SERIES OF THE CONSTANTIN HERING FOUNDATION

Booklet 1

Ethanol in Hahnemann’s Q-Potencies



Pharmaceutical principles, calculation of the amount of ethanol ingested and quantitative assessment

Martina Schäfer

Pharmaceutical-technical assistant (PTA) · Heilpraktikerin (licensed non-medical practitioner)

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Notes

This booklet has been prepared with the greatest professional and editorial care. Despite careful checking, errors cannot be entirely ruled out.

The information provided is intended for professional information and does not replace individual pharmaceutical advice or medical or therapeutic assessment in the individual case.

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1. Introduction

1.1 Background and aims

The question of ethanol exposure during the therapeutic use of Hahnemann's Q-potencies is discussed both among professionals and in public. Attention is often focused on the ethanol concentration of the ready-to-use medicinal solution, while the amount of ethanol actually ingested with the prescribed single dose is usually left out of consideration.

For a proper assessment, however, the concentration of the medicinal solution is not the only relevant factor. What matters is the amount of ethanol that is actually ingested with the therapeutically prescribed single dose.

The aim of this booklet is to present the pharmaceutical principles required for this and to calculate, in a transparent way, the amount of ethanol ingested when a Q-potency is used, on the basis of a practice-based, exemplary dosing scheme. The order of magnitude of the result is then assessed against suitable reference points.

1.2 Target readership

This booklet is intended for pharmaceutical and therapeutic professionals and for anyone who wishes to obtain sound and transparent information on this subject.

1.3 Structure of the booklet

The booklet is divided into four consecutive chapters and a final list of references.

After the introduction, the pharmaceutical principles and the functions of ethanol in the manufacture and preparation of Q-potencies are explained. The amount of ethanol ingested when a Q-potency is used is then calculated step by step and assessed quantitatively. In addition, comparative values from foods and beverages are used to illustrate its order of magnitude.

2. Pharmaceutical principles

2.1 Ethanol – chemical and pharmaceutical properties

Ethanol is a monohydric alcohol with the molecular formula C_2H_6O. Owing to its molecular structure, ethanol has both hydrophilic and lipophilic properties and is miscible with water in any proportion. These properties allow substances of differing polarity to be dissolved and form an essential basis for its wide range of pharmaceutical uses.[1–3]

Ethanol evaporates rapidly even at room temperature. This property is particularly important in manufacturing and processing steps in which ethanol is used as a temporary solvent or carrier medium.[1]

In addition to these physicochemical properties, ethanol has a concentration-dependent antimicrobial effect. The interplay of these properties allows it to be used for a variety of pharmaceutical purposes.[4]

2.2 Pharmaceutical functions and uses of ethanol

Ethanol fulfils various functions in pharmacy. It is used in particular as a **solvent and co-solvent** (an additional solvent in a solvent mixture), **extraction medium, carrier medium and preservative**. At correspondingly higher concentrations, ethanol is also used, owing to its antimicrobial properties, in **antisepsis and disinfection**.[3–5]

As a solvent and co-solvent, ethanol allows solutions to be prepared with substances whose solubility in water is limited. By changing the proportion of ethanol, it is possible to influence how well predominantly water-soluble or predominantly fat-soluble substances dissolve in the mixture.[1–3]

As extraction media, ethanol and ethanol–water mixtures are used to obtain soluble constituents from plant starting materials. Which constituents can be extracted depends, among other things, on the ethanol content of the extraction medium.[5]

Ethanol can also be a component of the carrier medium of a liquid medicinal preparation. The dissolved components are then present in an ethanol-containing liquid that serves as the base of the medicinal preparation. In this case, ethanol remains a component of the finished preparation.[3]

Owing to its antimicrobial properties, ethanol at a suitable concentration can have a preservative function and contribute to the microbiological stability of a medicinal preparation.[3–6]

2.3 Ethanol in the manufacture and preparation of Q-potencies

Several of the pharmaceutical properties of ethanol described above are exploited in the manufacture and preparation of Q-potencies. During potentisation, ethanol serves as the dilution medium[1]. Q-potencies are a series of potencies described by Hahnemann; their manufacture is set out in § 270 of the 6th edition of the *Organon der Heilkunst* (Organon of the Healing Art).[7]

In the further manufacturing process, ethanol serves as a carrier medium. It allows the potentised preparation to be applied to globules and, owing to its volatility, evaporates completely during the subsequent drying.[7]

To prepare the ready-to-use medicinal solution, one globule is dissolved in an ethanol–water mixture. The ethanol it contains – 20 % v/v in the practical example presented here – lies within a concentration

[1] In the accompanying note, Hahnemann refers to the medium used in dynamisation as the “Verdünnungs-Medium” (dilution medium) and describes the use of spirit of wine (Weingeist) in the successive potentisation steps.

range described in the pharmaceutical literature for the antimicrobial preservation of aqueous preparations, and thus contributes to the microbiological stability of the ready-to-use medicinal solution.[6]

The European regulatory authority explicitly states this connection: ethanol is used as an extraction solvent in herbal medicinal products and in the manufacture of mother tinctures for homoeopathic preparations; most liquid homoeopathic preparations are likewise formulated in hydro-alcoholic solution, using the ethanol concentrations laid down in the manufacturing methods of the European Pharmacopoeia or, in its absence, in the pharmacopoeias officially used in the Member States (source 3, pp. 10 f.).[3]

2.4 Manufacturing function and ethanol exposure

For the following discussion, a distinction must be made between the technical functions of ethanol in manufacture and the amount of ethanol that is actually ingested when the ready-to-use Q-potency is taken.

The relevant factors for calculating ethanol exposure are the ethanol concentration of the medicinal solution and the individually prescribed number of drops and amount taken.

3. Calculation of the amount of ethanol ingested

With regard to the manufacture of the Q-potency, the following worked example follows Hahnemann's original instructions in the Organon der Heilkunst (6th edition). For its use, a practice-based dosing scheme is presented as an example.

The scheme serves to calculate the amount of ethanol ingested in a transparent way and does not constitute a general dosing recommendation. The results are assessed in Chapter 4.

3.1 Starting point of the calculation

The calculation is based on three quantities: the ethanol concentration of the medicinal solution, the prescribed number of drops and the amount taken from the dosing solution.

What matters for the assessment is the amount of ethanol actually ingested with the single dose – not merely the ethanol concentration of the medicinal solution.

3.2 Basis of calculation

The prescribed single dose is determined by two quantities:

- the number of drops of medicinal solution used to prepare the dosing solution, and
- the amount taken from it.

Both quantities are set individually and may vary from prescription to prescription.

The worked example set out in full in sections 3.3 to 3.5 corresponds to the highest level of the practice-based scheme: five drops of a medicinal solution containing 20 % v/v ethanol are made up with water to a total volume of 150 ml; five teaspoons, i.e. 25 ml, of this dosing solution are then taken.

The scheme provides for once-daily use; the single dose is therefore also the daily dose. In practice, the daily amount taken from the dosing solution is additionally graded by age and developmental stage. The number of drops used for preparation is set individually and can range from one to five drops in the scheme presented.

