

5 April 2019



# Implementation of the risk assessment principles as laid down in the EFSA GMO Panel 2017 Guidance document

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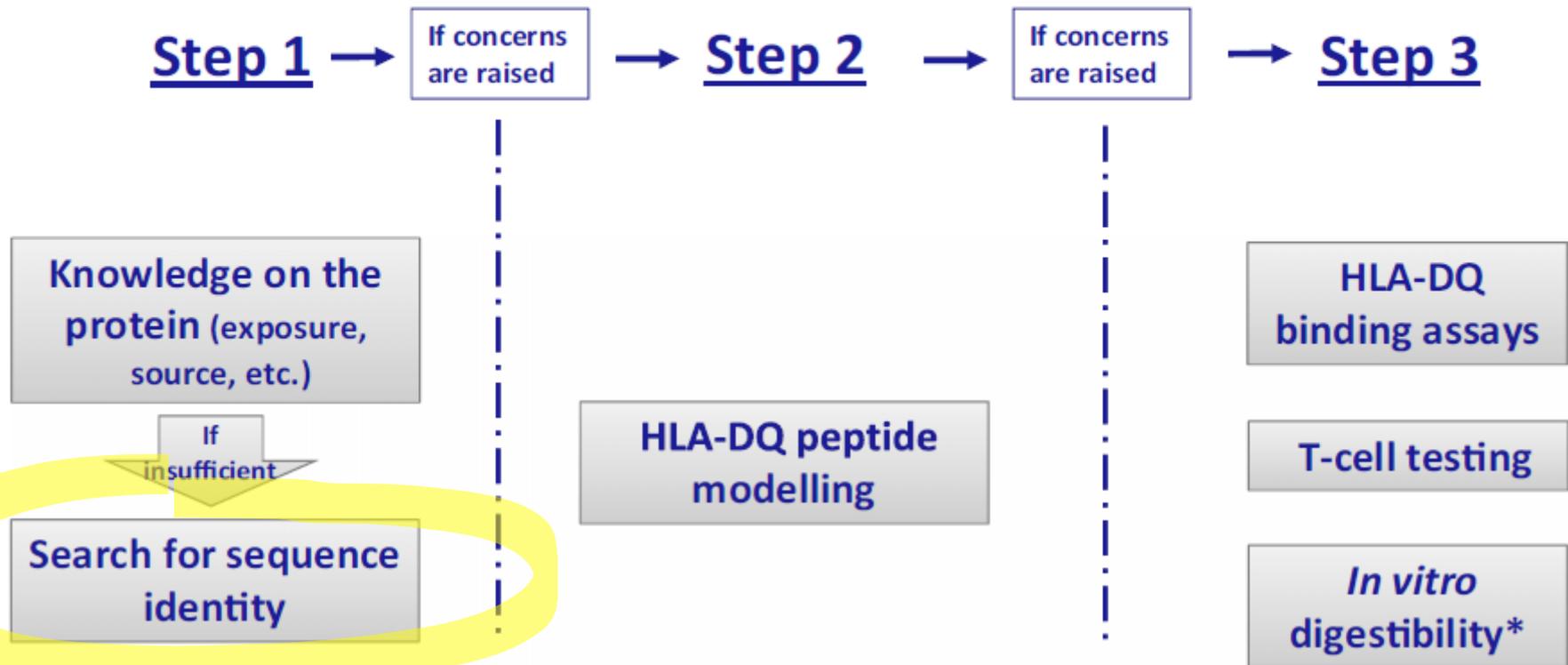
# CELIAC DISEASE - SAFETY ASSESSMENT

## Main aspects to highlight

- Real harmonisation between applicants
- Overall approach proposed by applicants in line with EFSA 2017 guidance document
- Stepwise approach:
  - Knowledge on the source and the protein
  - Searches 

{	with perfect match	{	with motif
	with partial match		without motif
  - HLA-DQ modelling
  - *In vitro* testing

## Stepwise approach for risk assessment



# Celiac disease – DQ2 T-cell epitopes

## DQ2 restricted epitopes

[Sollid et al., 2012. Immunogenetics, 64, 455-460](#)

