



Novel Food Consortium

Information on EIHA joint application

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overall strategy



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Our position



Novel Food

(art.10 / EIHA Consortium)

Natural occurring level

Traditional food

(art. 4 / EIHA Secretariat)

Why a novel food application

*Secure your market
and stay **legal***

- To achieve a **legal and planning security** for your company in the European hemp industry and its CBD market
- NF registration will
 - will **stop legal risk**, will save cost for legal advice
 - allow **considerable profit** margins in the B2C sector
 - lead to a **priceless image gain**
- The European Community (EU) has **510 million residents**, Europe has a total of 740 million residents, most of Europe shows good income levels (next to China **Europe is the largest market** for consumer goods in the world)
- **Full exploitation** of the **market potential**, including the correct and permitted marketing of CBD as food and food supplement
- **Value enhancement for your brand!**

Why joining us

Share knowledge and costs

- Common challenge = **common reply**
- **EIHA** official **EFSA Stakeholder**
- Stronger together (political message)
- **Safe products** for consumers
- for a **fair burden sharing**, based on the **economic performance** of the participating companies

We will ensure that

- **free rider effects** by entities that are not willing to contribute are avoided
- the **worldwide turnover of international brands** and/or **globally operating companies** as a basis for the assessment of the special contribution are considered

As this

- is **in the industrial policy interest** of the members of EIHA and
- is the **appropriate in relation to** already mentioned **benefits**



February 2020 → **pragmatic** approach

- **70 mg CDB max** daily intake (EFSA 10 mg, EIHA 100 mg)
(based on Epidolex study)
- Obligation to undergo a **valid NF application** by 31/03/2021
- FSA did not recognise natural occurring level

What EIHA proposes...

- **NF App based on study for CBD isolate and Full Spectrum Extracts**
- Meet the deadline
- Provide Regular Members with proof of ongoing NF app

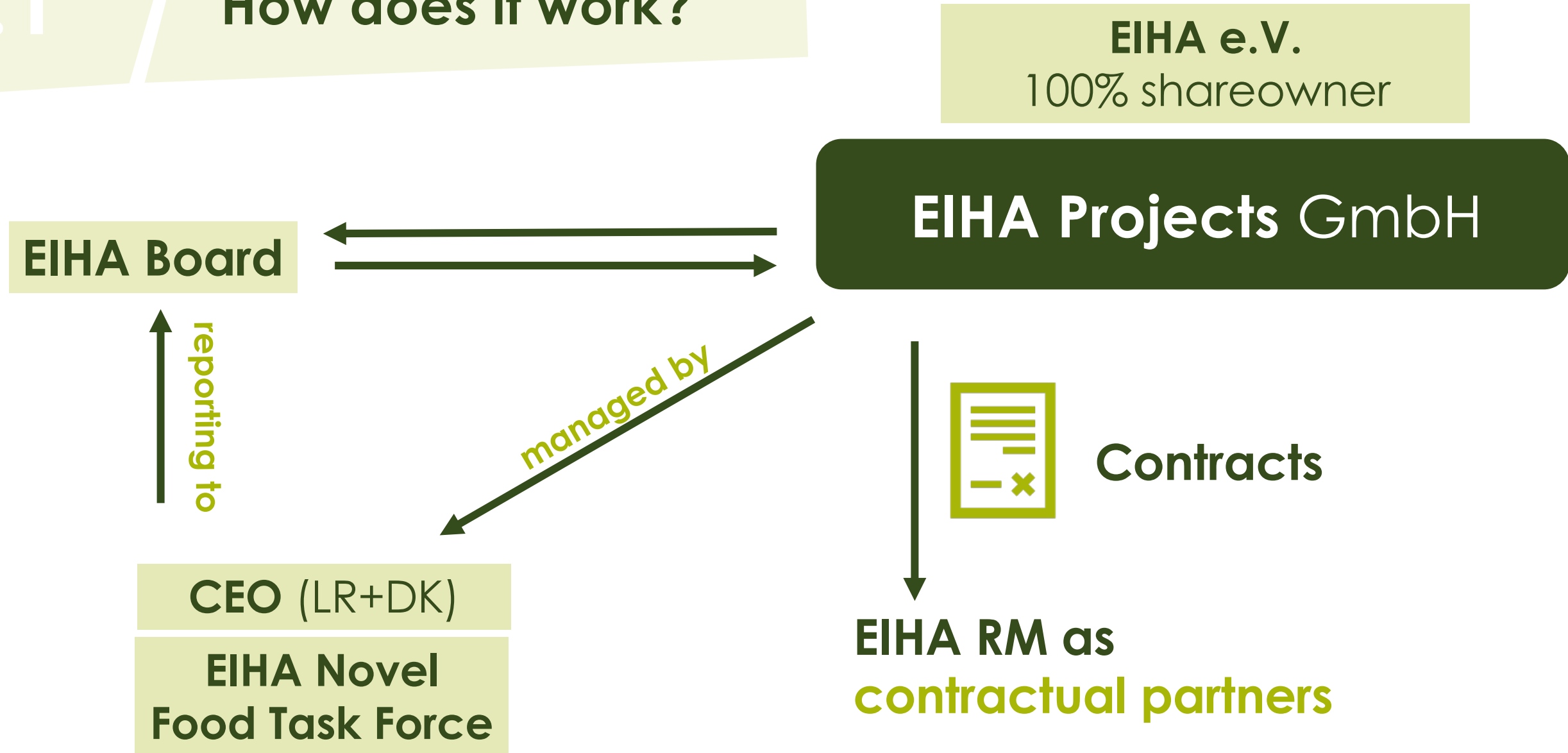
How does it work?

