European Federation of Associations of Health Product Manufacturers

EHPM Position Paper on Ethylene Oxide Contamination in the Food Sector

Brussels, 27/10/2021

EHPM believes in the European food safety system which is one of the most detailed and strictly regulated frameworks that guarantees a high level of safety for consumers. EHPM and its members vividly support a science-based approach to the risk assessment to determine safety concerns and define the necessary actions with respect to food safety. The current ethylene oxide (EtO) situation has been seriously taken into account by EHPM and its members, since it is affecting the whole supply chain on a global scale.

EHPM's members are mainly importers of ingredients and generally have little impact on the root causes of this crisis. Thus, food business operators (FBOs) active in the food supplement sector, are seriously affected by an involuntary contamination with EtO. In fact, FBOs active in the food supplement sector do not deliberately add EtO in the manufacturing process of food supplements. Food supplements are products meant to support the consumers' well-being and FBOs implement good manufacturing practices and high-quality standards that exclude the use of unauthorised and dangerous pesticides.
This is why FBOs in the food supplement sector are currently implementing a series of measures to continue guaranteeing the safety of their products which are meant to support consumers' well-being including better controls on raw material.

FBOs in the food supplements sector are concerned about the lack of clarity/certainties on the results of the analysis of EtO levels made on products.

EHPM and its members acknowledge the EtO classification as carcinogenic, reprotoxic and mutagenic[1] and therefore fully support the strict implementation of the EU regulations which foresee no tolerance for the presence of EtO in foodstuffs.

We are aware that Regulation (EC) No 396/2005 provides that a content of EtO can be determined from the sum of 2-chloroethanol (2-CE) and EtO. However, multiple recent RASFF alerts have been issued where the analyses detected the presence of 2-CE only.

[1] https://echa.europa.eu/substance-information/-/substanceinfo/100.000.773

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This is due to the fact that the analytical methods currently used are based on the detection of 2-CE only in products which do not require EtO fumigation throughout their entire supply chain and where EtO is often absent as itself. Indeed, the test methods used have been designed to determine EtO and 2-CE as main EtO metabolite but these methods are validated for commodities plausibly fumigated where EtO was used during early steps of agronomic practices, as recently observed for sesame seeds and tea. On the contrary, these methods seem not to be perfectly reliable for food supplements or minerals, where only traces of 2-CE are often found. There is not a unified testing approach with different laboratories using different methods. This has resulted in differences in results between laboratories for the same sample.

According to the current scientific knowledge, EHPM and its members have reasons to believe that the presence of 2-CE is not necessarily an indicator of contamination with EtO and they consider the pivotal importance of a revision of the analytical threshold and methods for the determination and quantification of EtO in food and food supplements. Moreover, EHPM and its members believe that toxicological data of EtO derivatives such as 2-CE should be reconsidered and verified.

By means of this paper, we would like to share with the Commission arguments in support of this thesis.

Limits and concerns on methods for the quantification of EtO

In the last two decades of the last century, different methods were proposed to analyse EtO in food. Gas Chromatography coupled with mass spectrometry has been considered the method of choice to analyse this residue. No unique preparative methods have been released, but food matrix is almost unequivocally processed and EtO could be detected as it is or, more often due to its instability, as the sum of EtO and its main degradation product in food, 2-CE, expressed as EtO. Some methods also consider the total conversion of EtO in 2-CE before the quantification.

Regulation (EC) No 396/2005 specifies that marketable food should comply with the limit of 0.1 ppm of EtO+2-CE residues expressed as EtO. Specific different limits are considered such as in oilseeds (0.05 ppm).
The recent revision of data on EtO levels in different foods from German laboratories[2] [3] has depicted that consistent and reliable results have been obtained in samples probably fumigated, often from India, when EtO+2-CE residues expressed as EtO is in the range of 1 ppm.

[2] relana® Communication Note 21-02 – Ethylene oxide and 2-Chloroethanol, Version 2021/05/03
[3] Statement on ethylene oxide und 2-chloroethanol in calcium carbonate (updated version), Lach & Bruns Partnerschaft Consulting Chemists, 25th August 2021.

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Nevertheless, some important concerns have arisen when EtO+2-CE residues expressed as EtO are near the acceptable limit of 0.1 ppm, that is the limit of analytical determination.

Two major points have been pointed out:

1 The repeatability of data is low because reliant to used instrument and detection method.

As the determination of the presence of EtO is detected indirectly from the presence of a metabolite (i.e. by analysing the 2-CE), differences in analytical conditions and extraction techniques used by different laboratories lead to variations in EtO degradation giving inconsistent results for metabolite determination.

2 When residues are at very low levels, often 2-CE but not EtO could be detected in multiresidual analysis.

As Regulation (EC) No 396/2005 requires the compliance of the sum of EtO+2-CE for the analysis of EtO in food, it is noteworthy that 2-CE level detected should be strictly related to the original presence of EtO but, currently, as below argued, there are many reasonable doubts that in food 2-CE could originate from other sources different from EtO conversion.

