# Draft Statement on Exposure Assessment of Food Enzymes - Examples -

**Holger Zorn**
**CEF Panel Member**

Info Session on Applications – Food Enzymes – Technical meeting with stakeholders on refinement of exposure estimates

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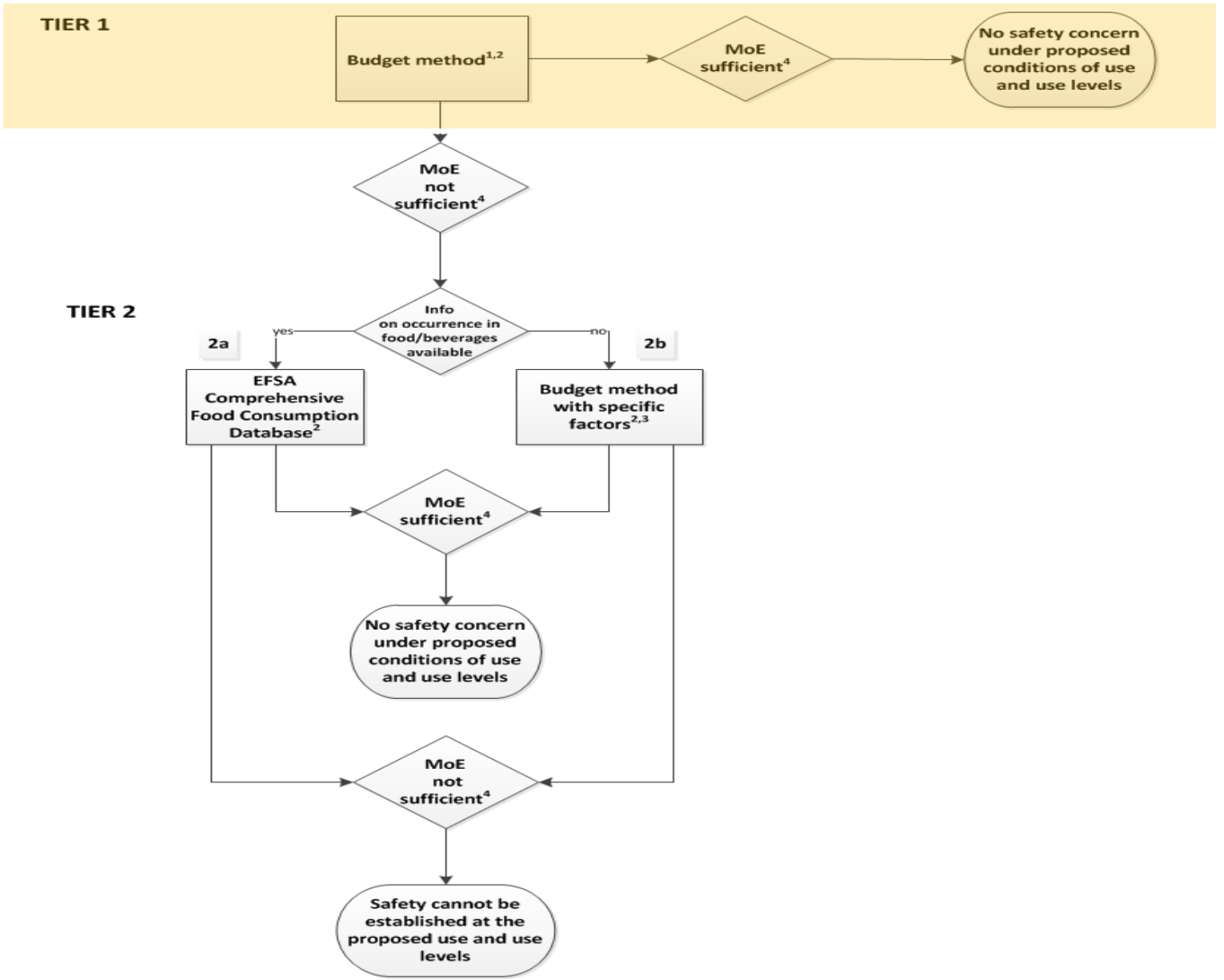
# TIERED APPROACH FOR EXPOSURE ASSESSMENT



