

 From:
 (GROW)

 To:
 \_ Bio Basic Europe Srl"

 Cc:
 (GROW): GROW D4

Subject: RE: Ares(2019)3357916 - RE: Question about CosIng update

**Date:** mercredi 22 mai 2019 16:59:18

Attachments: <u>image002.png</u>

image003.jpg image004.jpg image005.jpg image006.jpg

Dear Mr.

pear ivir.\_\_\_\_\_,

Thank you for your email.

We would like to inform you that it falls outside the remit of the commission services to provide such information.

The <u>Cosmetics Regulation (EC) No. 1223/2009</u> with its entry 306 of Annex II, makes specific reference 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*". Please note that there is no mentioning of THC levels anywhere in the Cosmetics Regulation.

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 (<u>Schedules as at 16 May 2018</u>) 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.

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.

According to the <u>WHO ECDD critical review</u>, 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".

Cannabidiol is not included as such in the Schedules of the Single Convention on Narcotic Drugs of 1961. Therefore, we consider Cannabidiol outside the scope of entry 306 of Annex II to the Cosmetics Regulation 1223/2009 (CosIng entry on Cannabidiol - Synthetically Produced). However, if it is prepared from banned substances such as extracts or tinctures or resin of Cannabis Cannabidiol would fall under the scope of the Convention and the prohibition II/306 should apply. Based on the above, the prohibition is applicable based on the material used (allowed or prohibited) for the production of CBD. Please note that the Cosmetics Regulation (EC) No. 1223/2009 makes no reference to purity or the THC content for Cannabis related ingredients. In addition, according to Article 4 of the Cosmetics Regulation (EC) No. 1223/2009 it is up to the responsible person (and not the commission services) to ensure that a product complies with the relevant legal obligations ("For each cosmetic product placed on the market, the responsible person shall ensure compliance with the relevant obligations set out in this Regulation). Furthermore, according to Article 3 of the Cosmetics Regulation (EC) No. 1223/2009 "A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably

foreseeable conditions of use". Therefore, we would kindly ask you to reflect on the definitions of the Single Convention carefully and the respective prohibitions in the Cosmetics Regulation.

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 find this information helpful.

Kind regards,



## **European Commission**

DG for Internal Market, Industry, Entrepreneurship and SMEs

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From:
- Bio Basic Europe Srl
Sent: Wednesday, May 22, 2019 4:37 PM
To:
(GROW)
Cc:
(GROW); GROW D4

Subject: R: Ares(2019)3357916 - RE: Question about Coslng update

Dear , thank you for your reply!

So, can't the cannabidiol from natural origin be used in cosmetic products even if THC is absent?

Can Cannabis sativa extracts be used in cosmetic products only if extracted from seed?

Sorry for my questions but I have diffcults to interpret what written in the Coslng.

Thank you so much for your helpfulness.

Kind regards.

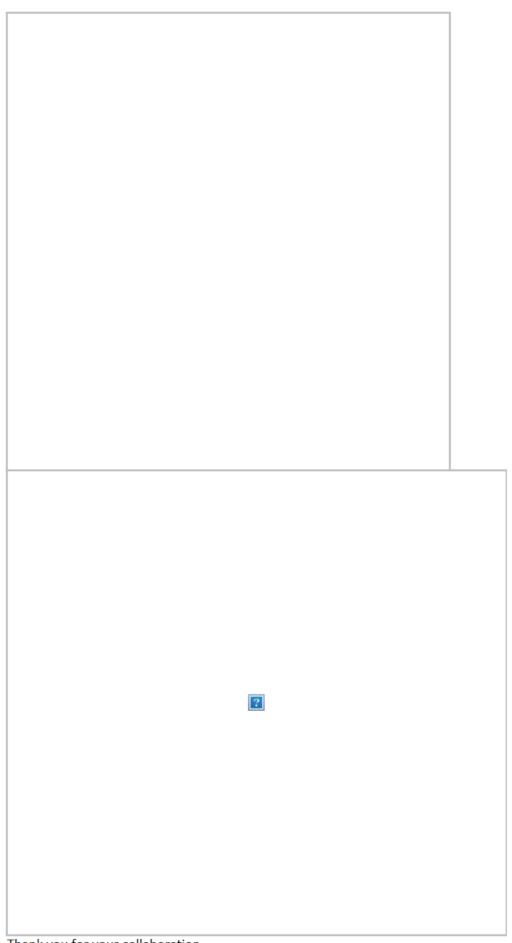
## Toxicology Department



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<b>Oggetto:</b> Ares	s(2019)3357916 - RE: Question about CosIng update	e
Dear Mr.	,	
Thank you for	r your email.	
The CosIng da	atabase updates concerning Cannabis-related ingred	dients were made to
reflect the cor	ntent of the single convention on narcotic drugs in	March 2019.
We hope you	find this information helpful.	
Kind regards,		
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European Co	ommission	
	al Market, Industry, Entrepreneurship and SMEs	
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Thank you for your collaboration.

Kind regards.





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