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MINUTES

MEETING OF

THE EXPERT GROUP FOR AGRICULTURAL MARKETS, in particular concerning aspects falling under the single CMO Regulation – Arable crops and Olive Oil

Joint with

THE CIVIL DIALOGUE GROUP ARABLE CROPS - COTTON, FLAX AND HEMP SECTORS

14 March 2022

Chair: AGRI.E4

Delegations present for the expert Group: All Member States were present except Malta and Romania.

Delegations present for the CDG: All Organisations were present, except Confédération Européenne de la Production de Maïs (C.E.P.M), EuropaBio, European Biodiesel Board (EBB), European Coordination Via Campesina (ECVC), European Federation of Food, Agriculture and Tourism Trade Unions (EFFAT), Fertilizers Europe, Pesticide Action Network Europe (PAN Europe), Stichting BirdLife Europe (BirdLife Europe).

1. Approval of the agenda

The agenda of the meeting was approved.

2. Nature of the meeting

The meeting was non-public and took place virtually, through Interactio.

3. List of points discussed

3.1. Opening

The Chairwoman welcomed the speakers and the participants to the second part of the exceptional GREX-CDG event dedicated to the hemp sector and, in particular, to the impact of the European Court of Justice (ECJ) ruling in the case C-663/18.

This joint meeting follows up on the exchanges that had taken place in the similar exceptional joint event organised by the Commission on 26 April 2021 that focused on the functioning of the market for several hemp-derived products. The aim of the meeting was to facilitate the discussions between the actors of the hemp sector, Member States representatives and the Commission services on the policy and legal context related to the production of hemp and the use of the hemp extracts, in particular CBD.

According to the Court ruling, CDB is not part of Annex I of the TFEU and therefore, is not an agricultural product covered by the CAP legislation. Although DG AGRI is not the most concerned amongst the Commission's services with the outcome of the above Court ruling, the clarifications provided by the ECJ in this case opens new outlet opportunities for the EU hemp growers and hemp sector in general.

3.2. Presentations by the Commission

Commission's representatives dealing with the development and implementation of policies linked to narcotic drugs (DG HOME) could not attend the meeting due to the fact that the 65th session of the UN Commission on Narcotic Drugs was taking place at the same time. However, their position concerning the implications of the ECJ ruling in the case C-663/18 was prepared in advance of the joint meeting and the following key messages were communicated to the participants:

- Court's reasoning in this case cannot be applied automatically to any hemp or cannabis-derived product and a case-by-case assessment is necessary.
- While CBD as such is not considered a drug, it still has to comply with different provisions in order to be placed on the market, depending on its final use, for example, the General Food Law, the novel foods regulation, the Cosmetics regulation etc.
- The interpretation of the Court of Justice in this case is binding for the EU institutions but also for the Member States. Therefore, Member States are also responsible for applying this Court ruling in their national law.
- The judgment does not amount to a legalisation of the recreational use of cannabis at EU level. Amongst others, cannabis, cannabis resin, extracts and tinctures and THC (tetrahydrocannabinol) remain considered as drugs by the International Drug Control Conventions and by various acts of EU law. Member States are obliged to take the necessary measures to ensure that crimes linked to drugs are punishable.

a) CAP Reform: rules on hemp cultivation and direct payments (DG AGRI)

DG AGRI presented the eligibility conditions for receiving direct payments for hemp, the current rules under the Regulation 1307/2013 and Regulation 639/2014 and the changes applicable from January 2023 contained in Regulation 2021/2115 and Regulation 2022/126. The main changes applicable from January 2023 concern the increase of the maximum THC content to 0.3% for eligibility to direct payments and the fact that there is no longer an automatic request to withdraw from the market varieties with THC content over 0.3%, if the national legislation allows for a THC content above 0.3%. As a result of these changes:

- Members States have to ensure that the THC limit established at national level is not lower than 0.3%.
- Member States have the obligation to inform the hemp growers that the varieties with THC content over 0.3% are not eligible for direct payments.

The Implementing Regulation on IACS (controls) is not yet published.

b) Cannabis and Hemp-derived ingredient in cosmetic products: state of play (DG GROW)

DG GROW presented the state of play of the use of hemp-derived ingredients used in the cosmetic products. The speaker gave an overview of the Cosmetic Products Regulation (CPR) where narcotics, natural and synthetics, listed in Tables I and II of the Single Convention on narcotic drugs of 1961 are prohibited in cosmetic products (entry 306 of Annex II to the CPR).