# EXAMPLE 1: APPLICATION OF TIER 1

**Table 1:** Typical uses and proposed use levels of **food enzyme 1**

| process | proposed use level of the food enzyme (mg TOS/kg raw material) |
|---|---|
| cereal-based processes | up to 20 mg TOS/kg of starch |
| brewing processes and other cereal-based beverage processes | up to 10 mg TOS/kg of starch |

# EXAMPLE 1: APPLICATION OF TIER 1

**Assumptions:**

- cereal based foods (e.g. bread) typically contain 50 % starch
  (70 % flour in bread x 70 % starch in flour)
- 1 kg grain is used for the production of 6 L beer and grain contains 70 % starch
  (1/6 x 0.7 = 0.12)

**Table 2:** Conversion factors for cereal-based processes

| food | proposed use level (mg TOS/kg starch) | conversion factor | proposed use level (mg TOS/kg final food) |
|---|---|---|---|
| cereal-based processes | 20 | 0.50 | 10 |
| brewing processes and other cereal-based beverage processes | 10 | 0.12 | 1.2 |

# EXAMPLE 1: APPLICATION OF TIER 1

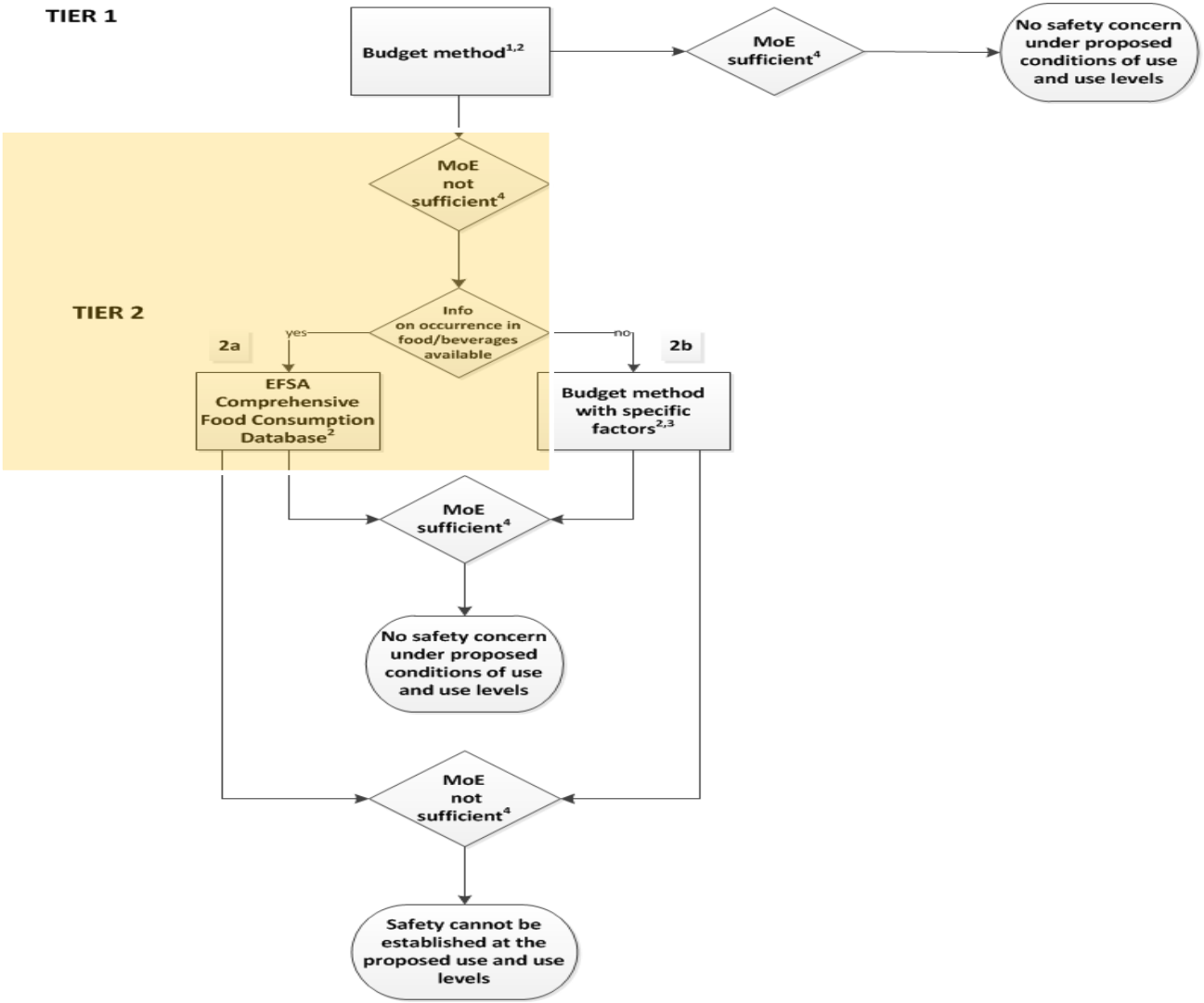
**Table 3:** Exposure calculation according to Tier 1 (screening step)