All calculations assume a volume of 0.05 ml per drop of medicinal solution, 0.05 ml per pipette drop taken from the dosing solution and 5 ml per teaspoon. These volumes are calculation assumptions; the actual volumes depend on the dropper and the measuring device used and may deviate slightly from the values assumed.

Table 1 applies the calculation to the age and developmental stages of this scheme. For each stage, it shows the calculated amount of ethanol when the dosing solution is prepared with one or with five drops of medicinal solution.

For the model calculation, the stage "from start of complementary feeding" begins at the earliest possible time, the start of the 5th month of life after four completed months. According to the German recommendations, the actual start of complementary feeding lies – depending on the individual development of the child – between the start of the 5th and the start of the 7th month of life. The next stage begins on the 3rd birthday; primary-school age is set at 6 years for the model curve.[10]

The calculation proceeds in three steps: first, the volume of ethanol contained in the five drops is determined. This volume is then converted into a mass using the density of ethanol. Finally, it is calculated what proportion of this mass of ethanol is ingested with 25 ml (5 teaspoons) of the 150 ml dosing solution.

3.3 Calculation of the amount of ethanol in the medicinal solution

The starting point of the following calculation is the medicinal solution used in the practical example, with an ethanol content of 20 % v/v. In the first step, the amount of ethanol is determined that enters the dosing solution with the number of drops prescribed in the example, i.e. five drops.

With the drop volume of 0.05 ml assumed for the calculation, the total volume of these five drops is:

An ethanol content of 20 % v/v means that 100 ml of the medicinal solution contains 20 ml of ethanol. For the calculation, the percentage is entered as the decimal 0.20.

5 drops × 0.05 ml = 0.25 ml medicinal solution

0.25 ml × 0.20 = 0.05 ml ethanol

The five drops therefore carry 0.05 ml of pure ethanol into the dosing solution prepared later.

3.4 Conversion of ethanol volume into ethanol mass

For the quantitative comparison, the calculated volume of ethanol is converted into a mass of ethanol. For this purpose, a density of ethanol at 20 °C of 0.789 g/ml[2] is used.[3,8]

Density indicates the mass of a given volume of liquid. At a density of 0.789 g/ml, 1 ml of ethanol has a mass of 0.789 g. The mass of the 0.05 ml of ethanol calculated above is therefore obtained by multiplying by the density.

Formula

Ethanol mass = ethanol volume × density

Calculation:

Given ethanol volume: 0.05 ml

Density of ethanol (20 °C): 0.789 g/ml

0.05 ml × 0.789 g/ml = 0.03945 g ethanol

0.03945 g = 39.45 mg ethanol

The five drops of medicinal solution containing 20 % v/v ethanol thus contain 39.45 mg of ethanol.

3.5 Calculation of the amount of ethanol actually ingested

In the worked example presented, the five drops of ethanol-containing medicinal solution are made up with water to a total volume of 150 ml.

Key point: Adding water does not change the absolute amount of ethanol. It only reduces the ethanol concentration of the solution.

The 39.45 mg of ethanol calculated above is distributed evenly throughout the entire dosing solution.

The 39.45 mg of ethanol is contained in the entire 150 ml of dosing solution. Since 25 ml of this is taken in the example, the amount of ethanol per millilitre is determined first and then multiplied by the amount taken, 25 ml.

Calculation of the ethanol concentration:
39.45 mg ÷ 150 ml = 0.263 mg ethanol/ml
The dosing solution thus contains 0.263 mg of ethanol per millilitre.

[2] The European Pharmacopoeia gives a relative density of 0.790–0.793 for anhydrous ethanol; the EMA uses a specific gravity of 0.789. The present calculation is based on 0.789 g/ml.

Calculation of the amount of ethanol ingested:
0.263 mg/ml × 25 ml = 6.575 mg ≈ 6.58 mg ethanol
The amount of ethanol actually ingested with the dose is therefore 6.58 mg.

The amount taken, 25 ml, corresponds to one sixth of the total 150 ml of dosing solution. Accordingly, one sixth of the total 39.45 mg of ethanol it contains is ingested.

Table 1: Practice-based grading of the amount of ethanol ingested by age and developmental stage

Age or developmental stage	Daily amount taken from the dosing solution	Ethanol with 5 drops of medicinal solution	Ethanol with 1 drop of medicinal solution
Preterm infant model (1.5 kg)	2 pipette drops (0.10 ml)	0.0263 mg (26.3 µg)	0.00526 mg (5.26 µg)
Infants until the start of complementary feeding	3 pipette drops (0.15 ml)	0.0395 mg (39.5 µg)	0.00789 mg (7.89 µg)
From earliest possible start of complementary feeding (4 months)	1 teaspoon (5 ml)	1.32 mg	0.263 mg
From the 3rd birthday	2 teaspoons (10 ml)	2.63 mg	0.526 mg
From primary-school age (model: 6 years)	3 teaspoons (15 ml)	3.95 mg	0.789 mg
From the 12th birthday	up to 5 teaspoons (25 ml)	6.58 mg	1.32 mg

Calculation assumptions: medicinal solution containing 20 % v/v ethanol, made up with water to a total volume of 150 ml, 0.05 ml per drop or pipette drop and 5 ml per teaspoon.

The practice-based scheme does not constitute a general dosing recommendation; the dosage of a Q-potency is determined individually. The preterm infant model assumes a body weight of 1.5 kg. Very small preterm infants below 1,000 g are not covered by this scheme.

Note on the total volume of the dosing solution: if, with the same number of drops, the solution is made up to 200 ml instead of 150 ml and the same amount is then taken, the amount of ethanol ingested is arithmetically 25 % lower.

Figure 1 shows the range calculated in Table 1 for each age and developmental stage. The logarithmic axis allows amounts in the microgram and milligram ranges to be shown together.