EIHA Consortium will secure **various product formulations** to cover every possible CBD related product

- Specifications with max levels or ranges
- ChemSafe will lead the tox studies
- on CBD as well as THC (to increase the actual thresholds)
- 5 years protection (property of the studies)
 - economic advantage

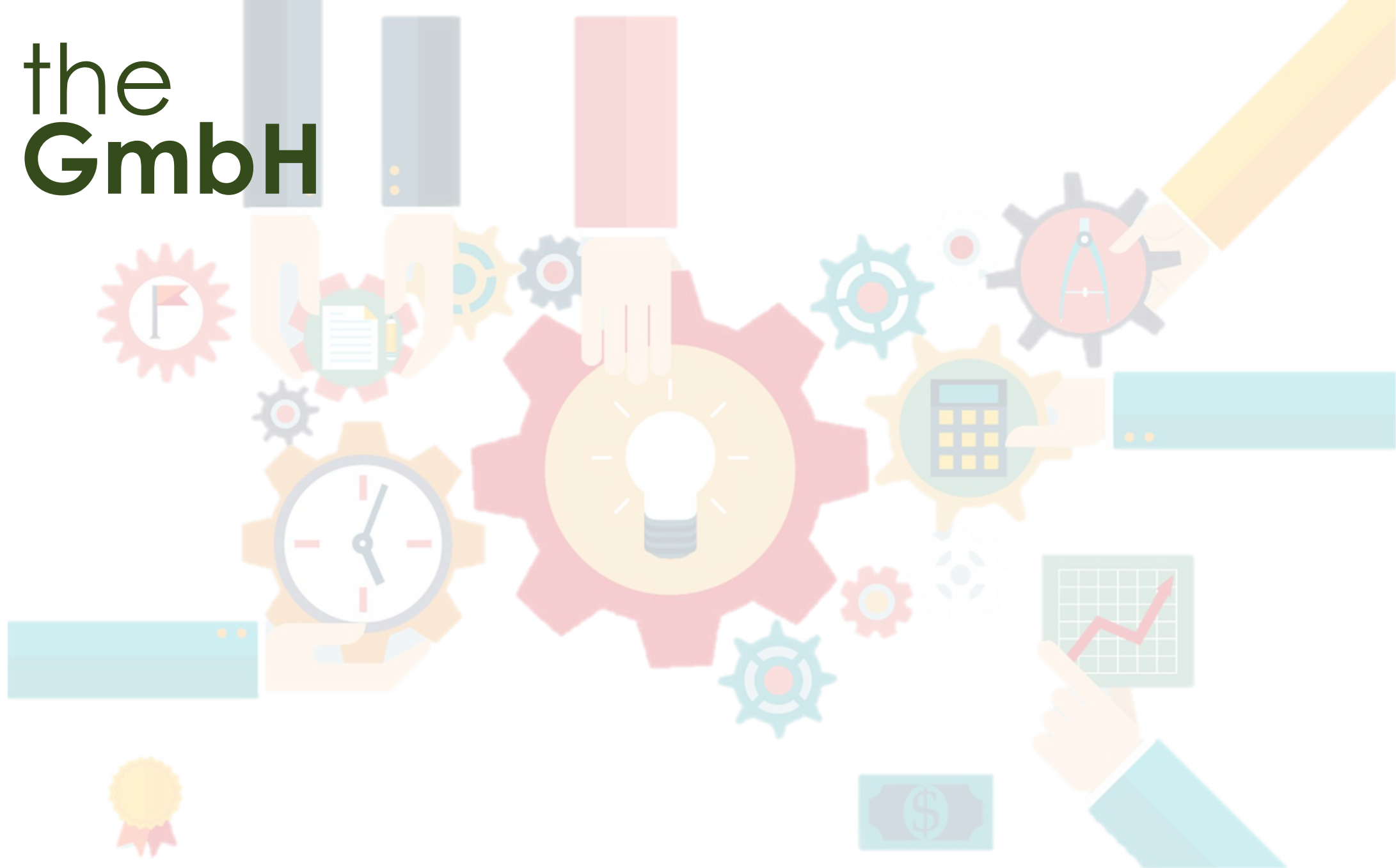
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How does it work?