| food | consumption (kg or L final food / kg bw/d) | proposed use level (mg TOS/kg final food) | calculated exposure (mg TOS/kg bw/d) |
|---|---|---|---|
| solid food | 0.05 | 10 | 0.5 |
| non-milk beverages | 0.1 | 1.2 | 0.12 |
| TOTAL | | | 0.62 |

## Calculation of the Margin of Exposure (MoE)

$$\frac{\text{NOAEL (320 mg TOS/kg bw/day)}}{\text{estimated exposure (0.62 mg TOS/kg bw/day)}} = \text{MOE (516)}$$

# TIERED APPROACH FOR EXPOSURE ASSESSMENT



# EXAMPLE 2: APPLICATION OF TIER 2A

**Table 4:** Typical uses and proposed use levels of **food enzyme 2**

| process | proposed use level of the food enzyme (mg TOS/kg raw material) |
|---|---|
| French fries process | up to 30 mg TOS per kg potato |
| sliced potato chips process | up to 400 mg TOS per kg potato |
| potato granule process/extruded snacks such as snack pellets | up to 400 mg TOS per kg potato |

**Table 5:** Conversion of use levels from raw material to final food

| food | max. proposed use level (mg TOS/kg potato) | conversion factor | max. proposed use level (mg TOS/kg final food) |
|---|---|---|---|
| potato | 400 | 1 | 400 |

# EXAMPLE 2: APPLICATION OF TIER 2A

**Table 6:** Exposure calculation according to Tier 1 (screening step)

| food | consumption (kg final food /kg bw/d) | max. proposed use level (mg TOS/kg final food) | calculated exposure (mg TOS/kg bw/d) |
|---|---|---|---|
| solid food | 0.05 | 400 | 20 |
| TOTAL | | | 20 |

$$\frac{\textbf{NOAEL (1,040 mg TOS/kg bw/day)}}{\textbf{estimated exposure (20.0 mg TOS/kg bw/day)}} = \textbf{MOE (52)}$$

→ further refinement according to Tier 2A

# EXAMPLE 2: APPLICATION OF TIER 2A

Refinement step 1: Identification of food categories using EFSA´s standardised food classification and description system **FoodEx1**

| | Matrix code | Matrix description | Matrix short description | Hierarchical code | Hierarchical level | Valid from | Valid to | Current validity | Parent code | EFSA Food C |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | | | |
| 2 | A.01.00000 | All matrices | All matrices | A | | 01.03.20 | | Yes | | |

| | A | B | C | D | E | F | G | H | I | J | K |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | | | | | | | y/n |
| 2 | A.01.000 | Potato bread | Potato bread | A.01.04.0( | 4 | 01/03/2009 | | Yes | A.01.000 | C01B | y |
| 3 | A.01.000 | Potato-rye bread | Potato-rye bread | A.01.04.0( | 4 | 01/03/2009 | | Yes | A.01.000 | C01B | y |
| 7 | A.01.000 | French fries | French fries | A.03.01.0( | 3 | 01/03/2009 | | Yes | A.01.000 | C05 | y |
| 8 | A.01.000 | Potato flakes | Potato flakes | A.03.01.0( | 3 | 01/03/2009 | | Yes | A.01.000 | C05 | y |
| 9 | A.01.000 | Mashed potato powder | Mashed potato powder | A.03.01.0( | 3 | 01/03/2009 | | Yes | A.01.000 | C05 | y |
| 11 | A.01.000 | Potato fried | Potato fried | A.03.01.0( | 3 | 01/03/2009 | | Yes | A.01.000 | C05 | y |
| 12 | A.01.000 | Potato baked | Potato baked | A.03.01.0( | 3 | 01/03/2009 | | Yes | A.01.000 | C05 | y |
| 13 | A.01.000 | Potato croquettes | Potato croquettes | A.03.01.0( | 3 | 01/03/2009 | | Yes | A.01.000 | C05 | y |
| 20 | A.01.001 | Potatoes and vegetables meal | Potatoes and vegetables meal | A.19.03.0( | 3 | 01/03/2009 | | Yes | A.01.001 | C14A | y |
| 21 | A.01.001 | Potatoes and meat meal | Potatoes and meat meal | A.19.03.0( | 3 | 01/03/2009 | | Yes | A.01.001 | C14A | y |
| 22 | A.01.001 | Potatoes, meat, and vegetables meal | Potatoes, meat, and vegetables meal | A.19.03.0( | 3 | 01/03/2009 | | Yes | A.01.001 | C14A | y |
| 23 | A.01.001 | Potatoes and cheese meal | Potatoes and cheese meal | A.19.03.0( | 3 | 01/03/2009 | | Yes | A.01.001 | C14A | y |
| 24 | A.01.001 | Fish and potatoes meal | Fish and potatoes meal | A.19.06.0( | 3 | 01/03/2009 | | Yes | A.01.001 | C14A | y |
| 27 | A.01.001 | Potato crisps | Potato crisps | A.20.01.0( | 3 | 01/03/2009 | | Yes | A.01.001 | C05 | y |