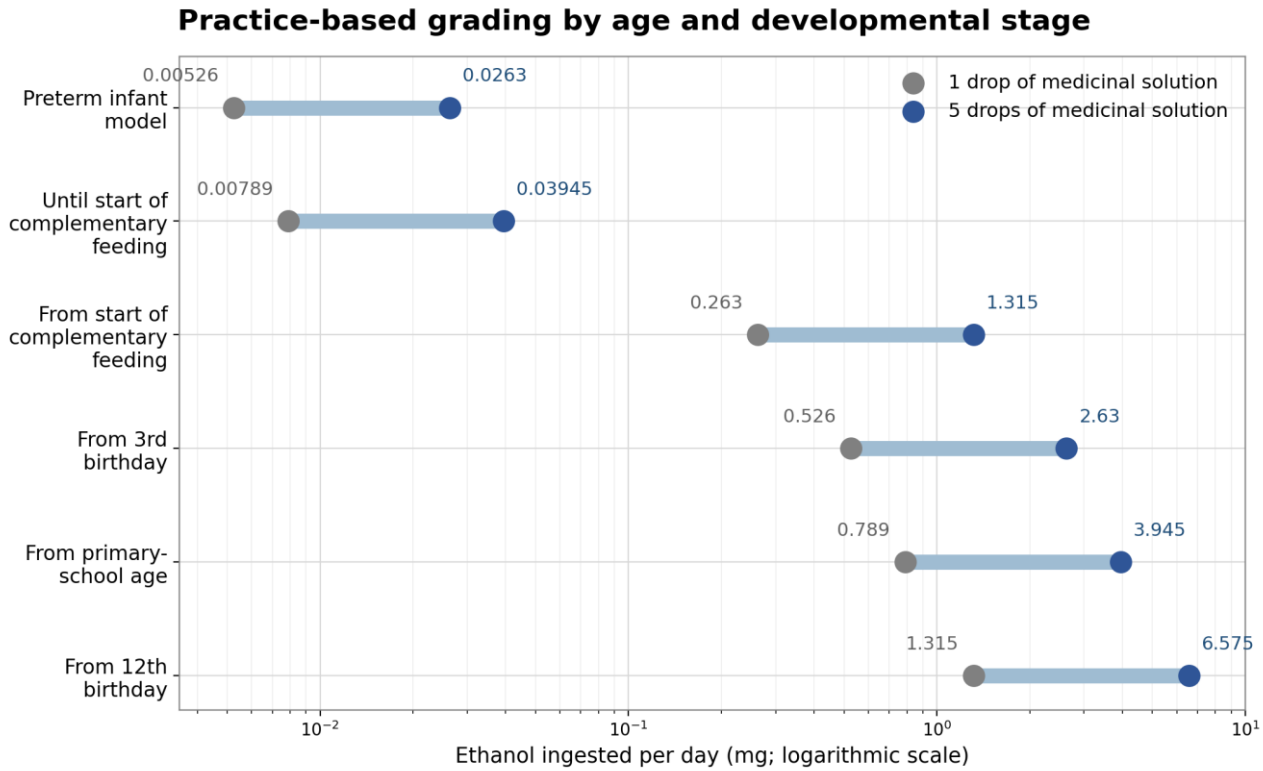


Figure 1: Practice-based grading by age and developmental stage. For each stage, the connected points show the calculated range when the dosing solution is prepared with one to five drops of medicinal solution.

3.6 Summary of the calculation

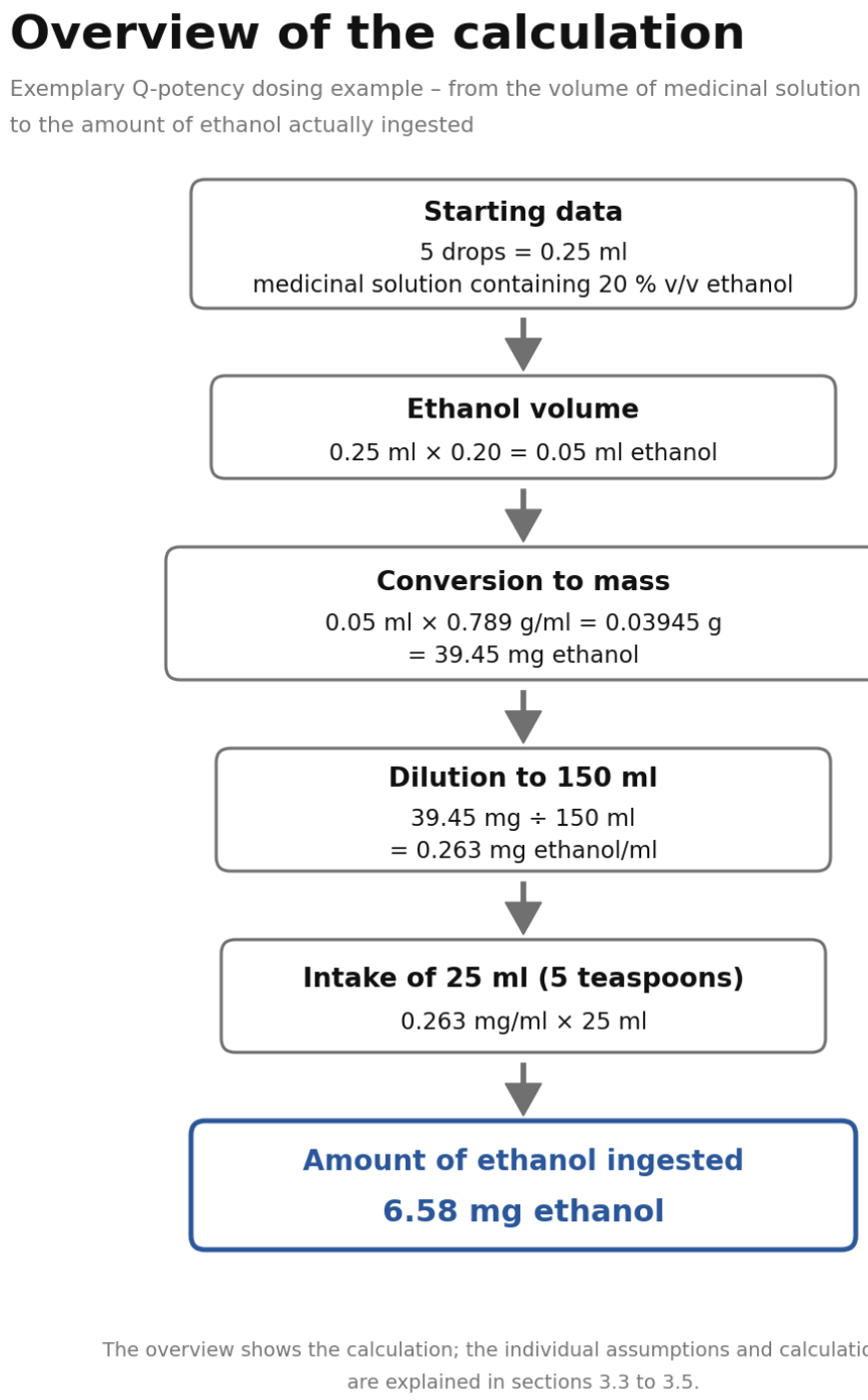


Figure 2: Exemplary calculation for the upper worked example with five drops of medicinal solution and an amount taken of five teaspoons.

4. Assessment of the amount of ethanol ingested

The amounts of ethanol calculated in Chapter 3 are assessed below in terms of their order of magnitude, on the basis of published findings and regulatory documents.

4.1 Why an assessment is needed

A calculated result alone does not allow any statement about its health or pharmacological significance. Its order of magnitude only becomes meaningful through comparison with suitable reference points.

4.2 Reference points for the assessment

For the quantitative comparison, European documents on ethanol exposure from medicinal products are used.

In European pharmaceutical legislation, homoeopathic medicinal products are defined as a separate category of medicinal products. No specific European guideline on ethanol exposure from homoeopathic medicinal products was identified in the research for this booklet.[11]

The main reference points are the requirements of the *European Medicines Agency* (EMA) on the labelling of ethanol-containing medicinal products and a document of the *Committee on Herbal Medicinal Products* (HMPC), in which ethanol exposure in children is considered in relation to body weight.

The HMPC document refers explicitly to herbal and traditional herbal medicinal products. Since homoeopathic medicinal products are not herbal medicinal products, the values described there are used not as requirements directly transferable to Q-potencies, but as supplementary quantitative points of comparison.

