



‘Scientifically Sound Guidelines for THC in Food in Europe’

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Scope of the Report



- Issue:
 - Lack of common regulation across Europe on THC content in food.
 - EFSA report in 2015 on THC in feed may affect food regulations.
- Action:
 - EIHA requested nova to evaluate and propose new scientifically derived values for THC content in hemp foods.
- Aim:
 - Contribute to the development of scientifically sound THC guidance values for hemp foods at the European level.



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Sponsors



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thank you very much!

- EIHA
- Hempro International GmbH & Co. KG
- CANAH INTERNATIONAL SRL
- Nutiva
- PROPAGANDA PRODUCTION S.R.O
- Hemp Factory GmbH
- Hempflax BV
- AGROPRO UAB
- HANF FARM GmbH



Summary of the Report



1. Review of current THC limits and guidance values:
 - Guidance values:
 - Germany
 - Others (adopting German values)
 - THC limits:
 - Switzerland -> Aims at avoiding psychotropic effects
 - Belgium
 - THC in hemp raw materials:
 - Canada
 - Industrial Pledges:
 - Australia and NZ:
 - USA



2. EFSA report:

- **Title:** *‘Opinion on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin’*
- Background: THC in Swiss milk
- Several delays, now due in the second half of June



3. Scientific background:

- Data consumption for the years 2011-2012 in Germany
 - EU level data not available

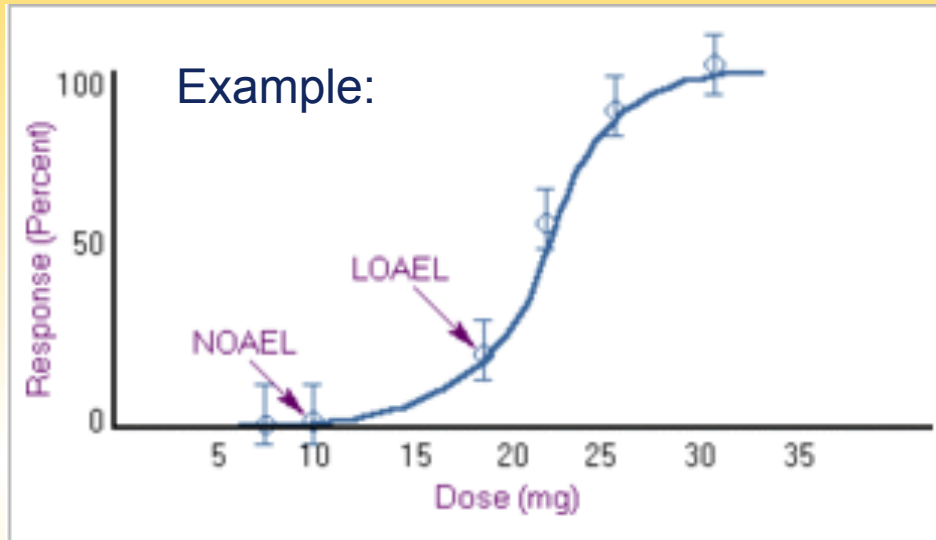
- Lowest Observed Effect Level (LOEL) derived from literature:
 - 2.5 mg of THC person/twice daily

- Uncertainty factor: 20
 - Inter-individual variations (2)
 - Higher vulnerability of foetuses and neonates (5)
 - Potential interference with other substances (2)

- Acceptable Daily Intake (ADI):
 - 0.120 mg (for an average 70kg adult)



NOEL and LOEL vs NOAEL and LOAEL



Same graphical concept,
but different meaning

- NOELs and LOELs do not necessarily imply toxic or harmful effects.
- May be used to describe beneficial effects, or in some cases, any measurable biological effect of chemicals.