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the GmbH



Foundation & administrative requirement for RM:

- Foundation of **EIHA projects GmbH**, a 100% subsidiary of EIHA
- the GmbH **acquires all rights** according to the NF Regulation and manages these
- **Members become** contractual **partners** of the GmbH
- the GmbH **transfers the rights** of Art. 26 NF-reg to the members and contractual partners
- transfer is only made **for members' and contractors'** own brands in order to avoid free-rider effects

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products **formulation**



CONFIDENTIAL

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Timeline

	COSTS	2020						2021												2022												
		06	07	08	09	10	11	12	01	02	03	04	05	06	07	08	09	10	11	12	01	02	03	04	05	06	07	08	09	10	11	12
Project Initiation (contract signature, etc.)		■	■	■																												
THC Tox Study (90-day study as for OECD 408)	380.000,00 €				* ■	■	■	■	■	■	■	■	■																			
THC Clinical Study (Tolerability study on humans) 200 subject 400 subject	736.000,00 € 1.174.000,00 €				* ■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■								
Stability Studies - shelf life (est. 10.000 €/product) Accelerated Long term (if needed)	40.000,00 €				* ■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	
Analytical Study on CBD products (CoA + 5 batches analysis)	190.000,00 €				* ■	■	■	■																								
Biblio CBD Isolate Dossier - FSA submission	18.000,00 €					* ■	■	■			■																					
CBD extract - Tox Study Package (TOX + GENTOX + REPRO)	1.600.000,00 €							* ■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	
CBD Dossier preparation (4) - EFSA submission	70.000,00 €																							■	■	■	■	■	■	■	■	
Chemsafe Monitoring	11.500,00 €																															
	14.000,00 €																															
	6.000,00 €																															
	32.000,00 €																															
TOTAL COST	3.097.500,00 €																															
TOTAL COST	3.535.500,00 €																															

Notes:

- 1) All testing phases invoiced directly to the consortium
- 2) Chemsafe work will be invoiced directly to the consortium
- 3) Still waiting for confirmation from lab about the payment installments