This chapter deals exclusively with the amounts of ethanol calculated on the basis of the practice-based scheme for the use of a Q-potency. No conclusions about homoeopathic medicinal products in general can be drawn from it.

4.3 Quantitative comparison of the calculated amount of ethanol

For the upper worked example of the practice-based scheme presented in Chapter 3, an ingested amount of 6.58 mg of ethanol per single dose, and thus per day, was calculated. This value is the upper example figure for the following comparison; the lower stages are shown in Table 1.

For ethanol in medicinal products there are various reference points, which must be distinguished from one another in terms of their meaning and scope.

The current EMA version on the labelling of ethanol-containing medicinal products uses body-weight-related labelling thresholds for orally, parenterally and inhaled administered medicinal products. Each threshold determines the amount of ethanol above which the corresponding labelling text is required. Even for an amount of ethanol above 0 mg, the amount contained per dose must be stated; from 15 mg ethanol/kg body weight per dose and from 75 mg/kg per dose, further statements are required in stages. These thresholds, however, do not mark a toxicological or clinical boundary between harmless and harmful amounts.[12]

What a labelling threshold is – and what it is not

The term must be distinguished from two other quantities with which it is easily confused. An effect threshold denotes the lowest dose at which an effect occurs; toxicologically it is determined via the highest dose without an observed adverse effect and the lowest dose with an observed adverse effect. A tolerable intake is derived from this by applying safety factors; it already lies well below the effect threshold. A labelling threshold, by contrast, determines the amount above which information must be given. The EMA states this explicitly in its background document: the thresholds denote the values above which a statement becomes necessary (source 3, p. 18).[3]

The levels are indeed based on effects, but they are set with a wide margin. According to the EMA, no perceptible effect is to be expected below 15 mg/kg per dose; this level corresponds to the amount of ethanol an adult ingests with about 10 ml of wine, and to a calculated rise in blood ethanol of 2.5 mg/100 ml. The middle level, from 15 to below 75 mg/kg, corresponds to 10 to 50 ml of wine. For an adult weighing 70 kg, the 75 mg/kg level corresponds to about 5.25 g of ethanol, i.e. about 50 ml of wine, and to a rise of 12.5 mg/100 ml; it is justified by the fact that, in studies in adults performing complex tasks, effects first became apparent above similar values (source 3, pp. 18 f.).[3]

For comparison, the same source cites a 210 ml glass of wine: for an adult weighing 70 kg, it corresponds to about 300 mg/kg and a rise of 50 mg/100 ml — the value that corresponds to the legal limit for driving in many Member States of the European Union. Between the first labelling level and this order of magnitude lies a factor of 20 (source 3, pp. 8 and 19).[3]

For oral, parenteral and inhaled use there is also a declaration threshold of zero: ethanol must be declared in any amount; there is no lower limit. For amounts below 15 mg/kg per dose, the EMA provides a text that states the amount contained and explicitly states that the small amount of alcohol in this medicine will not have any noticeable effects (source 3, p. 4). For this order of magnitude, therefore, the provision is not the absence of a statement but an affirmative statement.[3]

The statements refer to the single dose and not to daily exposure; the EMA justifies this by the fact that the effects considered, on reaction ability and coordination, are short-term (source 3, p. 24). In the practice-based scheme of this booklet, the single dose and the daily amount are the same, so the comparison applies to both reference quantities.[3]

Body-weight-related assessment

For the quantitative assessment, the different orders of magnitude of the units used must first be noted: 1 g = 1,000 mg

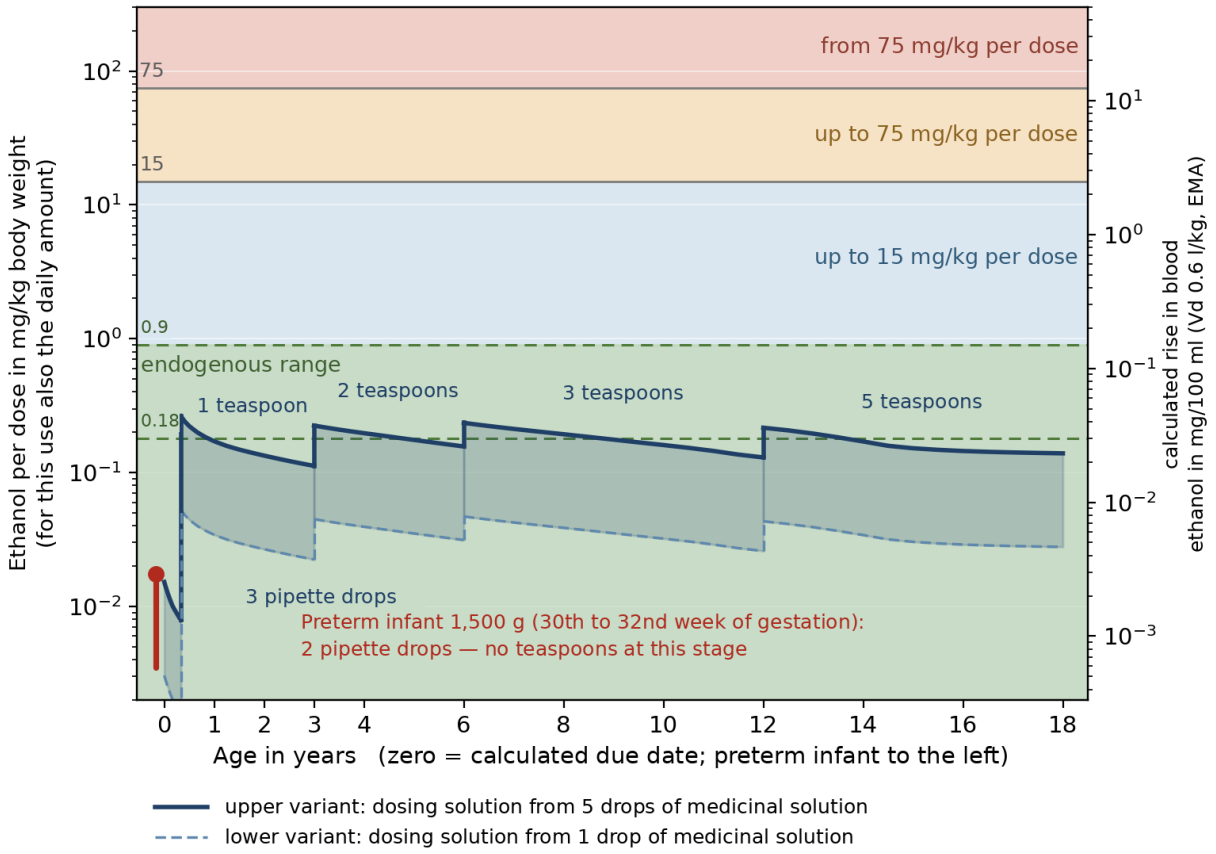
The 6.58 mg of ethanol calculated in the dosing example thus corresponds to 0.00658 g of ethanol.

The amount of ethanol corresponding to a labelling threshold of 15 mg/kg is calculated by multiplying 15 mg/kg by the respective body weight. For the example body weight of 20 kg used in the HMPC document, this gives 300 mg of ethanol per single dose.

