEUnited	
• UNITIS	

ANNEX I

Working Group on Cosmetic Products: List of Acronyms

ACRONYM	**FULL NAME**

ORGANISATION

BEUC	The European Consumer Organisation
CE	Cosmetics Europe

CCE	Cosmetics Consultants Europe
EFEO	European Federation of Essential Oils
EffCI	European Federation for Cosmetic Ingredients
ERPA	European Cosmetics Responsible Person Association
IFRA	International Fragrance Association
NATRUE	The International Natural and Organic Cosmetic Association
SMEUnited	Association of Crafts and SMEs in Europe
UNITIS	European Organization of Cosmetic Ingredients Industries and Services

MEMBER STATES

AT	Austria
BE	Belgium
BG	Bulgaria
CZ	Czechia
CY	Cyprus
DE	Germany
DK	Denmark
ES	Spain
EE	Estonia
EL	Greece
FI	Finland
FR	France
HR	Croatia
HU	Hungary
IE	Ireland
IT	Italy
LT	Lithuania
LU	Luxembourg
LV	Latvia
MT	Malta
NL	The Netherlands
PL	Poland
PT	Portugal
RO	Romania
SE	Sweden
SK	Slovakia
SI	Slovenia

OTHER STATES

IS	Iceland
NO	Norway
TR	Turkey

OTHER

CMR	Substances classified as carcinogenic, mutagenic or toxic for reproduction
COM	European Commission
COSCOM	Standing Committee on Cosmetic Products
CLP	Classification, Labelling and Packaging Regulation
CPNP	Cosmetic Products Notification Portal

CPR	Cosmetic Products Regulation
DG GROW	Directorate General Internal Market, Industry, Entrepreneurship and SMEs
EP	European Parliament
GRA	Generic Risk Approach
GPSD	General Product Safety Directive
INCI	International Nomenclature Cosmetic Ingredient
MAF	Mixture Assessment Factor
MS	Member State(s)
Q1	Quarter 1
SCCS	Scientific Committee on Consumer Safety
SVHC	Substance of Very High Concerns
RDB	Regulatory Scrutiny Board