

LEGAL FRAMEWORK 3-D FOOD PRINTING



Agenda

- Current and potential applications of 3 D food printing
- Legal positions & liabilities various parties involved
- Legal qualification of printed food & implications
- Legal requirements for marketing printed food



Applications 3 D printed food

Current applications

- mainly “fun products”



Future applications

- are expected to include mass production consumer products and house appliances (cf. home breweries)
- are likely to extend to care setting (cf. medtech) for preventing malnutrition, addressing swallowing issues and enabling personalized approach

COLUMN



Louise O. Fresco

Anders over voedsel denken - door Big Mac

...good practices in de sector en duurzaamheid (geen vlees waarvoor land ontbost is). Maar het interessantste effect van de Big Mac is dat hij de aanzet heeft gegeven tot talloze alternatieven: vega- en algenburgers, handgemaakte lokale burgers en haute cuisine gourmet burgers. Ook dringt het besef door dat het vlees van de Big Mac (de vezels die nog aan de karkassen hangen) eigenlijk een nuttige vorm van afvalgebruik vormen. Het 3D-printen en personaliseren van Big Macs van laboratoriumvlees of vegetarische eiwitten is binnen handbereik.

NRC, 19 April 2017
(Dutch national paper)



3D-geprint eten voor Isala-patiënt

ZWOLLE - Voedsel uit een 3D-printer: als het aan Isala in Zwolle ligt, komt het eraan. Het kan de remedie zijn tegen ondervoede patiënten. Boerenkool, rode kool, wortels, dop erwtjes of zalm worden als 'moes' of 'paté' in de printer gestopt, waarna het als 'gewoon' eten op je bord belandt. Maar mét toegevoegde voedingsstoffen. Het moet dé manier zijn om mensen die weinig voedsel tot zich kunnen nemen, toch een volledige maaltijd te bieden.

De Stentor, 26 augustus 2016 (Dutch regional paper)

Liabilities parties involved (1)

Manufacturer food printer

- Food printer must comply with EU Machinery Directive 2006/42 and national implementing legislation.
- “Machinery”: *assembly fitted with a drive systems, consisting of linked components, at least one of which moves, joined together for specific application.*
- Machinery should conform to essential health and safety requirements re. design and construction.
- Before placing on the market, manufacturer should assess conformity to safety standards > CE mark
- Enforcement by national MS authorities



Liabilities parties involved (2)

Raw materials supplier

- Raw materials = ingredients = food stuffs > **General Food Law Regulation 2002/178** and its national implementations (NL: Commodities Act / Warenwet)
- Food: *every substance intended to be ingested by humans*
- Basic requirement: food safety!
- **Food safety** is responsibility of so-called Food Business Operator (FBO): any person or entity active in the production / processing / distribution of foodstuffs
 - Traceability requirement: identification of FBO one level up, one level down.
 - **ISO 22000**: self-regulatory standards applied by food industry



Liabilities parties involved (3)

Consumer

- Consumer takes role of producer > "prosumer"
- Home appliances: in case of safety or quality issues, consumer has claim against printer manufacturer and supplier of raw materials > what is his own share of responsibility?
- Care setting: hospital / elderly home takes on responsibilities of food manufacturer > What share of responsibilities when when patients experience problems with 3 D printed food?
- In both settings, clear contractual arrangements are required for all conceivable safety and quality issues.



Status of printed food (1)

Potential Novel Food

- 3 D printed food may qualify as a Novel Food under the Novel Foods Regulation 2283/2015.
- Novel Foods are foods that prior to 1997 did not form part of the regular diet within the EU.
- Current NF Regulation contains 10 product categories, including the new production process:

food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances;

- Little is yet known about the effects of the 3D production process on the food > any safety issues?

Status of printed food (2)

Implications of NF status

- If and when 3D printed food qualifies as Novel Food > prior marketing authorization will be required.
- FBO involved needs to prepare application dossier for Commission > competent authorities MS.
- EFSA will be asked for safety opinion if a MS has reasonable safety concerns.
- Advantage of new NF Regulation: general authorizations.

Consumer setting: authorization requirement not likely to apply.

Care setting: hospitals are recommended to take NF requirements seriously.

Marketing requirements (1)

3D printed food could be used for personalized nutrition:

- Fortified foods: Regulation 1925/2006
- Food supplements: Directive 2002/42 and national implementing legislation (MS have some liberty to set national rules)

e.g. level of Vit. D should not exceed 4.5 microgram per 100 Kcal foodstuff

- Medical foods: Regulations 609/2013 and 2016/128
- Infant formula: Regulation 609/2013 and 2016/127

These are highly regulated foods for vulnerable groups > should meet strict compositional criteria



Marketing requirements (2)

Labelling requirements & claims

- Raw materials to be used as ingredients for 3D printing should contain clear instructions for use > Food Information Regulation 1169/2011.
- If any nutrition or health claims are made re. those ingredients > relate to the foodstuff *as prepared* > Health Claim Regulation 1924/2006.

e.g. high in fibers > requires 6 g fibers / 100 g food product

e.g. high protein > requires that 20 % of the energy of the food is provided by protein

- No health claims may be made re. medical foods > Regulation 2016/128.

Conclusions



- 3D printed food is obtained by using a technology relatively new in the food supply.
- Such new technology presents new challenges for defining the responsibilities of the stakeholders involved and its end user.
- 3D printed may qualify as Novel Food > prior market authorisation required for professional trade in such products.

Axon Lawyers



Alliance of
European
Life Sciences
Law Firms

- Amsterdam based law firm with international focus
- Fully dedicated to life sciences, focus on food business
- Assisting high tech companies marketing innovative food products
- Founder of European Alliance of Life Sciences Law Firms
- Reporting current food law developments at blog FoodHealthLegal

AXON

science based lawyers

Axon is looking
for a new
associate and
trainee lawyer



Food Health Legal
legal and regulatory blog