300 mg ÷ 6.58 mg = approx. 45.6

At a body weight of 20 kg, the upper worked example of 6.58 mg reaches about 2.2 % of the first EMA labelling threshold. Conversely, the threshold of 300 mg is about 45.6 times higher. The calculated example amount therefore does not come quantitatively close to this threshold.

The following figure compares the age- and development-related stages of the practice-based scheme with the EMA labelling levels. The body weights are taken from the reference percentiles of the Robert Koch Institute (RKI); throughout, the lower of the two sex-specific values of the 3rd percentile is used, i.e. the lightest child within the reference range.



The levels determine which text must appear in the package leaflet.
They are not safety limits or maximum amounts.
up to 15 mg/kg per dose — the amount is stated, together with the sentence that the small amount of alcohol will not have any noticeable effects. There is no lower limit: ethanol must be declared in any amount.
15 to below 75 mg/kg per dose — additionally a statement that refers only to younger children.
from 75 mg/kg per dose — statements for all age groups, plus on epilepsy, liver disease and ability to drive.
Dashed: endogenous blood ethanol level, 0.03 mg/100 ml as the usual value, 0.15 mg/100 ml as the upper limit.

Figure 3: Age- and development-related stages of the practice-based scheme in relation to the EMA labelling levels. The bands indicate which text is required in the package leaflet in each case; they are not safety limits. For the conservative model calculation, the one-teaspoon stage begins at the earliest possible start of complementary feeding after four completed months; the two-teaspoon stage begins on the 3rd birthday. The line jumps upwards with each dose increase and then falls again because the child continues to grow. The preterm infant model with 1,500 g is shown in red and lies to the left of the calculated due date, because this weight corresponds approximately to the 30th to 32nd week of gestation; the RKI curves provide no reference weights for preterm infants. In preterm and newborn infants, only pipette drops are used, never teaspoons.[9,10,12]

The smallest margin within the age-related model curve occurs at the earliest possible start of complementary feeding: with an RKI 3rd-percentile reference weight of 4.99 kg, the first EMA labelling threshold is 74.85 mg. This compares with 1.315 mg of ethanol in the upper one-teaspoon variant. The threshold is therefore about 56.9 times higher; no stage of the practice-based scheme comes quantitatively close to it.[9,12]

This model calculation assumes the earliest possible time. The recommendations of the German network Gesund ins Leben (Healthy Start – Young Family Network) give a time window for the introduction of complementary foods: at the earliest at the start of the 5th and at the latest at the start of the 7th month of life, i.e. not before the age of 17 weeks and not later than 26 weeks. The window takes into account the infant's nutritional requirements, individual differences in motor development and aspects of sensory acceptance and allergy prevention.[38]

Within this window, the developmental stage decides. Signs of readiness include the waning tongue-thrust reflex — the tongue no longer immediately pushes solid food out of the mouth —, the ability to hold the head and to sit upright with support, and interest in new foods. Most children can move puree with the tongue at five to six months; in some these skills develop earlier, in others

later. The great variability of motor development is explicitly emphasised: ages given for milestones are only guide values.[38]

The switch to the one-teaspoon stage shown in the model is therefore a calculation assumption and does not represent a point in time that exists with such precision. It lies at the early edge of the recommended time window. At the late edge — at the start of the 7th month of life, with an RKI 3rd-percentile reference weight of 5.91 kg — the margin to the first labelling threshold is about 67-fold instead of 56.9-fold. The value of 56.9 thus denotes the arithmetical lower bound of the recommended time window and not the expected case.[9,12,38]

The 6.58 mg is not a universally valid figure for the use of Q-potencies, but the upper value of the practice-based scheme and the result of the calculation assumptions set out in section 3.2.

How the thresholds have changed

The thresholds in force today are the result of a consultation process, and their reference quantity has changed several times in the course of it. Under the 2003 version of the guideline, an absolute amount per dose applied: below 100 mg of ethanol per dose, it had to be stated that the medicinal product contains small amounts of ethanol — explicitly for the purpose of reassuring parents and children about the low alcohol content (source 3, p. 34). A draft from 2014 proposed a body-weight-related value of 6 mg of ethanol per kilogram per day, and only for children aged two to six years. Arithmetically, the 6.58 mg ingested in the upper dosing example would correspond to this value only at a body weight of about 1.10 kg:

6.58 mg ÷ 6 mg/kg = 1.097 kg ≈ 1.10 kg

In practical terms, this means that only at a body weight of about 1.10 kg would the upper example amount correspond to the then reference value of 6 mg/kg. For all children with a higher body weight considered in the practice-based scheme, the body-weight-related amount lies below it.

This draft value is not part of the current labelling system and must not be used as a current labelling threshold. Above all, however, the figures 6 and 15 are not directly comparable: the draft value referred to the daily amount and to a single age group, whereas the current threshold refers to the single dose and applies to all age groups.[13]

Across the three versions, therefore, not only the numerical value has changed, but also, three times, the reference quantity: from an absolute amount per dose (2003), via a body-weight-related daily amount for a specific age group (2014 draft), to a body-weight-related single dose without an age band (since 2018).

For the assessment of the present worked example, this has no consequences, because the result is the same under all three versions: 6.58 mg per dose compared with 100 mg under the 2003 version; a calculated reference weight of 1.10 kg under the 2014 draft; and 0.329 mg/kg at a comparative body weight of 20 kg compared with 15 mg/kg under the current version. Across three versions and three reference quantities, the amount considered falls into the lowest level.[3,12,13]

Supplementary assessment on the basis of the HMPC document

In a reflection paper on herbal and traditional herbal medicinal products, the HMPC likewise considers ethanol exposure in children in relation to body weight. For children between 6 and 12 years of age, maximum acceptable amounts of ethanol per intake in the gram range are derived there, depending on the assumed body weight.

For example, for a six-year-old child with an assumed body weight of 20 kg, 1.5 g, i.e. 1,500 mg of ethanol, per intake is calculated.

Converting to the same unit makes the difference in size particularly clear:

HMPC example: 1,500 mg ethanol
Upper worked example of this booklet: 6.58 mg ethanol

Since the HMPC document refers to herbal and traditional herbal medicinal products, this comparison

serves solely as a quantitative illustration and not as a requirement directly applicable to Q-potencies.[14]

4.4 Special population groups

The current EMA labelling system links statements for certain population groups to the amount of ethanol per dose. From 15 mg ethanol/kg body weight per dose, statements for pregnancy, breastfeeding and alcohol dependence are required; from 75 mg/kg per dose, additionally for epilepsy and liver problems. The meaning of these thresholds as labelling thresholds was explained in section 4.3.[12]

Below 15 mg/kg per dose, none of these population-specific statements is required. For this level, the EMA instead provides for the amount contained to be stated together with the statement that the small amount of alcohol will not have any noticeable effects (source 3, p. 4).[3]

4.4.1 Infants and children

In infants and younger children, the assessment must take particular account of body weight, the maturity of the metabolic pathways and the specific dosage prescribed.