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Individual fees

Turnover	Number of Members	Consortium Partner Fee*	Consortium Partner Fee TOTAL	Consortium Fee 2020 (40%)	Consortium Fee 2021 (40%)	Consortium Fee 2022 (20%)
< 1 Mio	101	15.000,00 €	1.515.000,00 €	6.000,00 €	6.000,00 €	3.000,00 €
1-3 Mio	15	25.000,00 €	375.000,00 €	10.000,00 €	10.000,00 €	5.000,00 €
3-6 Mio	7	35.000,00 €	245.000,00 €	14.000,00 €	14.000,00 €	7.000,00 €
6-10 Mio	2	55.000,00 €	110.000,00 €	22.000,00 €	22.000,00 €	11.000,00 €
10-20 Mio	2	90.000,00 €	180.000,00 €	36.000,00 €	36.000,00 €	18.000,00 €
> 20 Mio	2	140.000,00 €	280.000,00 €	56.000,00 €	56.000,00 €	28.000,00 €
Total			2.705.000,00 €			

* based on averaged turnover of the last three years

Resolution on the principles of the special contribution structure for the Novel Food Joint Application by EIHA e.V.

The joint application for Novel Food approval requires, including all relevant toxicological studies, an estimated financial expenditure of up to € 3,500,000. Therefore, a fee structure must be found that reflects the industrial policy interests of the members and participants in the joint application in a proper and fair manner. The main tasks for EIHA are to finally achieve a legal and planning security for the European hemp industry and its CBD market, including a level playing field for all European companies and global players, as well as to avoid free rider effects by entities that are not willing to contribute.

There are members of the EIHA who are active in the production and processing of biomass. In addition, there are also trading companies for which a license will allow considerable profit margins in the B2C sector.

In addition, there are foreign members who operate worldwide and are members of the EIHA in Europe only with their branches. The use of the turnover of such branches as a basis for the assessment of the special contribution would certainly not be in the industrial-political interest of all European members of the EIHA.

The EIHA Board and the EIHA Task Force therefore propose the following principles for the joint project and the assessment of the special contribution:

- Companies that are active CBD-related product sector (definition CBD-related product sector: the company is involved in hemp biomass and/or raw materials (leaves, flowers, pellets) and/or processed products (extracts, premixes, oils, isolates etc.) and/or services (extraction, purification, isolation etc.) are therefore assessed on the basis of their annual turnover with these products for the assessment of the special contribution,
- If a holding company is a member of the EIHA, it must declare the worldwide consolidated net turnover of its subsidiaries in the CBD-related product sector and have it insured by a tax consultant in writing,
- If a subsidiary of a holding company is a member of the EIHA, the worldwide consolidated net turnover of the holding is the basis for the assessment and the holding must declare the worldwide turnover of its subsidiaries in the CBD-related product sector and have it insured by a tax consultant in writing,
- Members who have been granted permission by EIHA projects GmbH to exercise the rights under Art. 26 Novel Food Regulation may only use them for their own brands and may not transfer or assign them to other companies, especially not in B2B white label distribution,
- a subsequent licensing after completion of the admission procedure for individual trademarks outside of an existing EIHA membership will be made possible; the final decision on this will be made by the Board of Directors. In this respect, the EIHA Novel Food Task Force will develop a separate contribution structure. Licensing though will cause a higher contribution than participating in the project from the beginning,
- Companies that do not yet generate sales of CBD-related products, but only intend to do so in the future, will be taken into account with an estimated turnover for determining their special contribution, which will be agreed upon by the Board and the applicant in each individual case,

- If the member wishes a corresponding assignment of their rights to another legal entity, this can be decided by the management on a case-by-case basis, after consultation with the EIHA board and the NF task force of the EIHA. In this case, the former holder of the rights will give up his rights under this contract completely and transfer them to the new holder of the rights. The amount of the special contribution to be paid by the member will then be based on the actual or estimated CBD-related turnover of the new right holder. Due to the administrative work involved in the transfer, EIHA projects GmbH will charge an administration fee of € 2,500.00.
- Trading companies that do not sell their own brands are not mandatorily partners of the joint project and are not required to pay the special contribution, but for their marketing efforts and/or support of the industry they can join the project and pay the special contribution on a voluntary basis,
- Surpluses, either by licenses or unneeded funds, will be paid out to the members on a pro rata basis, or used for the industrial policy objectives of EIHA or future projects, after a majority decision by the regular members who paid a special contribution,
- false or omitted information can lead to exclusion from the association.