Epitope	Motif	Reference
DQ2.5-glia- $\alpha$ 1a	P F P Q P Q L P Y	Arentz-Hansen et al. (2000)
DQ2.5-glia- $\alpha$ 1b	P Y P Q P Q L P Y	Arentz-Hansen et al. (2002)
DQ2.5-glia- $\alpha$ 2	P Q P Q L P Y P Q	Arentz-Hansen et al. (2000)
DQ2.5-glia- $\alpha$ 3	<b>E L P Y</b>	Vader et al. (2002b)
DQ2.5-glia- $\gamma$ 1	<b>E L P Y</b>	Sjöström et al. (1998)
DQ2.5-glia- $\gamma$ 2	<b>E L P Y</b>	Qiao et al. (2005), Vader et al. (2002b)
DQ2.5-glia- $\gamma$ 3	<b>Q Q F</b>	Arentz-Hansen et al. (2002)
DQ2.5-glia- $\gamma$ 4a	<b>Q Q F</b>	Arentz-Hansen et al. (2002)
DQ2.5-glia- $\gamma$ 4b	<b>F A</b>	Qiao et al. (2005)
DQ2.5-glia- $\gamma$ 4c	<b>F A</b>	Arentz-Hansen et al. (2002)
DQ2.5-glia- $\gamma$ 4d	<b>F A</b>	Qiao (unpublished)
DQ2.5-glia- $\gamma$ 5	<b>S V</b>	Arentz-Hansen et al. (2002)
DQ2.5-glia- $\omega$ 1	<b>S V</b>	Tye-Din et al. (2010)
DQ2.5-glia- $\omega$ 2	<b>S V</b>	Tye-Din et al. (2010)
DQ2.2-glut-L1	<b>E Q</b>	Vader et al. (2002b)
DQ2.5-glut-L2	<b>E Q</b>	Stepniak et al. (2005), Vader et al. (2002b)
DQ2.5-hor-1	<b>Q/E-X1-P-X2</b>	Tye-Din et al. (2010), Vader et al. (2003)
DQ2.5-hor-2	<b>Q/E-X1-P-X2</b>	Vader et al. (2003)
DQ2.5-sec-1	P F P Q P Q Q P F	Tye-Din et al. (2010), Vader et al. (2003)
DQ2.5-sec-2	P Q P Q Q P F P Q	Vader et al. (2003)
DQ2.5-ave-1	P Y P E Q Q E P F	Arentz-Hansen et al. (2004), Vader et al. (2003)
DQ2.5-ave-1b	P Y P E Q Q Q P F	Arentz-Hansen et al. (2004), Vader et al. (2003)

# Celiac disease – DQ8 T-cell epitopes

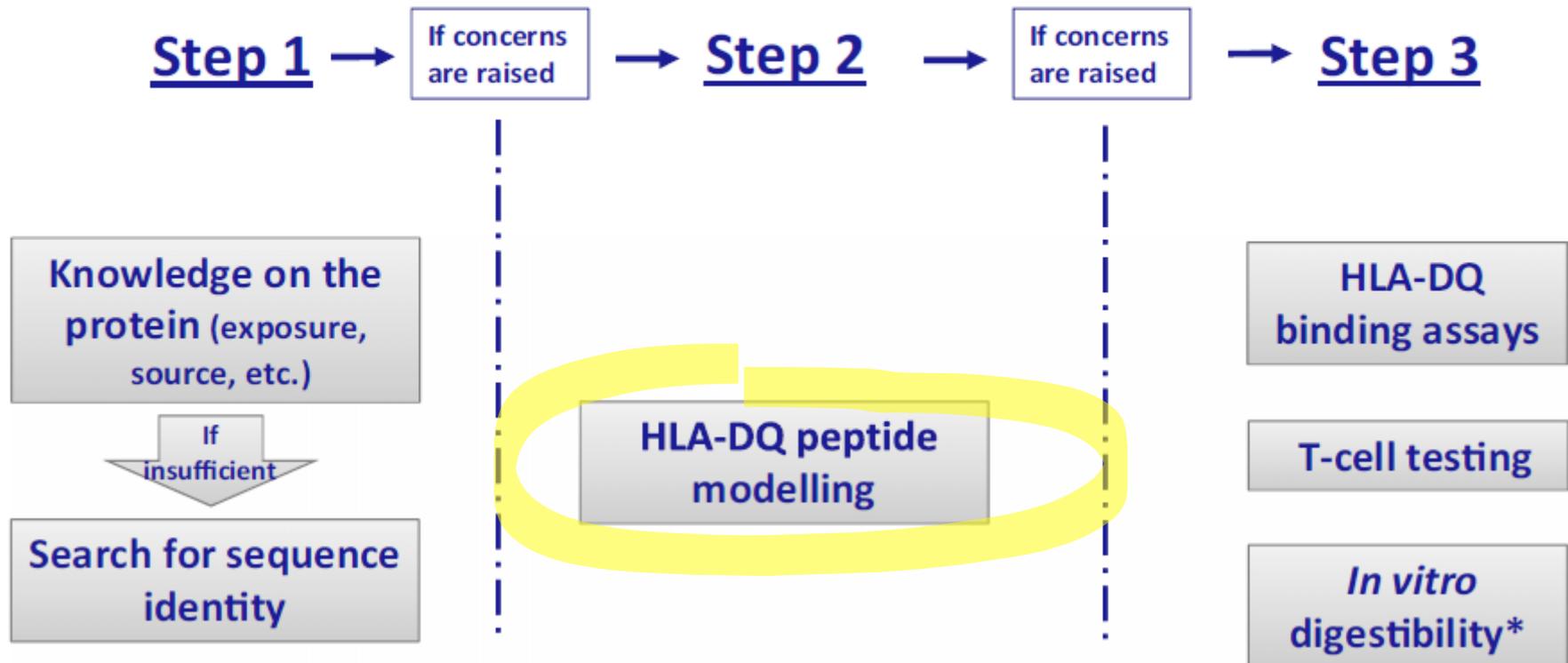
[Sollid et al., 2012. Immunogenetics, 64, 455-460](#)