The HMPC document recommends that ethanol-containing herbal medicinal products be used in newborns and children under two years of age only where sufficiently justified. The EMA background document points out that the concomitant use of other medicinal products containing propylene glycol or ethanol can contribute to accumulation of ethanol and adverse effects, particularly in young children with low or immature metabolic capacity.[3,14]

In the practice-based scheme, the Q-potency is used once daily. The grading by age and developmental stage in Table 1 ranges from two pipette drops of dosing solution in preterm infants to five teaspoons from the 12th birthday. Within each stage, the number of drops used to prepare the dosing solution is set individually.

The relationship between the stages is noteworthy. In the preterm infant model, about 0.0175 mg/kg is ingested at a body weight of 1.5 kg; in the one-teaspoon stage, at the RKI 3rd-percentile reference weight of 4.99 kg, it is about 0.264 mg/kg. The body-weight-related amount is therefore about fifteen times lower in the smallest children — they receive considerably less not only in absolute terms but also per kilogram of body weight.[9]

This grading is a traditional rule of application. It arose in treatment practice and has been passed on as a recommendation over generations; it was not derived from considerations of metabolic physiology. That it coincides with the fact that the elimination pathways of preterm and newborn infants are not yet fully mature is a correspondence, not a derivation.

Very small preterm infants receiving intensive care are not covered by the practice-based dosing scheme. This limitation is based on the practical conditions of use and is not a statement about the tolerability or safety of Q-potencies in these children.

Metabolism, elimination and possible accumulation

After oral intake, ethanol is predominantly metabolised. Acetaldehyde is formed first and is then further converted to acetate. The conversion takes place mainly in the liver. In addition to alcohol dehydrogenase, other enzyme systems, in particular catalase, are involved in ethanol metabolism.[25,26]

In preterm and newborn infants, these metabolic pathways are not yet fully mature. Studies of

perinatal liver tissue show a markedly lower content of alcohol dehydrogenase than in adults, whereas catalase was found in comparable or in some cases higher amounts. A proportional reduction in overall ethanol elimination can therefore not be inferred from the reduced activity of a single enzyme.[25]

This is consistent with the reported measurements: elimination rates of 0.06 to 0.11 g per kilogram per hour have been described for preterm infants, which is within the range of the rate of about 0.1 g/kg/h usual in adults (source 3, p. 15). This does not allow a robust calculation of the elimination time for the amounts considered here; it does show, however, that overall elimination is not slowed to the extent that the lower activity of a single enzyme might suggest.[3,37]

The available data on elimination rates in infants come predominantly from individual cases of acute ethanol intoxication. They relate to considerably higher blood ethanol concentrations and do not allow a robust calculation of the elimination time for the microgram and milligram amounts determined in the present dosing scheme.[26]

Studies of ethanol-containing medicinal products in preterm infants found predominantly low blood ethanol concentrations, but in some cases elevated concentrations of the intermediate acetaldehyde. In a more recent study, certain ethanol metabolites in urine increased with repeated exposure to medicinal products; the increase was more pronounced in particularly immature infants. This does not demonstrate accumulation of unchanged ethanol, but it does show that, with repeated use, the formation of metabolites and the maturity of the elimination pathways must also be taken into account.[27–29]

For the assessment, the order of magnitude of the amounts administered there is decisive: the single doses studied averaged 7.24 mg of ethanol, with a range of 2.27 to 78.42 mg per dose (source 3, pp. 18 and 23). The smallest single dose occurring there is thus about sixty to ninety times higher than the daily amount calculated in the practice-based scheme for infants and preterm infants.[3,27]

In the upper preterm infant example of the practice-based scheme, 0.0263 mg of ethanol is ingested per day. At the body weight of 1.5 kg chosen for this model calculation, this corresponds to about 0.0175 mg/kg body weight per day. The repeated exposures to medicinal products described in the more recent preterm study ranged from 0.04 to 3 mg/kg body weight per day and were thus above this calculated value; the medicinal products and exposure patterns studied, however, were different.[28,29]

Under the conditions of the once-daily dosing scheme presented, relevant accumulation of unchanged ethanol is not to be expected.

If other ethanol-containing medicinal products are used at the same time, their amounts of ethanol must be added for the overall assessment; in the upper dosing example, the Q-potency contributes 6.58 mg of ethanol per day.

Finally, it should be noted that the calculation assumption used for conversion into a blood ethanol level errs on the side of caution: the EMA uniformly assumes a volume of distribution of 0.6 l/kg and points out that this simplification overestimates the blood ethanol level, particularly in children. The body's water content falls from about 92 per cent in the preterm infant and 75 per cent in the term newborn to about 60 per cent over the course of the first year of life; with the same amount per kilogram, a larger water space means a lower concentration. The values calculated for preterm and newborn infants are therefore more likely to be too high than too low (source 3, p. 15 and Annex 1, p. 32).[3]

4.4.2 Pregnancy

Independently of the EMA labelling system, general health recommendations advise complete abstention from alcoholic beverages during pregnancy. No amount of alcohol can be specified that can be regarded as safe for the unborn child.[15]

For ethanol as a component of a medicinal product, by contrast, the amount actually ingested is decisive. In the practice-based scheme of this booklet, the Q-potency is used once daily; the single dose and the daily amount are therefore the same. If other ethanol-containing medicinal products are used, their amounts must be added for the overall assessment.

Model-based assessment of the order of magnitude

For an assessment, the calculated rise in blood ethanol can be given. With an assumed body weight of 65 kg and the volume of distribution of 0.6 l/kg assumed by the EMA, the distribution space is 39 l (source 3, Annex 1, p. 32):[3]

6.58 mg ÷ 39 l = 0.169 mg ethanol/l = 0.017 mg/100 ml

According to the measurements compiled in the EMA background document, the endogenous ethanol content of the blood is about 0.03 mg/100 ml, with a range of 0 to 0.15 mg/100 ml. It is produced in metabolism and by the fermentation of carbohydrates by the intestinal flora (source 3, p. 17).[3,35]

The calculated rise from the upper example amount is thus about half the usual endogenous value and within its range of variation. According to the conversion table of the same source, the upper example amount corresponds, at a body weight of 70 kg, to less than 1 ml of beer or wine (source 3, Annex 1, p. 33).[3]

On the order of magnitude of the studies on which the general recommendations are based: in a study of 32,870 women, malformation rates did not differ between non-drinkers and women drinking fewer than two alcoholic drinks a day — corresponding to about 24 g, i.e. 24,000 mg, of ethanol per day; above this amount, increased rates were observed (source 3, p. 21).[3,36]

A 200 ml glass of wine contains about 18,900 mg of ethanol (Table 2), i.e. about 2,900 times the upper example amount.[24]

The general recommendation to abstain from alcoholic beverages during pregnancy remains unaffected by this; as explained, it concerns a different order of magnitude. If there are concerns in an individual case, use should be agreed with the prescribing professional.[15]

4.4.3 Breastfeeding

Independently of the regulatory labelling system, it is recommended to abstain from alcoholic beverages while breastfeeding.[16]

For an ethanol-containing medicinal product, the factors relevant to possible exposure of the breastfed infant are the amount of ethanol actually ingested by the mother and the time interval before breastfeeding. The ethanol concentration in breast milk follows that in the mother's blood and falls again with it.[17,31–33]

Model-based maximum estimate

For a deliberately conservative estimate, it is assumed that the entire amount of ethanol ingested in the upper example, 6.58 mg, is distributed evenly in the distribution space of a mother weighing 60 kg without prior metabolism. With an assumed volume of distribution of 0.6 l/kg, the distribution space is 36 l.[30]

6.58 mg ÷ 36 l = 0.183 mg ethanol/l

On the additional assumption that the ethanol concentration in breast milk equals this theoretical maximum concentration and that a 150 ml feed takes place at exactly this time, the feed would arithmetically contain about 0.027 mg, i.e. 27 µg, of ethanol.[31–33]

0.183 mg/l × 0.150 l = 0.027 mg = 27 µg ethanol

With an infant body weight of 5 kg assumed for the model calculation, this corresponds to about 0.0055 mg/kg body weight.