Selected food categories from EFSA Foodex Classification System

# EXAMPLE 2: APPLICATION OF TIER 2A

Refinement step 2: Calculation of exposure using the EFSA Comprehensive Database

- consumption statistics (mean and 95$^{th}$ percentile) based on individual consumption

**Table 7:** Estimated mean and high level consumption of potato-based foods in five population groups across all dietary surveys (g /kg bw per day)

| | toddlers | children | adolescents | adults | elderly |
|---|---|---|---|---|---|
| | (12–35 months) | (3–9 years) | (10–17 years) | (18–64 years) | (> 65 years) |
| mean | 1.59 | 2.96 | 1.36 | 0.95 | 0.56 |
| high level p95 | 4.93 | 8.29 | 4.99 | 3.19 | 1.88 |

# EXAMPLE 2: APPLICATION OF TIER 2A

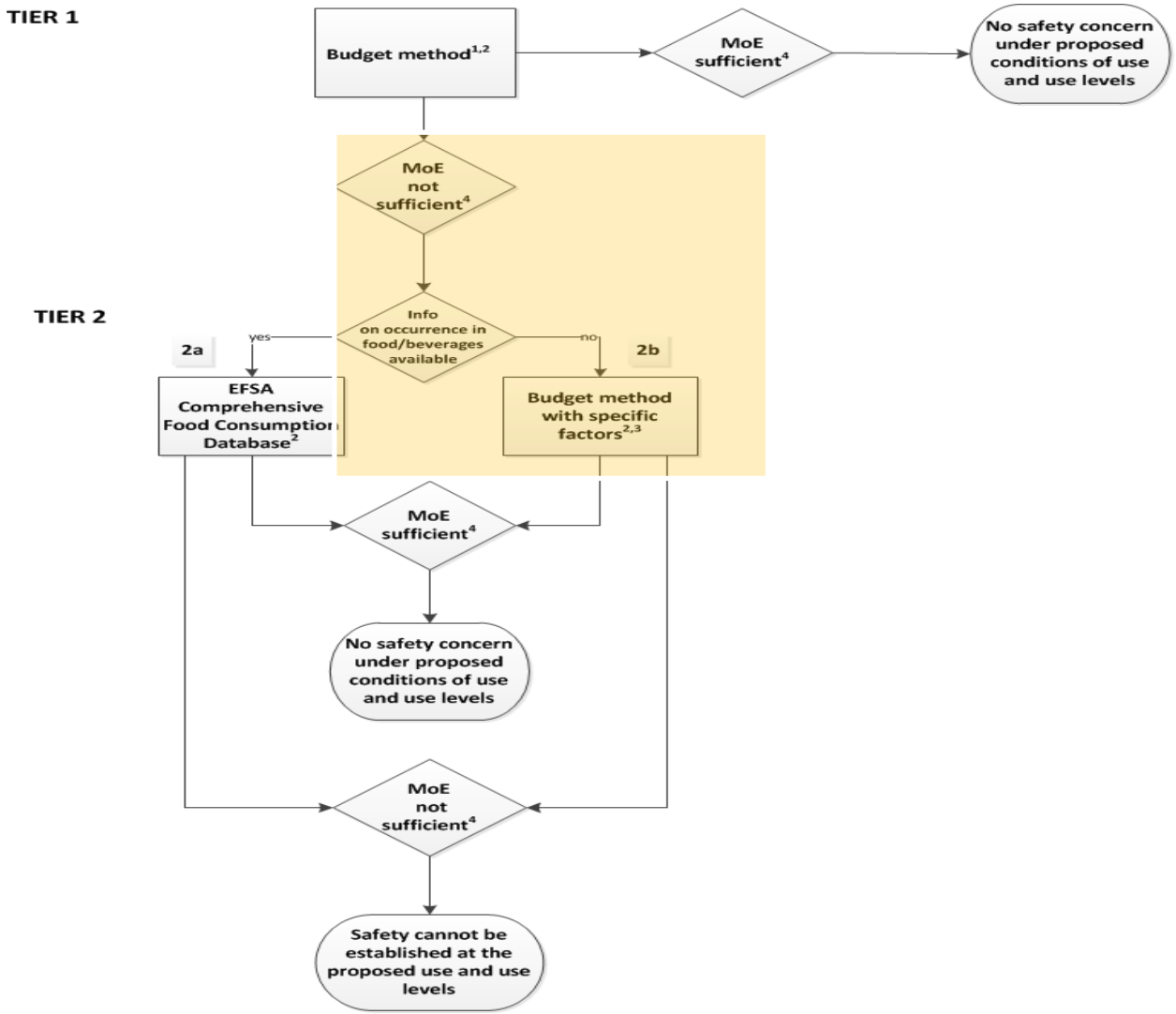
**Table 8:** Exposure calculation according to Tier 2A