Consumption patterns per category and resulting total THC uptake (in $\mu\text{g}/\text{kg}$)

PRODUCTS	ORIGINAL BgVV THC GUIDANCE VALUES (mg/Kg)	PROPOSED THC GUIDANCE VALUES (mg/kg)	AVERAGE CONSUMPTION (g/DAY/PERSON)	UPTAKE IN μg THC/DAY/PERSON (GUIDANCE VALUE * CONSUMPTION = UPTAKE)
Oils (Hemp Oil)	5	10	7	70.00
High Volume' foods: Protein (Hemp Tofu, Hemp Milk)	0.15	0.15	466	69.90
High Volume' foods: Carbohydrates (Bread, Baked Goods, Pasta, Breakfast Cereal)	0.15	0.1	308	30.80
Low Volume' foods (Protein Shakes, Sweets)	0.15	0.35	158	55.30
			ml*day*person	
Alcoholic beverages (Beer, Wine, Spirits)	0.005	0.01	370	3.70
Non-heated Non-alcoholic beverages (Soft Drinks, Fruit Juices)	0.005	0.01	424	4.24
Heated Non-alcoholic beverages (Tea, Infusions)	0.005	0.01	210	2.10

TOTAL	236.04
ADI twice daily minus total	3.96

Application of proposed nova guidance values on intermediate goods based on recipes

PRODUCT CATEGORY	PRODUCT	NOVA GUIDANCE VALUES	PERCENTAGE OF HEMP INTERMEDIATE ON HEMP FINAL PRODUCT *	MAX LEVEL OF THC IN INTERMEDIATE HEMP PRODUCT	INTERMEDIATE PRODUCT
Oils	Oil	10		10	Oil
High Volume foods: Protein	Milk	0.15	9 %	1,665	Dehulled hemp seeds
High Volume foods: Carbohydrates	Breakfast cereals	0.1	6.5 %	1.5	Hulled/dehulled hemp seeds
Low Volume foods	Chocolate bars	0.35	12 %	2.8	Hulled/dehulled hemp seeds
	Protein shakes	0.35	10 %	3.5	Hemp protein
Beverages	Tea	0.01	10-15 %	0.06-0.1	Hemp leaves

* As estimated from recipes

Final nova-Institute proposal for THC regulation

	NOVA PROPOSAL ON INTERMEDIATE AND FINAL	THC GUIDELINES	THC LIMITS			INDUSTRIAL PLEDGE	
		GERMANY – BgVV	SWITZERLAND*	BELGIUM	CANADA **	AUSTRALIA AND NEW ZEALAND	USA
<i>Raw material & intermediate</i>							
Hemp Seeds	2.5	-	10	5	-	5	1.5
Hemp Oil	10	5	20	10	10	10	5
Hemp Flour/Hemp Protein	3.5	-	-	5	10	5	-
<i>Ready-to-eat products</i>							
Oils: Hemp oil	10	5	20	10	10	10	5
High Volume' foods (Proteins):							
Hemp Tofu	0.15	0.15	1	0.2	-	-	-
Hemp Milk	0.15	0.005	0.2	0.2	-	0.2	-
High Volume' foods (Carbohydrates): Bread, Baked Goods, Pasta, Breakfast Cereal	0.1	0.15	2	0.2	-	-	-
Low Volume' foods: Sweets, Snacks	0.35	0.15	-	0.2	-	-	-
Alcoholic beverages:							
Spirits	0.01	0.005	5	0.2	-	0.2	-
Beers	0.01	0.005	0.2	0.2	-	0.2	-
Non-heated non-alcoholic beverages: Soft Drinks	0.01	0.005	0.2	0.2	-	0.2	-
Heated Non-alcoholic beverages: Herb and Fruit Teas	0.01	0.005	0.2	0.2	-	0.2	-

* Aims at avoiding psychotropic effects, ** Only applies to THC and not to total THC



Next Steps



- 1st Step finished: Report open for discussions and feedback
 - Deadline: 12th of June 2015
- Future activities:
 - EFSA paper published (mid June): We expect much lower levels in food derived from hemp feed
 - EIHA will analyze the paper and take an official position accordingly
 - EU Commission will evaluate both reports
 - Hearings will take place in Brussels



Thank you for your attention!



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