0.027 mg ÷ 5 kg = 0.0055 mg/kg body weight

The modelled infant exposure thus corresponds to about 0.037 % of the first EMA labelling threshold of 15 mg/kg body weight; the threshold is therefore arithmetically about 2,700 times higher. Since the EMA threshold was developed for the direct amount of ethanol in a medicinal product per dose and not for indirect exposure via breast milk, this comparison serves solely to illustrate the order of magnitude.

Even under deliberately conservative model assumptions, the amount of ethanol calculated for the breastfed infant is quantitatively considerably lower again than the direct intake in the upper dosing example.

4.4.4 Liver disease

Liver disease can affect hepatic metabolic and elimination processes to varying degrees. However, the presence of liver disease alone does not allow direct conclusions to be drawn about the extent of any change in hepatic elimination capacity.[18]

For the quantitative assessment, the small order of magnitude of the amount of ethanol considered must also be taken into account: at a comparative body weight of 20 kg, the upper dosing example corresponds to an amount of ethanol of 0.329 mg/kg body weight. This is about 0.44 % of the EMA labelling threshold of 75 mg/kg per dose, above which a statement on liver problems is required. The threshold is thus about 228 times higher.[12]

4.4.5 Epilepsy

The relationship between ethanol and epileptic seizures is complex and has been described in particular for larger amounts of alcohol and in connection with alcohol withdrawal. For very low ethanol exposures, such as those considered in the present dosing example, no direct conclusions about seizure risk can be drawn from these data.[19,20]

For the quantitative assessment, the same threshold applies as for liver disease: the statement on epilepsy is required from 75 mg/kg per dose. At a comparative body weight of 20 kg, the upper dosing example corresponds to 0.329 mg/kg, i.e. about 0.44 per cent of this threshold; the threshold is about 228 times higher. For an adult weighing 70 kg, the amount ingested is 0.094 mg/kg, and the threshold is then about 800 times higher.[12]

On the substance of the matter, the EMA background document summarises the state of research: in people with epilepsy, occasional and light to moderate alcohol consumption is not associated with alcohol-related seizures, and complete abstinence is not strictly necessary as long as alcohol is handled responsibly. Seizures after heavy drinking typically occur six to forty-eight hours afterwards and are classified as withdrawal seizures (source 3, p. 20).[3,20]

In its information leaflet, a patient organisation names only the consumption of considerable amounts as promoting seizures: 1.4 litres of beer or 0.7 litres of wine or more. Converted, this is about 55,000 or 66,000 mg of ethanol; at a body weight of 70 kg, this corresponds to 790 to 950 mg/kg. This amount is ten to thirteen times higher than the labelling threshold of 75 mg/kg and about eight to ten thousand times higher than the upper example amount of the practice-based scheme.[34]

The most sensitive group is also explicitly named there: in people with idiopathic generalised epilepsy, the seizure risk is increased above this amount; moderate consumption below it, however, is not associated with an increased seizure risk even in this group.[34]

The same source states that the blood levels of most antiepileptic drugs are not changed by moderate alcohol consumption; however, adverse effects such as double vision, drowsiness and balance disorders may be intensified. Such intensification presupposes a sedative effect, which is not to be expected with amounts in the milligram range.[34]

If a seizure occurs after moderate alcohol consumption, the cause, according to the same source, usually lies elsewhere — in lack of sleep or irregular intake of medication. None of these circumstances applies to taking a Q-potency.[34]

No contraindication can be derived from this for the amounts considered in the practice-based scheme. If there are concerns in an individual case, for instance in epilepsy that is difficult to control, the decision on the amounts taken should be agreed with the prescribing professional.

4.4.6 Abstinence in alcohol dependence

Alcohol-related cues can trigger conditioned responses. This also applies to olfactory and gustatory cues; the extent and clinical significance of this cue reactivity vary between individuals. Possible responses include a desire for alcohol (craving).

In people living in abstinence, the assessment of an ethanol-containing Q-potency should therefore not be based solely on the amount of ethanol actually ingested. The individual situation, the stability of abstinence and known alcohol-related triggers must be taken into account. A small absolute amount of ethanol does not permit any general statement about protection against relapse; it should also be considered whether an ethanol-free alternative is preferable.[21–23]

Since no specific data on ethanol exposure from Q-potencies in special population groups were identified, the dosage should be determined individually and, in case of uncertainty, agreed with the prescribing professional.

4.5 Illustrative comparison with selected foods and alcoholic beverages

To illustrate the order of magnitude, the amount of ethanol ingested in the dosing example is compared with selected amounts of ethanol that have been detected analytically in foods or that result arithmetically for alcoholic beverages.[24]

This comparison serves solely as a quantitative illustration. It compares the absolute amounts of ethanol in the portion or reference quantities stated in each case, not equal volumes. Foods, alcoholic beverages and medicinal products differ in their composition, use and regulatory classification and are therefore not directly comparable.

Table 2: Comparison of amounts and concentrations of ethanol to illustrate their order of magnitude

Item compared	Reference quantity	Amount of ethanol	Ethanol content (% vol / % v/v)
Q-potency dosing example	**25 ml**	**6.58 mg**	**≈ 0.033 % v/v**
Apple juice	200 ml	12–132 mg	≈ 0.008–0.084 % v/v***
Orange juice	200 ml	32–146 mg	≈ 0.020–0.093 % v/v***
Yoghurt	100 g	< limit of quantification to 20 mg	–
White wine vinegar*	100 ml	264 mg	≈ 0.335 % v/v***
Bread and bakery products	100 g	< limit of quantification to 1,280 mg	–
Beer (5 % v/v)**	330 ml	13,019 mg	5 % v/v
Wine (12 % v/v)**	200 ml	18,936 mg	12 % v/v
Spirit (40 % v/v)**	20 ml	6,312 mg	40 % v/v

* A single measured value is available for the white wine vinegar tested. The published value was converted to the reference quantity stated and is not to be understood as a generally valid ethanol content of white wine vinegar.

** The figures for the alcoholic beverages are calculated example values based on the stated alcohol concentrations and the density of ethanol.