| food | consumption (kg final food/kg bw/d) | proposed use level (mg TOS/kg potato) | calculated exposure (mg TOS/kg bw/d) |
|---|---|---|---|
| solid food | 0.00829 | 400 | 3.32 |
| TOTAL | | | 3.32 |

**Calculation of the Margin of Exposure (MoE)**

$$\frac{\text{NOAEL (1,040 mg TOS/kg bw/day)}}{\text{estimated exposure (3.32 mg TOS/kg bw/day)}} = \text{MOE (313)}$$

# TIERED APPROACH FOR EXPOSURE ASSESSMENT



# EXAMPLE 3: APPLICATION OF TIER 2B

**Table 9:** Typical uses and proposed use levels of **food enzyme 3**

| process | proposed use level of the food enzyme (mg TOS/kg raw material) |
|---|---|
| starch processing for glucose syrup production | up to 10 mg TOS/kg of starch |
| cereal-based processes | up to 20 mg TOS/kg of starch |

# EXAMPLE 3: APPLICATION OF TIER 2B

**Assumptions:**

- sugar candies / caramels typically contain 60 % glucose syrup
- cereal based foods (e.g. bread) typically contain 50 % starch
- soft drinks typically contain 14 % glucose syrup

**Table 10:** Conversion factors

| food | proposed use level (mg TOS/kg starch) | conversion factor | proposed use level (mg TOS/ kg or L final food) |
|---|---|---|---|
| solid food | 10 (for glucose syrup) | 0.60 | 6.0 |
| | 20 (for cereal based processes) | 0.50 | 10.0 |
| non-milk beverages | 10 | 0.14 | 1.4 |

# EXAMPLE 3: APPLICATION OF TIER 2B

**Table 11:** Calculation of exposure according to Tier 1 (screening step)

| food | consumption (kg or L/kg bw/d) | max. proposed use level (mg TOS/kg or L final food) | calculated exposure (mg TOS/kg bw/d) |
|---|---|---|---|
| solid food | 0.05 | 10 | 0.50 |
| non-milk beverages | 0.1 | 1.4 | 0.14 |
| TOTAL | | | 0.64 |

**Calculation of the Margin of Exposure (MoE)**

$$\frac{\text{NOAEL (175 mg TOS/kg bw/day)}}{\text{estimated exposure (0.64 mg TOS/kg bw/day)}} = \text{MOE (273)}$$

→ further refinement according to Tier 2B

# EXAMPLE 3: APPLICATION OF TIER 2B

Refinement step 1: Identification of food categories for both processes which are likely to contain the enzyme/ingredient using EFSA´s standardised food classification and description system **FoodEx1**

Refinement step 2: Calculation of the percentage of solid food and beverages that potentially contain the enzyme in relation to total intake of solid food and beverages, respectively. The derived factor provides an indication of the proportion of food potentially containing the enzyme and is applied in the budget method.