As the ECJ concluded that CBD should not be considered as a drug under the UN Single Convention on Narcotic Drugs, DG GROW will re-examine the ingredients used in cosmetics and evaluate whether the prohibition under entry 306 is still applicable. To this purpose the Commission services have prepared a draft Non-paper presented in the Working Group on Cosmetic Products. The preliminary analysis showed that most of the hemp-derived ingredients should not be prohibited *a priori* in cosmetic products, provided that the public safety conditions are met. The next steps include the revision of the draft non-paper based on the comments received by Member States and stakeholders, a further discussion in the relevant Working Group and, possibly, the launch of a call for data for such ingredients and the performance of a safety assessment by the Scientific Committee on Consumer Safety (SCCS). Follow-up regulatory measures might also be envisaged.

c) THC as a contaminant in hemp-derived products and CBD as novel food (DG SANTE)

DG SANTE also provided its views regarding the ECJ ruling in the case C-663/18. Thus, CBD and other non-psychoactive cannabinoids extracted from any part of the hemp plant may be qualified as food, provided that other conditions regarding the definition of food in the General Food Law (Regulation (EC) No 178/2002) are met. The same is valid for 'synthetic' CBD, i.e. not extracted from the hemp plant. Products that qualify as 'food' are subject to the EU acquis applicable to food which includes rules on novel foods, contaminants, food labeling food supplements etc. The procedure to insert a product in the Novel Food Catalogue was presented. CBD is considered as 'novel' food, regardless of its levels in the source material as all Member States considered that no history of consumption was demonstrated for food containing Cannabis Sativa L. extracts (e.g. cannabidiol).

DG SANTE gave also an overview on THC as contaminant in food. The entry into application of the maximum levels of $\Delta 9$ -THC in food is expected for 1 January 2023. The proposed maximum level for hemp seeds and ground hemp seeds, (partially) defatted hemp seed and other hemp seed derived/processed products with the exception of hemp seed oil are 3 mg/kg while for hemp seed oil the proposed maximum level is 7.5 mg/kg. The relevant maximum levels for $\Delta 9$ -THC in feed are under discussion.

3.3. Questions and answers session

In relation to a question about **national legislation on THC limits for industrial hemp**, DG AGRI responded that Member States need to notify to the Commission any amendment concerning the THC limit in their national legislation. If the varieties cultivated in the current marketing year have a THC content over 0.2 % and this is within the national limit established by the Member State then those varieties can be cultivated but are not eligible for direct payments.

In reply to a question whether a hemp variety complying with THC limits intended for the production of flowers is eligible for coupled support, DG AGRI stressed that for the purpose of the coupled support there is no distinction with regard to the intended use of the hemp plant. The main conditions to be fulfilled concern the THC content that has to be within the limit of set in the EU legislation, as well as the other eligibility criteria for coupled support.

In relation to a question on whether the EU directive on the marketing of seeds is applicable regardless of the use of the seed (for example industrial or medicinal use), DG SANTE replied that the marketing of hemp seeds is covered by Council Directive 2002/57/EC. According to this directive, only officially certified hemp seeds intended for agricultural production (and not for ornamental purposes) can be marketed within the EU. Moreover, according to the Council Directive 2002/53/EC, only varieties of hemp that are included in the Common Plant Variety Catalogue can be marketed in the EU for agricultural purposes. There are currently 68 authorised hemp varieties. The EU seeds legislation does not lay down any requirements for the THC content of hemp seeds. The marketing of any propagating material of hemp is not covered by EU legislation.

One participant invited the Commission to indicate where in EU legislation the **concept of 'beyond reasonable doubt' in regard of contaminants** is defined and where the **maximum levels of contaminants** are set. DG SANTE replied that the provisions on the measurement of uncertainty are included in the general legislation on sampling and analysis of contaminants, however, a specific percentage of **measurement for uncertainty** level has not been established. Taking into account the legal analytical performance criteria that have to be complied with by the laboratories it could be estimated that the expanded measurement uncertainty will be in the range of 40-60%. The Commission will see how to address and communicate clarity on expanded measurement uncertainty and how to take this into account when evaluating the compliance of the analytical result with the maximum levels in the best possible way.

In reply to a question as regards the **hemp entries in Feed catalogue** DG SANTE replied that the entries in this catalogue will be updated accordingly later this year as the 0.3% limit applies only as from 01 January 2023.

As regards a question on whether a product with a THC level above the limits set by the Commission but below the limits set by the Member State should be considered acceptable in that Member State, DG SANTE replied that EU Regulation setting the maximum limits for THC as contaminant in food will enter into application on 1 January 2023. From that date those specific limits will apply uniformly to all Member States. Products that have lawfully been placed in a Member State's market before 1 January 2023, respecting the limits established by

the national regulation that may be higher than the ones set by EU legislation, may remain on the market until the end of their life or the end of stocks.