*** % vol (German: Vol.-%) and % v/v (volume/volume) are equivalent expressions of the volume fraction. For example, 5 % vol or 5 % v/v corresponds to an ethanol volume of 5 ml per 100 ml of liquid. The figures for the liquid comparators were derived arithmetically from the published amounts of ethanol using an ethanol density of 0.789 g/ml.

The analytical studies show that ethanol contents can vary even within individual food groups. The ranges shown therefore refer to the products tested in each case and are not to be understood as generally valid ethanol contents of the respective food group.

Since the reference quantities differ, a comparison of the absolute amounts does not in itself allow any statement about concentration. The last column of the table therefore converts the same facts to a uniform reference: in terms of equal volumes, the dosing solution of the upper dosing example, at about 0.033 % v/v, lies within the range of the fruit juices tested — about 0.008 to 0.084 % v/v for apple juice — and below the white wine vinegar tested, at about 0.335 % v/v.[24]

The EMA itself cites the same orders of magnitude in its background document: a 200 ml glass of fruit juice may contain anything from virtually nothing to over 100 mg of ethanol. For the diet of a six-year-old child, a daily ethanol intake from foods of about 10.3 mg per kilogram of body weight is estimated, with temporarily higher values of 12.5 to 23.3 mg/kg (source 3, pp. 17 f.).[3,24]

At a comparative body weight of 20 kg, the upper example amount of the practice-based scheme corresponds to 0.329 mg/kg, i.e. about one thirtieth of this estimated daily intake from normal food.

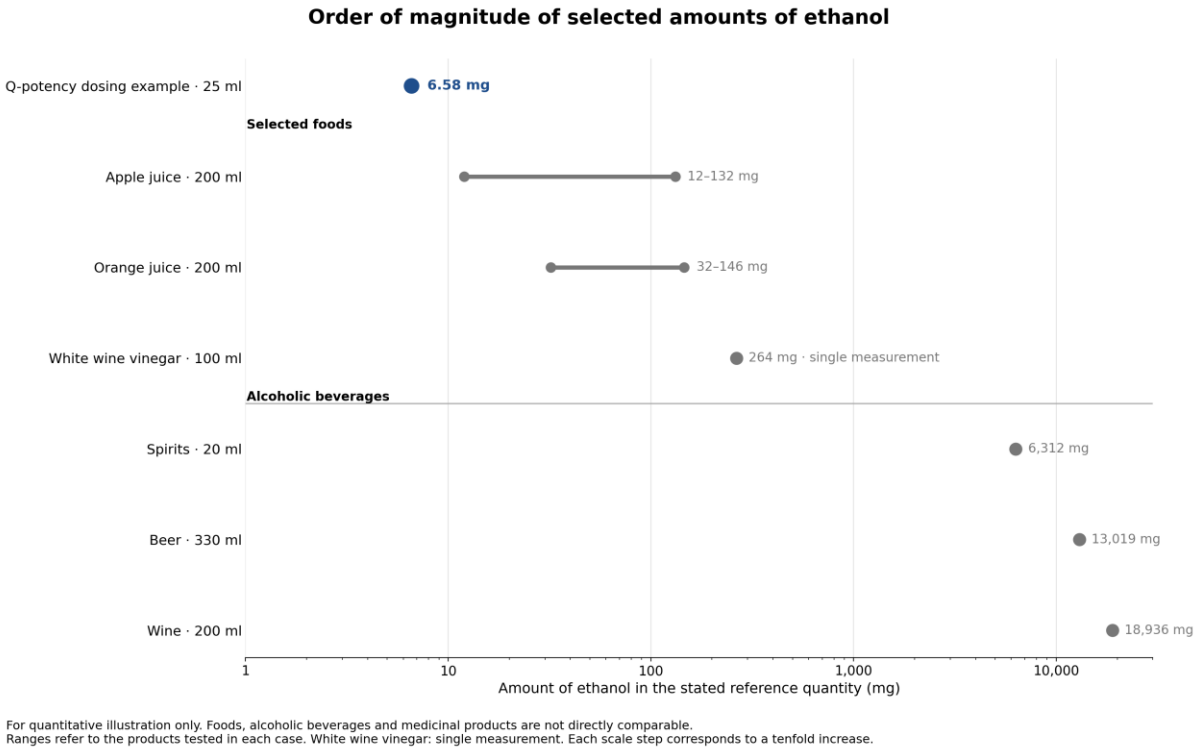


Figure 4: Graphical representation of the amounts of ethanol compared in Table 2. The logarithmic axis makes the different orders of magnitude visible.

4.6 Summary and conclusions

In the upper worked example of the practice-based scheme, a maximum of 6.58 mg of ethanol is ingested per single dose and day. At a comparative body weight of 20 kg, this corresponds to 0.329 mg/kg body weight and thus to about 2.2 % of the first EMA labelling threshold of 15 mg/kg per dose. The threshold is about 45.6 times higher.

When the scheme is linked by age to the RKI reference weights, the margin is even greater: even at the arithmetically narrowest point – the earliest possible start of complementary feeding – the threshold is about 56.9 times higher than the upper example amount of this stage, and about 67 to 72 times higher with the later start usual in practice. No stage of the practice-based scheme touches the first EMA labelling threshold.

Table 1 and Figure 1 show the calculated amounts of ethanol for the individual age and developmental stages. The fully explained calculation of the upper example is summarised in Figure 2. Figure 3 compares the age-related assignment of the scheme with the body-weight-related EMA labelling levels.

Under the conditions of the once-daily dosing scheme presented, relevant accumulation of unchanged ethanol is not to be expected. This conclusion is based on the very small calculated daily amount, the interval of about 24 hours between doses and the available data on ethanol metabolism in infants and preterm infants.

For breastfeeding, the deliberately conservative model calculation gives a possible infant exposure of about 27 µg, or 0.0055 mg/kg body weight. This value, too, lies quantitatively far below the first EMA labelling threshold used for comparison, without the threshold thereby becoming a specific requirement for indirect exposure via breast milk.

Table 2 and Figure 4 additionally place the upper worked example in context using selected foods and

alcoholic beverages. This comparison illustrates absolute amounts without equating the different products and contexts of use.

In liver disease, the large quantitative margin to the liver-related EMA labelling threshold must be taken into account alongside the individual metabolic situation. If other ethanol-containing medicinal products are used at the same time, their amounts of ethanol must be added for the overall assessment. In abstinent people with alcohol dependence, on the other hand, the alcohol-related smell or taste cue may be relevant irrespective of the small absolute amount of ethanol.

What follows from this – and what does not

For the amounts calculated in the practice-based scheme, the current labelling system requires no statements beyond the declaration of the amount contained; for this order of magnitude, the EMA provides the text that the small amount of alcohol will not have any noticeable effects (source 3, p. 4).[3]

This implies no statement about tolerability in an individual case and no statement about other ethanol-containing preparations, whose content may be higher by orders of magnitude. The EMA also explicitly states that the effect of long-term intake of even small amounts of ethanol from medicinal products on the health and development of children has not been studied (source 3, pp. 3 and 21). This limitation remains regardless of the calculated order of magnitude.[3]

The decision on use in an individual case remains with the prescribing professional.

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