# EXAMPLE 3: APPLICATION OF TIER 2B

**Table 12:** Exposure calculation according to Tier 2B

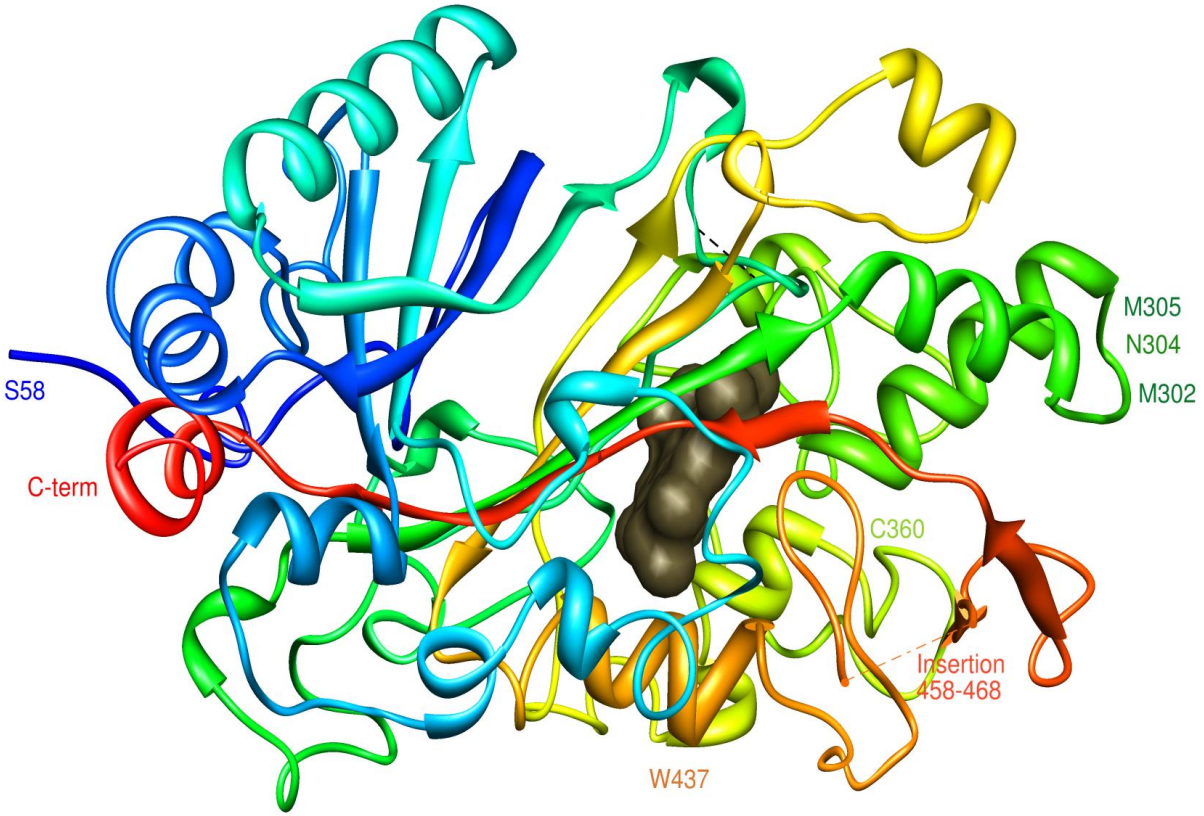
| food | consumption (kg or L/kg bw/d) | proposed use level (mg TOS/kg final food) | percentage of foods potentially containing the enzyme/total food or beverages consumed | exposure (mg TOS/kg bw/d) |
|---|---|---|---|---|
| solid food | 0.05 | 10 | **0.64*** | 0.32 |
| non-milk beverages | 0.1 | 1.4 | **0.11*** | 0.015 |
| TOTAL | | | | 0.335 |

*** hypothetical example**

**Calculation of the Margin of Exposure (MoE)**

$$\frac{\text{NOAEL (175 mg TOS/kg bw/day)}}{\text{estimated exposure (0.34 mg TOS/kg bw/day)}} = \text{MOE (515)}$$

# EXPOSURE ASSESSMENT OF FOOD ENZYMES




## Many thanks!