The special contributions are collected and managed by EIHA projects GmbH, a 100% subsidiary of EIHA e.V. EIHA projects GmbH acquires all rights under the Novel Food Regulation and administers and transfers the rights to its members according to the above principles. All members must sign a project contract with EIHA projects GmbH, in which the further details are regulated, to participate in the joint application.

The first special contribution shall be collected in three instalments. The first prepayment of 40% will be requested by EIHA projects GmbH in July 2020, another 40% in July 2021 and the remaining instalment payment of 20% upon completion of the project, which means by final settlement of all costs regarding the toxicological studies.

Turnover is measured based on the average annual turnover of the last three completed financial years before the year the instalment is required (for example: the financial years 2017-2019 are used for the first instalment in 2020). If no revenue was generated in a year, that year is not considered in the average value calculation.

In the case a further special contribution is decided on later by the general meeting, the previous paragraph applies accordingly.

Based on these principles, the following special contribution structure is proposed:

Chart will be shown at the online General Meeting of EIHA e.V. at the 15th of June 2020

For members who have not submitted their application for membership to the EIHA until 15.08.2020, the special fee increases as follows (the basis of assessment is the fee as determined by the General Assembly in June 2020)

- | | |
|--|-----|
| - raise by 16 August 2020: increase by | 5% |
| - raise by 1 January 2021: increase by | 10% |
| - raise by 1 August 2021: increase by | 15% |
| - raise by 1 January 2022: increase by | 25% |

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Resolution on the admission of new members to EIHA e.V.

The EIHA e.V. carries out approval procedures for various ingredients/supplements/food-products made from industrial hemp (Cannabis Sativa L.) for the authorisation as novel food within the Novel Food Regulation (under art 10 of 2015/2283). The fees for members are based on the annual turnover of the member companies. In order to ensure that existing members are not disadvantaged and to avoid free-rider effects, new members that farm, produce or distribute CBD-related products will only be accepted if there are no relevant links under company law between the applicant and other companies from the hemp or food industry.

Incorrect answers to the following questions may lead to the application for admission as a member of the EIHA being rejected. If a wrong answer to the following questions is found after admission as a member, this is a serious reason for exclusion from the association according to § 4 para. 7 of the statutes of the EIHA e.V., as this would be against the interests of the association and its members.

Exclusion from the association has the consequence that rights arising from the approval as novel food cannot or can no longer be asserted.

Corporate law interdependencies exist in particular if the potential member is affiliated, holds an interest or is otherwise associated with or in another company in the hemp and food industry (comparable to the definitions of § 15 of the German Stock Corporation Act, AktG). In particular, however, also if a partner of the potential member or a sole trader has an interest in a company of the hemp or food industry, either directly or indirectly.

Questionnaire:

Does your company deal with "CBD-related products" such as hemp biomass and/or raw materials (leaves, flowers, pellets) and/or processed products (extracts, premixes, oils, isolates etc.) and/or services (extraction, purification, isolation etc.) and do you want to become an EIHA member in order to participate in the joint application for the Novel-Food authorisation procedure?

If yes, please answer the following questions:

For sole traders:

Do you have or have had an interest in a company in the hemp or food industry, either directly or indirectly, with 10% or more of the shares?

If so, in which? _____

For companies:

Is your company affiliated with (comparable to the definitions of § 15 of the German Stock Corporation Act, AktG), has a shareholding of 10% or more of the shares or is it otherwise associated in another company of the hemp or food industry, either directly or indirectly?

If so, in which? _____

Is a shareholder of your company holding shares of 10% or more of the shares in another company of the hemp or food industry or is he associated in any other way, either directly or indirectly?

If so, to which one? _____



Thank
you