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~ LIFE SCIENCES BOUTIQUE ~  
CHAMBERS EUROPE 2017

# GDPR IMPACT ON HEALTH & NUTRITION INDUSTRY

Axon Seminar  
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health  
food  
technology

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## Introduction speakers

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AUTORITEIT  
PERSOONSGEGEVENS



## Agenda

- Examples of health & nutrition scenario's where personal data are key
- Essentials of GDPR, focusing on what's new?
- GDPR applied to practice in health & nutrition industry



## Personal data in health & nutrition

**The Washington Post**  
*Democracy Dies in Darkness*

### What the future of cooking might look like

6 December 2017 article on **food platform innit**, connecting the smart kitchen with software aimed at personalizing and automating cooking. App proposes highly customizable micro-cooking content.

Potentially, this system could suggest food based on:

- how many steps your fitness tracker registered that day?
- your genetic profile?



## Personal data in health & nutrition

**Persoonlijke Gezondheidscheck**

Wat is de gezondheidscheck over ons veelgestelde vragen contact inloggen **start de check**

werkgevers gemeenten verzekeraars medische professionals

**Doe de check**

Een gezonder leven begint met een goed inzicht in je gezondheid en advies op maat. Start nu jouw Persoonlijke Gezondheidscheck.

**Start de check**

**Een gezonde organisatie**

Krijg inzicht in de gezondheid van uw organisatie of gemeente en zorg voor fittere medewerkers, een grotere inzetbaarheid, meer productiviteit en een lager ziekteverzuim.

**Ga naar zakelijk**

**Persoonlijke Gezondheidscheck**

## Personal data in health & nutrition

**iGene**  
WE LOVE LIFE

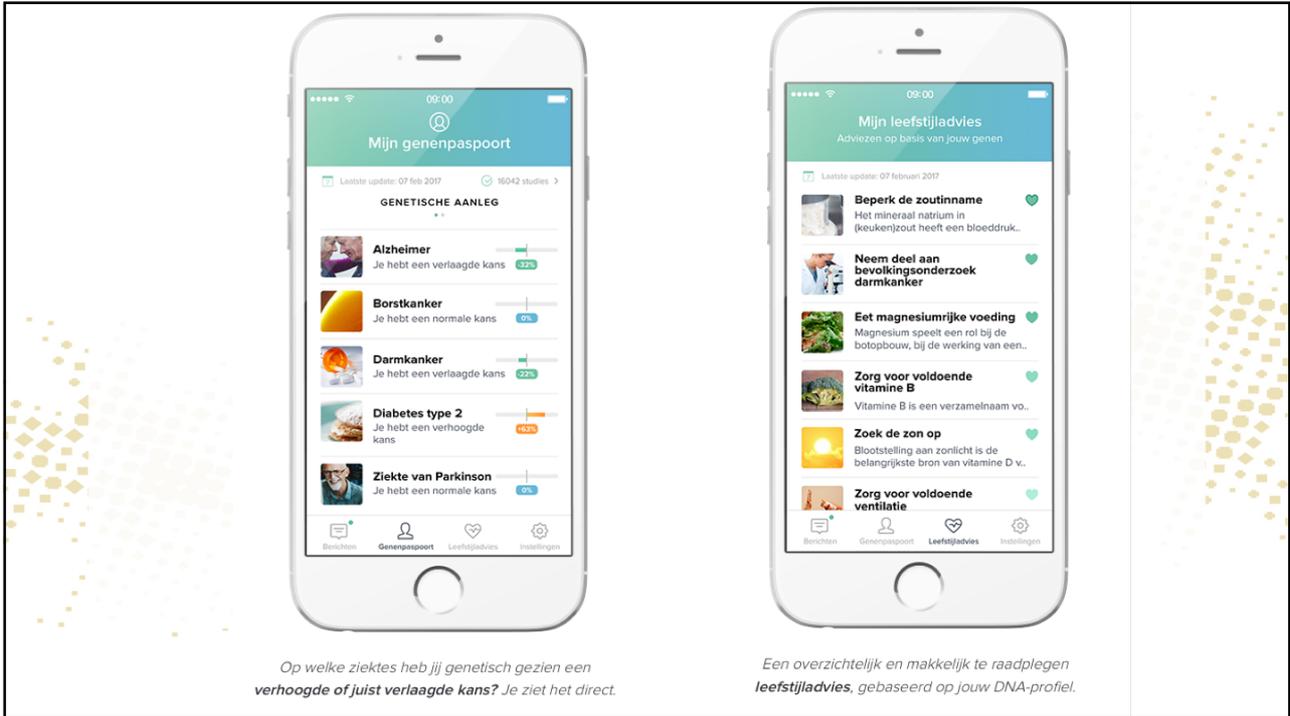
Home Hoe werkt het iGene Paspoort Over ons Informatie Contact