For this reason, it is debatable if updated methods should be applied, in order to fix large bias in EtO actual quantification. In fact, EtO rapidly reacts with several chemicals, such as alcohols, amines, organic acids and amides as well as electrophilic halogens[4]. EtO, when in contact with food is primarily converted in 2-CE, due to the presence of chlorinated salts in almost all natural matrices, but also into other metabolites.

Other sources of 2-chloroethanol (2-CE) contaminations: the calcium carbonate case

From the analytical results shared by our members, we have reasons to believe that the recent detected presence of 2-CE does not originate from EtO.
2-CE could be formed in several alternative ways in food matrices: indeed, ethylene is a plant hormone, commonly found in detectable traces in many plant derivatives and in high amount in some particular fruits and vegetables, such as bananas or avocados[5]; in presence of hypochlorite containing compounds, such as chlorinated water, from a theoretical point of view, it is plausible that the reaction between plant ethylene and chlorine may occur with 2-CE synthesis.

Moreover, the presence of 2-CE in foodstuffs, and other products actually has other possibilities of derivations other than the presence as a degradation product and precursor of EtO.
This has been recently postulated and discussed since only 2-CE but no EtO or other EtO degradation products such as 2-bromoethanol or dioxane was found in variable amount in

[4] https://www.sciencedirect.com/topics/engineering/ethylene-oxide
[5] https://doi.org/10.1093/fqsafe/fyz042

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sesame seeds of different origin from both conventional and organic cultivation, whereas some samples of sesame seeds from India and Africa clearly showed high levels of EtO+2-CE; authors concluded that level <0.5 ppm of only 2-CE in sesame seeds depict more likely an exogenous origin of this compound not related to the use of EtO.

Furthermore, 2-CE, but not EtO was found in minerals such as calcium carbonate. It is known that the aim of fumigation with EtO is to sterilise organic substances from microorganisms, especially *Salmonella* sp. and other pathogenic bacteria. The fumigations are primarily applied to commodities which are susceptible to microbial contamination, like spices or oilseeds.

Opposite to plant-based foods, calcium carbonate is not susceptible to microbial spoilage as:

- calcium carbonate is of mineral origin, hence the microbial load from the production process is expected to be very low; and
- calcium carbonate does neither deliver nutrients (such as sugars or proteins) nor water for microorganisms, therefore it is not a suitable habitat for microbial growth.

As a consequence, it makes no technical or economic sense to apply fumigation with EtO to calcium carbonate, as it is microbiologically stable.

Summarising what has been reported in Lach & Bruns's statement on ethylene oxide and 2-CE in calcium carbonate of the 25th of August, it must be considered that 2-CE is not only the main metabolite of EtO, but has several further sources:

- 2-Chloroethanol is commonly used as a precursor in the manufacture of a variety of industrial agents"[6];
- 2-Chloroethanol can be a metabolite obtained from other applications, for example from chlorine-based disinfection agents.

These additional sources increase the risk of contamination. Especially in the times of the SARS-CoV-2 pandemic, a significantly increased use of disinfectants takes place worldwide. Common disinfectant agents include chlorine-based disinfectants, like hypochlorite that, as mentioned above, may react with natural occurring ethylene derivatives to produce 2-CE.

Lach & Bruns's experts concluded that *"the observed variations of the 2-chloroethanol level within the single batches clearly hint at contamination with 2-chloroethanol, not at an application of the prohibited fumigant ethylene oxide. It is recommended to further investigate the sources of the 2-chloroethanol content and minimise the level."*[7]

[6] PubChem: 2-Chloroethanol (compound), available online: https://pubchem.ncbi.nlm.nih.gov/compound/Ethylene%20chlorohydrin , accessed on August 23rd , 2021

[7] Statement on ethylene oxide und 2-chloroethanol in calcium carbonate (updated version), Lach & Bruns Partnerschaft Consulting Chemists, 25th August 2021.

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In conclusion, from the aforementioned points it could be underlined that the quantification of original presence of EtO in food primarily by means of the detection and quantification of traces of 2-CE may lead to dramatic analytical bias.

Further comments on this paragraph and on "Limits and concerns on methods for the quantification of EtO" can be found in Annex I.

Different toxicological profile of EtO and 2-CE

An important element to take into account is the different toxicological profile of EtO and of 2-CE.

EtO is listed as CAS (Chemical Abstract Service database) number 75-21-8 and has been classified as relevant under the European chemicals regulation REACH and subjected to the registration and evaluation procedure formulated in this regulation (Reg. (EC) No 1907/2006).

