From:
 __(GROW)

 To:
 @chimicahts.it"

 Cc:
 _(GROW)

 Subject:
 Ares(2019)414624 - RE: Help needed

 Date:
 mercredi 30 janvier 2019 13:03:23

Attachments: image003.png

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Dear Mr.

Thank you for your query.

Currently, there are internal discussions and we hope to provide you with clarifications in due course. In addition, we would kindly suggest to visit the CosIng database regularly, in order to follow any developments on cannabis/hemp-related issues.

However, we would like to take this opportunity to inform you that the CosIng database is an inventory of cosmetic substances and ingredients, <u>employed for labelling</u> cosmetic products throughout the EU. Please note that ingredient assigned with an INCI name that appears in the inventory section of CosIng does not mean it is to be used in cosmetic products nor approved for such use.

Entry 306 of Annex II to the Cosmetics Regulation 1223/2009 (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1493906428740&uri=CELEX:32009R1223) refers to "Narcotics, natural and synthetic: All substances listed in Tables I and II of the single Convention on narcotic drugs signed in New York on 30 March 1961".

Schedules I and II of the Convention are lists of drugs. According to Art. 1 "definitions" of the convention, "Drug" means any of the substances in Schedules I and II, whether natural or synthetic.

The list of drugs in Schedule I (Schedules as at 16 May 2018: http://undocs.org/ST/CND/1/Add.1/Rev.4) includes: CANNABIS and CANNABIS RESIN and EXTRACTS and TINCTURES OF CANNABIS.

Article 1 of the convention defines these terms as follows:

- (b) "Cannabis" means the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.
- (c) "Cannabis plant" means any plant of the genus Cannabis,
- (d) "Cannabis resin" means the separated resin, whether crude or purified, obtained from the cannabis plant.

Pursuant to Article 28 ('Control of cannabis') of the 1961 Convention, the 'Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes'.

Based on the above, ingredients derived from cannabis to the extent that they fall within the scope of the 1961 Convention should be banned in cosmetic products based on entry 306 of Annex II of the Cosmetics Regulation. It is up to the responsible person to provide the evidence and prove that their product is not falling within the scope of the Convention.

According to the WHO ECDD critical review (http://www.who.int/medicines/access/controlled-

substances/CannabidiolCriticalReview.pdf), cannabidiol 'is one of the naturally occurring cannabinoids found in cannabis plants. It is a 21-carbon terpenophenolic compound which is formed following decarboxylation from a cannabidiolic acid precursor, although it can also be produced synthetically'. CBD is not currently a scheduled substance in its own right (only as a component of cannabis extracts). In its letter of July 2018 to the UN Secretary-General (following a critical review of cannabidiol), the WHO recommended that preparations considered to be pure CBD should not be scheduled within the International Drug Control Conventions. In the letter annex, the WHO states that cannabidiol is not specifically listed in the schedules of the UN International Drug Conventions. However, if prepared as an extract or tincture of cannabis it is controlled in Schedule I of the Single Convention on Narcotic Drugs, 1961.

Based on the above, cannabidiol <u>may be prohibited</u> from use in cosmetic products, if it is prepared as an extract of cannabis (and therefore it is up to the responsible person to provide the necessary evidence that their ingredient in not falling under this category).

Please note that the views expressed in this email are not legally binding; only the Court of Justice of the EU can give an authoritative interpretation of Union law.

We hope you will find this information useful.

kind regards



European Commission

DG for Internal Market, Industry, Entrepreneurship and SMEs Unit D4 – Health Technology and Cosmetics

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From: GROW COSMETICS AND MEDICAL DEVICES < GROW-COSMETICS-AND-MEDICAL-

DEVICES@ec.europa.eu>

Sent: Thursday, January 24, 2019 12:11 PM

To: (GROW) @ec.europa.eu>

Subject: FW: Help needed

From:	<	@chimicahts.it>

Subject: Help needed

Good morning

I'm writing in regard with some issues that I'm encountering with CosIng.