In relation to a question on whether an **official and validated analytical method for THC in food and feed** will be presented, DG SANTE answered that there will be no official method described in the EU legislation but performance criteria are established in the EU legislation. Validated methods of analysis have to comply with these performance criteria when used for official control. Any method that complies with the performance criteria may be used. If in the future there is considerable evidence that the said methods give non comparable results, then the Commission may consider the need of establishing an analytical method in EU legislation.

One participant asked whether the Commission is assessing the **lawfulness of the manufacturing process of hemp extracts and isolates during the validation process of Novel Food applications**. DG SANTE responded that the Novel Food Regulation requires the Commission to verify whether the application falls within the scope of the Novel Food regulation and whether the applications fulfil the administrative and scientific requirements in the Novel Food regulation and its implementing rules.

In reply to a question regarding **additional provisions on THC**, DG SANTE confirmed that it will provide guidelines on aspects necessary for a correct and uniform enforcement of the EU maximum levels for THC across the EU, including for a correct application of the expanded measurement uncertainty and the concept of 'beyond reasonable doubt'. Given that the maximum levels have been established to ensure a high level of human health protection based on the Acute Reference Dose (ARfD) established by EFSA in 2015, there is no intention to revise upwards the maximum levels, unless EFSA, based on new scientific evidence, updates its opinion and revise the current Acute Reference Dose/Health Based Guidance Value.

3.4. Presentations by the participants

Introductory remarks from the President of EIHA.

The president of EIHA thanked the Commission and the Member States for the opportunity to discuss transparently about hemp during the joint CDG-GREX meeting. He reiterated the need for a clear positioning of the EU on the status of hemp and its derived products that should be considered as falling outside the scope of the Single Convention of Narcotic Drugs of 1961. Finally he praised the work of the EU institutions and welcomed the recent changes in the EU legislation as regards to the maximum level of THC on the field for the purposes of direct payments, as well as the establishment of THC limits for hempseed food products.

a) The impact on the market of the ECJ ruling in the case C-663/18

The representative of EIHA described the production process of hemp extracts and isolated CBD from the hemp plant. The speaker gave an overview of the many changes as regards to the 'Novel Food status' of hemp products, highlighting how until 2019 hemp extracts, leaves and flowers were not considered novel but traditional food by the European Commission, provided that no enrichment took place (i.e. no cannabinoids were added). Such categorisation perfectly mirrors the

current EIHA position and was based on proofs of relevant consumption of hemp products before 1997.

The representative of EIHA presented the content of its 'Novel Food application' project, the scope of the toxicological study on CBD and the clinical trial on THC and stated that EIHA would be happy to share the results with the Commission and the Member States once ready.

More generally, the speaker highlighted how the 'diverging hemp policies at national level' ended up 'fragmenting the market' and creating a situation of 'persistent unclearness' that do not act as incentives for investments and the development of the value chain. The speaker stressed the risk that imported goods will finally erode the market share of European companies that are particularly suffering from the competition of low price, imported CBD isolate. Nonetheless, the speaker expressed hope that the ECJ ruling in the case C-663/18 will eventually help the creation of a true single market with common rules applicable in all Member States.

The speaker underlined that the ECJ ruling in the case C-663/18 clarified that the CBD isolate extracted from the flowers and the leaves of hemp is not a narcotic drug but a food product. According to EIHA, the same reasoning should apply for the raw material (i.e. flowers and leaves) and full spectrum extracts (hemp extracts containing the full spectrum of substances including other cannabinoids, chlorophylls, terpenes, waxes, etc.).

As main suggestions on behalf of the EU hemp sector, the representative of EIHA:

- Called for a clear acknowledgement of the fact that all parts of the plant can be lawfully used and should not be considered as narcotic;
- Urged the Commission and the Member States to establish a true EU single market for all hemp derived food products with common rules;
- Asked the Commission and the Member States to recognise the traditional food status of hemp derived foods as per the EU position until 2019;
- Stressed the need to establish a common method of analysis for cannabinoids at EU level following the work initiated by DG TAXUD and to perform knowledge building for national public administrations.

b) Traceability measures for hemp flowers production and state of play of the regulation in France following the ECJ ruling in the case C-663/18

The representative of Inter-Chanvre informed the participants on the regulatory developments in France and more specifically on the national legislation (i.e. arrêté) authorising the harvesting of the entire plant (flowers and leaves were prohibited until now) published on 30 December 2021. As a precondition, the hemp grower has to be a farmer, to use varieties from the European catalogue (maximum THC level of 0.3%) and to have a professional contract (with an industrialist, extractor or distributor). The national legislation prohibits the sale of raw leaves and flowers and the cutting and sale of seedlings.