**Gezond blijven dankzij de kennis van je genen**

Met een iGene Paspoort krijg je inzicht in je eigen genen én een praktisch persoonlijk leefstijladvies, gebaseerd op jouw DNA-profiel.

**IGENE-KIT BESTELLEN**

Bestel nu de iGene DNA-kit en ontvang € 70 introductiekorting. Actie is geldig t/m 31 januari 2018.



## Personal data in health & nutrition



**Medical foods:** nutritional solutions supported by scientific research and clinical evidence



## Essentials GDPR



As per 25 May 2018 the GDPR applies in all Member States

- GDPR has direct effect and repeals Directive 95/46.
- NL: implementing Act GDPR for (1) withdrawing Dutch Data Protection Act, (2) creating statute Dutch Data Protection Authority and (3) substantiating the “known unknowns” in the GDPR.
- Material scope: covers processing of personal data
- Territorial scope: applicable to (1) controllers & processors based in the EU processing personal data, both in and outside EU and (2) controllers outside EU when offering services to EU data subjects and /or *monitoring* behaviour of EU citizens

## Essentials GDPR

Major changes in a nutshell

### **Rights of data subjects increased + strengthened**

- Data subject empowered by better understanding of and more control over processing of his/her personal data, e.g. data portability right

### **Obligations for controllers (and processors) have increased**

- stricter requirements for consent
- demonstration compliance GDPR & transparency
- Data Protection Impact Assessment / data protection officer
- privacy by design and privacy by default
- requirements processors

### **Enforcement serious stuff**

- Administrative fines can go up to 4 % annual turnover of entire group

## Essentials GDPR test your knowledge

### **Personal data**

any information relating to an identified or identifiable person

### **Anonymized data**

do not qualify as personal data unless the controller / processor has access to an identifier (e.g. identification number or factor(s) specific to physical / social / economic identity of data subject)

### **Special categories of personal data** (“*sensitive data*”)

genetic and biometric data, data concerning health i.a. facing strict rules for processing

### **Processing personal data**

any operation performed on personal data, whether or not by automated means: collection, storage, use, alteration, transmission etc.

## Essentials GDPR test your knowledge

### **Purpose limitation**

Collected for specified, explicit and legitimate purposes – same applies to any further processing.

### **Data minimisation**

Personal data shall be adequate, relevant and limited to the purpose - may require pseudonymisation.

### **Transparency**

Any natural person whose data are being processed knows what's going on: Who is the controller? What data are being processed for what purpose? Info should be easily accessible in clear language.

### **Accountability**

Controller needs to demonstrate compliance with GDPR.

## GDPR applied to practice medical foods

### What are the consequences of the right of erasure for clinical trials?

- Picture a manufacturer of medical foods fearing that trial results will be “depowered”.
- Right of erasure is embodied in article 17 GDPR.
- Data subject can invoke this right by withdrawing consent for further processing whereas there is no other legal processing ground.



## GDPR applied to practice medical foods

### Consequences of the right to erasure for clinical trials *continued*

- No absolute ground > does not apply to the extent processing is necessary for a limited number of grounds, including scientific research.
- c. 159 GDPR: concept of **scientific research** should be interpreted in a broad manner, including technological development and demonstration, fundamental research, applied research and **privately funded** research.
- What other conditions are applicable?
  - Appropriate safeguards for the data subject are put in place;
  - Accommodating the right to erasure would render impossible / seriously impair the objective for which the data were processed.