## DQ8 restricted epitopes

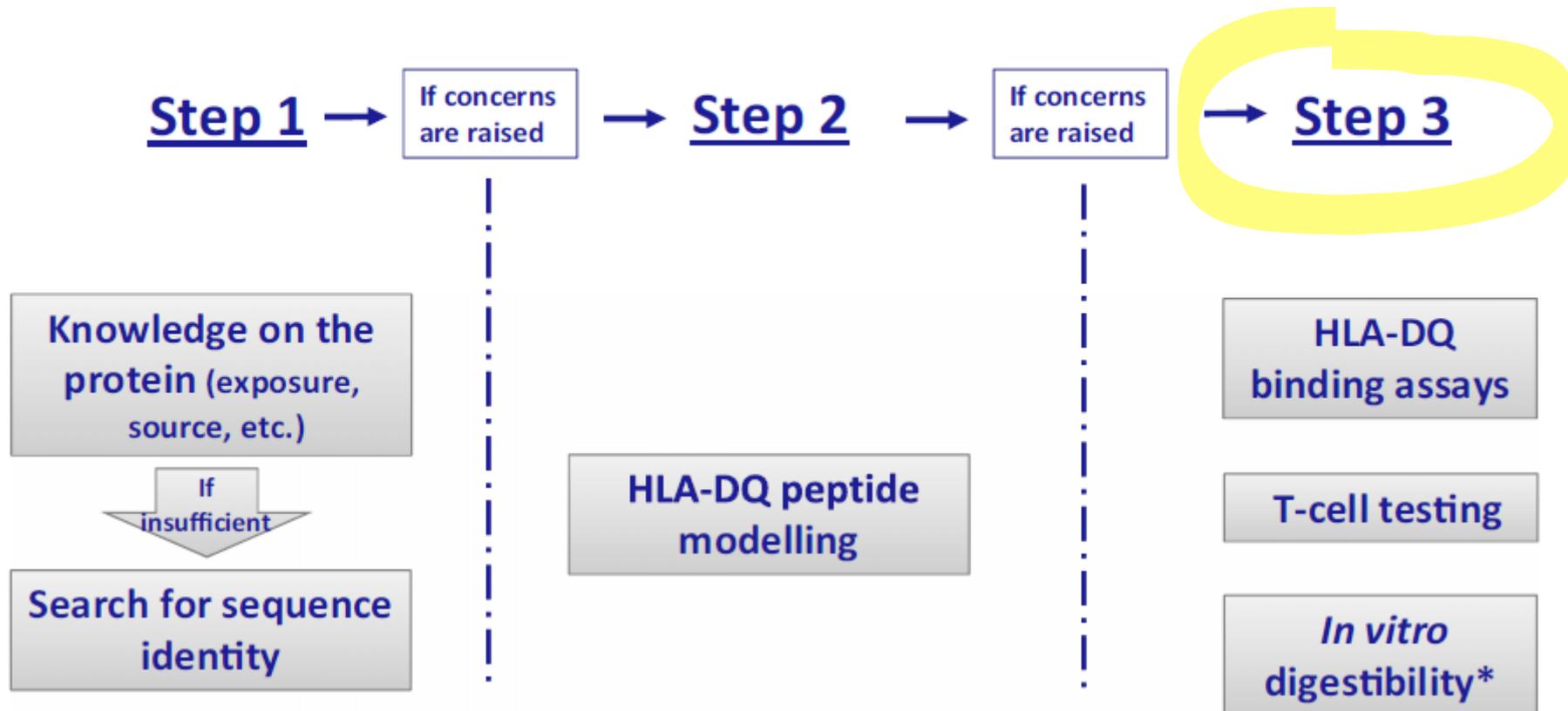
Epitope	Motif	Reference
DQ8-glia- $\alpha$ 1	<b>Q G S F Q P S Q Q</b>	van de Wal et al. (1998b)
DQ8-glia- $\gamma$ 1a	<b>Q Q P Q Q P F P Q</b>	Tollefsen et al. (2006)
DQ8-glia- $\gamma$ 1b	<b>Q Q P Q Q P Y P Q</b>	Tollefsen et al. (2006)
DQ8-glut-H1	<b>Q G Y Y P T S P Q</b>	van de Wal et al. (1999)

Partial matches without the Q/E-X1-P-X2  
to be investigated

## Stepwise approach for risk assessment



## Stepwise approach for risk assessment





- **Possible exclusion criteria:**
  - EFSA included few exclusion criteria
  - Additional exclusion criteria needed?
  - Tool should be practical keeping the case-by-case philosophy
- **Development of a database:**
  - Few databases available
- **HLA-DQ-peptide modelling**
  - Experience collected from applicants
- **Data submission**



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