The speaker underlined the need for traceability, i.e. in order to produce industrial hemp, the grower should be requested to declare the cultivated areas, provide the labels of the varieties used and the geo-location of its agricultural parcels to facilitate the control of the 30% of the surfaces. Inter-Chanvre therefore supports farmers' obligation to declare areas, varieties and geo-location via a tool compatible with CAP declarations in order to facilitate the organisation of controls by the Member States. The representative of Inter-Chanvre expressed the view that a possible solution for distinguishing the intended use of the hemp (flowers, fibres) is the inclusion of a specific code for hemp grown for flowers in the CAP declaration.

In addition, the speaker suggested that a European Hemp Observatory is established to allow for regular exchanges of information on the cultivated area, the development of the different hemp related markets (for seed, flowers and fibre) etc.

The representative of Inter-Chanvre also gave an update on the investments made by the sector in order to guarantee the quality of their products.

As regards the establishment of a European Hemp Observatory, the chairwoman recalled that there are already two CDG for fibre crops organised every year providing the hemp sector with the possibility to exchange information on the development of the EU hemp sector. The Commission is open to discuss more in details how to accommodate Inter-Chanvre's request in the context of the existing institutional framework.

As regards the inclusion of an additional code in the CAP declaration, the participants were informed that under the current CAP, this type of information is not required for areas used for the production of hemp (Article 17(7) of R. 809/2014). There is no intention to introduce such a legal provision under the current or the future legal framework. This type of detail is to be decided by the Member States, depending on the interventions set up and their corresponding eligibility requirements.

c) Implications of the ECJ ruling in the case C-663/18 on the organisation of the European Common Market

The representative of Agrinsieme presented a brief summary of the ECJ ruling. The speaker presented briefly the regulatory framework existing in several EU Member States: France, Lithuania, Croatia, Belgium, Luxemburg, Spain, Italy and Portugal. The speaker underlined that the differences in the national legislation could lead to a two speed Europe and the risk of distortion of competition. According to the speaker a unified solution at EU level is needed. This could be accomplished with appropriate regulatory instruments for the lawful production, processing and use of the whole hemp plant based on the interpretation of the ruling of the ECJ. Additionally, toxicological studies can address the various health issues concerning the safety of the product for human and animal consumption.

d) The cannabinoids market: analytical testing and certification challenges

The representative of UIVEC gave an overview of the different types of hemp extracts. It was reminded that there are more than 100 cannabinoids in the hemp plant, such as CBD, THC, CBG, CBN, CBC etc. These molecules can be extracted from the plant and generally used as ingredients for different markets (cosmetics, food and feed, but also therapeutic, etc.). Although naturally present in more or less

all parts of the plant, cannabinoids are mainly found in flowers and to a lesser extent in hemp leaves. An extraction process is carried out in order to obtain an ingredient. Several techniques exist, the most common being solvent extraction and CO2 extraction. Depending on the techniques used and the degree of refinement sought, it is possible to obtain different ingredients. Hemp extracts can be found in three types of ingredients:

- The Full Spectrum (FSHE) takes the form of an oil containing all potentially active cannabinoids present in the plant, narcotic and non-narcotic.
- The Broad Spectrum takes the form of a viscous dough in which a mixture of non-narcotic molecules is found. Psychotropic molecules may be present, but still below the regulatory limits set.
- The isolate is the clearest form, composed by at least 95% of a selected cannabinoid (98% by typical value).

The manufacture and use of the above ingredients oblige economic and industrial actors in the sector to provide certificates proving the absence of psychotropic molecules in the final product for consumer safety. This raises a problem in the current context of the development of the hemp extracts market: i.e. the lack of a standardised method of analysis at European and even global level. There is therefore an urgent need to define a standardised method for documenting cannabinoid levels and ensuring fair information to consumers. The main problem is to avoid having different results for the same product when tested by different laboratories. With the aim of solving this problem, UIVEC, in collaboration with the European Association BIPEA, is launching inter-laboratory tests (ring-tests) at European level. Another UIVEC certification project concerns a label which would be certified by an independent certifying body in order to guarantee the traceability and origin of CBD and other hemp extracts on the European market. This label will thus establish clear standards to ensure the quality and safety of products and reassure consumers about product conformity.