## GDPR applied to practice biological samples

### What is the impact of a request for erasure of personal data in the commercial setting of processing health data?

- Picture a company handling biological samples (e.g. faeces) to evaluate gut health.
- Such company cannot benefit from the exception re. scientific research, so it (neither its partners!) cannot continue to process such samples.
- How about the results obtained using these samples? Check specific legislation, e.g. MDR stating that the withdrawal of informed consent (IC) shall not affect the activities already carried out and the use of the data obtained based on IC before its withdrawal (art. 62 (5) Reg. 2017/745).

## GDPR applied to practice monitoring health

### How can you lawfully put in place a platform monitoring health data?

- Picture a company providing a so-called health check ("*APK van uw gezondheid*") via an online internet platform.
- No doubt explicit consent of data subject as sensitive data are involved.
  - Consent should be "clear affirmative act"
  - Pre-ticked boxes no go!
  - Withdrawal consent should be as easy as providing it
  - Burden of proof is on the controller / processor



## GDPR applied to practice monitoring health

### Platform monitoring health data *continued*

- Does business model include profiling, i.e. any form of automated form or processing personal data to evaluate certain personal aspects? In the affirmative: both a DPIA and a DPO may be required.
- Data Protection Impact Assessment and Data Protection Officer
  - Both DPIA + DPO are required processing on a large scale of sensitive data
  - DPIA required for systematic and extensive evaluation of personal aspects of natural persons, based on automated processing, including profiling significantly affecting the natural person
  - DPO required where the nature, scope and purpose of processing operations require regular & systematic monitoring

## GDPR applied to practice secondary use

### How to accommodate secondary use of clinical data or samples?

- Basic principle: each processing action should be covered by specific and separate consent.
- For scientific research, it is allowed that data subjects give their consent to certain areas of research, when it is not possible to fully identify the purpose of processing at the time of data collection (c. 33 GDPR)
- Criteria to assess if use of personal data for other purpose than for which they were initially obtained: (i) link between initial and secondary purpose, (ii) context of collection (i.e. reasonable expectations data subjects), (iii) nature of personal data and (iv) consequences of further processing (c. 50 and art. 6.4 GDPR).
- Performance studies using left over samples shall be conducted in accordance with applicable data protections laws (art. 75.3 IVDR).

# Guidance documents



Art. 29 Working Party has issued guidance on many topics:

- Anonymisation Techniques (WP 05/2014 adopted on 10 April 2014)
- Data portability (WP 242, adopted on 13 December 2016)
- Consent (WP 258, adopted on 17 November 2017)
- Transparency (open for consultation until 28 January 2018)

EU Guidance: Rules for business and organisations [https://ec.europa.eu/info/strategy/justice-and-fundamental-rights/data-protection/reform/rules-business-and-organisations\\_en](https://ec.europa.eu/info/strategy/justice-and-fundamental-rights/data-protection/reform/rules-business-and-organisations_en)

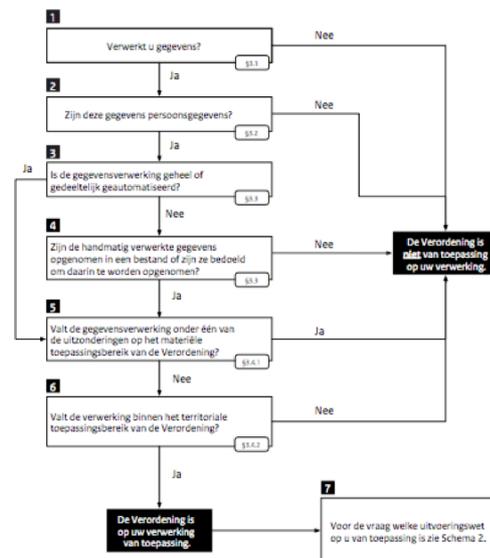
NL: Guidance on GDPR and on Implementing Act

Dutch

**Handleiding**  
**Algemene verordening**  
**gegevensbescherming**  
 en Uitvoeringswet Algemene verordening  
 gegevensbescherming

## Stroomdiagrammen en checklists

Schema 1: Is de Verordening op u van toepassing?





**KEEP  
CALM  
AND  
CALL  
AXON**



## Conclusions

- Protection of personal data is taken seriously under the GDPR, as being a fundamental right.
- Health & nutrition companies working with sensitive data need to make sure to be compliant.
- Be informed about the applicable requirements for the benefit of the reputé of your business and in order to avoid costly enforcement measures.

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