We are a consulting company for cosmetic products (formulation and regulatory). We are currently looking into formulating cosmetic products with hemp/cannabis derived ingredients for specific clients.

The market is full with such products but we are experiencing some regulation hiccups.

The problem is that all such ingredients show up in CosIng as restricted Annex II and therefore could not be used.

See one example below:



In reality, the web is full of articles, notifications and news about the fact that industrial hemp (Cannabis Sativa) was exempted from the 1961 New York convention already a long time ago also in EU.

Therefore, the restriction above should not apply but CosIng is still reporting it, not allowing us to formulate with such ingredients.

The problem is that the software we use for creating the Product information File is automatically taking eventual restrictions from CosIng, thus not allowing us to proceed with such ingredients.

Could you please:

- firstly, confirm to us that ingredients such as the one above are NOT restricted for use in cosmetics
- secondly, let us know if there is the possibility to update CosIng regarding this un-applicable restriction?

Thanks a lot in advance for your help.

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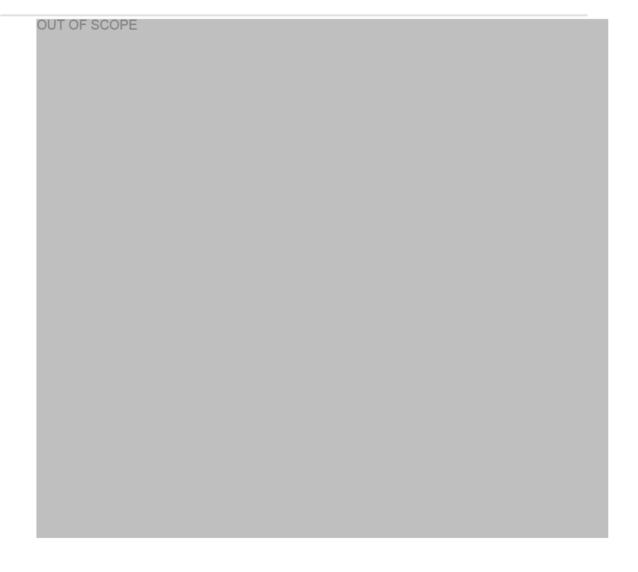
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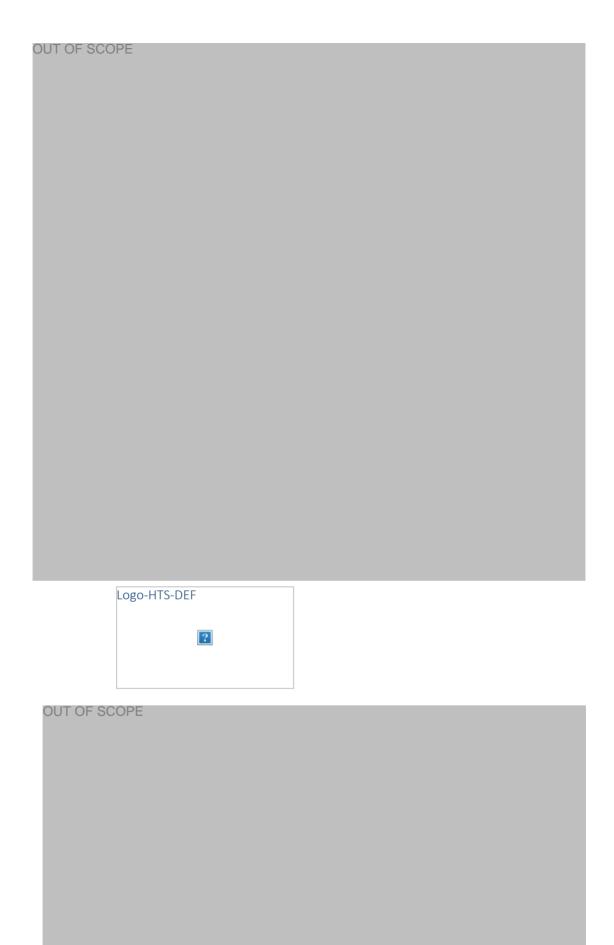
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