In reply to a question raised by a participant, the speaker clarified that in France the raw flowers are only sold in the CBD shops while hemp oil may be found in both CBD shops and pharmacies. Concerning a question on the sales of e-cigarettes containing CBD in France, the speaker responded that this is legal provided that Regulation (EC) No 1907/2006 is respected.

Regarding the ring tests, an EIHA representative underlined that the work on the standardisation of analytical methods is important and mentioned their support for the work coordinated by DG TAXUD at EU level and the tests conducted by public laboratories.

4. Conclusions/recommendations/opinions

There were no specific conclusions reached neither any recommendations nor opinions as a result of a voting during the meeting.

5. Next meeting

Next meeting of the CDG Arable Crops – Fibres will take place on 27 June 2022.

6. List of participants - Annex

(e-signed)

Michael SCANNELL

List of participants- Minutes

Joint Meeting of the EXPERT GROUP FOR AGRICULTURAL MARKETS, IN PARTICULAR CONCERNING ASPECTS FALLING UNDER THE SINGLE CMO REGULATIONS - SUBGROUP: ARABLE CROPS AND OLIVE OIL and the

CDG ARABLE CROPS – COTTON, FLAX AND HEMP SECTORS 14 March 2022

ORGANISATION
Bee Life-European Beekeeping Coordination (Bee Life)
European agri-cooperatives (COGECA)
European Council of Young farmers (CEJA)
European Environmental Bureau (EEB)
European farmers (COPA)
European Liaison Committee for Agriculture and agri-food trade (CELCAA)
FoodDrinkEurope (FoodDrinkEurope)
IFOAM Organics Europe
SACAR - Secrétariat des Associations du Commerce Agricole Réunies / Joint Secretariat of Agricultural Trade Associations (SACAR)
UIVEC Union des Industriels pour la Valorisation des Extraits de Chanvre
InterChanvre
Agrinsieme

MEMBER STATE	ORGANISATION
BELGIQUE/BELGIË (Belgium)	Departement of Agriculture and Fisheries
BELGIQUE/BELGIË (Belgium)	Flemish Departement of Agriculture
БЪЛГАРИЯ (Bulgaria)	Ministry of Agriculture
ČESKO	Ministry of Agriculture

(Czechia)	
DANMARK (Denmark)	Danish Agricultural Agency
DANMARK (Denmark)	The Danish Veterinary and Food Administration
DEUTSCHLAND (Germany)	Bundesanstalt für Landwirtschaft und Ernährung
EESTI (Estonia)	Ministry of Rural Affairs
EESTI (Estonia)	Ministry of Social Affairs
EESTI (Estonia)	Ministry of the Interior
ÉIRE/IRELAND (Ireland)	Department of Agriculture Food and the Marine
ΕΛΛΆΔΑ (Greece)	MINISTRY OF RURAL DEVELOPMENT AND FOOD
ESPAÑA (Spain)	MAPA
FRANCE (France)	FranceAgriMer
FRANCE (France)	Ministère de l'Agriculture
HRVATSKA (Croatia)	Ministry of Agriculture
ITALIA (Italy)	Ministero delle politiche agricole alimentari e forestali
KYΠΡΟΣ (Cyprus)	ministry of griculture
LATVIJA (Latvia)	Ministry of Agriculture
LATVIJA (Latvia)	The State Agency of Medicines
LIETUVA (Lithuania)	Ministry of Agriculture

LUXEMBOURG (Luxembourg)	Ministry of Agriculture - ASTZA
MALTA	
NEDERLAND (Netherlands)	Ministerie van Landbouw, Natuur en Voedselkwaliteit
NEDERLAND (Netherlands)	Rijksdienst voor Ondernemend Nederland
ÖSTERREICH (Austria)	Federal Ministry Agriculture, Regions and Tourism
POLSKA (Poland)	Ministry of Agriculture and Rural Development
PORTUGAL (Portugal)	MA- GPP
PORTUGAL (Portugal)	MA-DGAV
ROMANIA	
SLOVENIJA (Slovenia)	Ministry of Agriculture, Forestry and Food
SLOVENSKO (Slovakia)	Agricultural Paying Agency
SLOVENSKO (Slovakia)	Ministry of Agriculture and Rural Development
SUOMI/FINLAND (Finland)	Finnish Food Authority
SUOMI/FINLAND (Finland)	Ministry of Agriculture and Forestry
SVERIGE (Sweden)	Ministry of Enterprise and Innovation
SVERIGE (Sweden)	Statens Jordbruksverk