In this process, the following basic evaluation was prepared:
EtO is classified as a carcinogen of category 1B, as a mutagen of category 1B and also reprotoxic of category 1B[8]. Due to its sterilising effect, EtO is used in food and feed to kill bacteria, viruses, or fungi. This enables possible hygiene regulations to be complied with and ensured when importing food and feed into certain countries. Due to its properties, EtO falls within the regulatory scope of plant protection products within the EU. The placing of plant protection products on the market in the EU is regulated by Regulation (EC) No. 1107/2009. Under this regulation, no authorisation has been granted for the use of EtO.

Since EtO is a highly reactive molecule due to its chemical structure ("epoxide"), the conversion to products such as 2-CE, which are energetically more stable, takes place very quickly. It can be assumed that already a few days after an application of EtO to food products, it is no longer detectable in the food.

2-CE (also known as ethylene chlorohydrin) is classified as toxic (poisonous) by ingestion, inhalation, and skin contact[9]. A (moderate) mutagenic potential is also reported.
The available data indicates that 2-CE is significantly less mutagenic than EtO and, as such, presents a significantly reduced public health and safety risk[10].

[8] https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/26125
[9] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.003.146
[10] https://www.foodstandards.gov.au/code/applications/Documents/A412FA.pdf

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For the evaluation of 2-CE in food, a toxicological consideration after oral intake is decisive. 2-CE is neither carcinogenic, genotoxic nor toxic for reproduction[11]. The decisive factor for the toxicity of 2-CE is the medium-to-high acute systemic toxicity.

The toxicity of 2-CE is also questioned in the document "Risk assessment of ethylene oxide in sesame seeds" of the National Institute for Public Health and the Environment Ministry of Health, Welfare and Sport in cooperation with the Wageningen University[12]. This risk assessment refers to a statement of the EU scientific committee of 2002 considering 2-CE not being genotoxic *in vivo*. Furthermore, a reference is made to Australia New Zealand Food Authority (ANZFA) stating that it is not completely clear if 2-CE is genotoxic.

Finally, the comparison of the toxicity of EtO and 2-CE made on the basis of literature data leads to the conclusion that 2-CE is less toxic than EtO in terms of noxious exposure level and for its mechanism, since the latter is mutagenic, carcinogenic and teratogenic), whereas 2-CE is not. In fact, the estimated TDIs and ADIs for humans were 3.3 mg/exposed person per day for 2-CE and 0.1mg/exposed person per day for EtO, a 33-fold ratio.[13]

In light of the above considerations, **applying a read-across approach to evaluate 2-CE based on the characteristics of EtO is not scientifically sound. Therefore, we urge the EC to ask EFSA to undertake a complete safety assessment of 2-CE, as it is urgently necessary, rather than asking EFSA to check the possibility of endorsing the German Federal Institute for Risk Assessment (BfR) assessment, which is not conclusive**.

Regulatory Framework in the US & CANADA

We deem important to consider also that the maximum residue level (MRL) for EtO in sesame seeds in Canada is 7 mg/kg (EtO as a single substance, without 2-CE)[14]. For the degradation product 2-CE in sesame seeds, there is a separate maximum content of 940 mg/kg[15], which also applies in the USA at the same level[16].

[11] https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/75071
[12] https://www.rivm.nl/sites/default/files/202011/FO%20beoordeling%20ethyleenoxide%20in%20sesamzaad_final_20201025_anon.pdf
[13] Consumer risk assessment: residues of ethylene oxide and 2-chloroethanol in raw materials of plant origin incorporated in finished products - ADEPALE and FEDALIM - June 2021 - D. Marzin
[14] Pest Management Regulatory Agency, Health Canada, 2720 Riverside Drive, Ontario, PMRL2019-29, https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-maximum-residue-limit/2019/ethylene-oxide/document.html
[15] https://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php
[16] United States Environmental Protection Agency, Code of Federal Regulations (annual edition), Part 180 - Tolerances and exemptions for Pesticide Chemical Residues in Food, 40 CFR Ch. I (7-1-11 Edition) § 80.151, https://www.govinfo.gov/app/details/CFR-2012-title40-vol25/CFR-2012-title40-vol25-sec180-151

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In the EU, on the other hand, the maximum residue level (MRL) of 0.05 mg/kg for the sum parameter EtO and 2-CE, expressed as "EtO", is based on the fact that EtO is a pesticide active ingredient that is not approved in the EU. Consequently, the specific MRLs were set at the level of the respective analytical limits of determination in relation to the residue definition (here: sum parameters EtO and 2-CE). The establishment of separate MRLs for EtO and 2-CE in the USA and Canada, and the also widely differing values for the active substance and its degradation product, indicate on the one hand that "EtO" is predominantly present in the products in the form of its degradation product 2-CE, and on the other hand, that the toxicity of 2-CE is clearly different from that of EtO.

Legal observations

Finally, we would like to highlight some legal observations:

- *Applicability of Regulation (EC) No 396/2005*

The marketability of calcium carbonate in which EtO or, more correctly, its degradation product 2-CE is detected cannot be assessed on the basis of the maximum residue levels of Regulation (EC) No 396/2005. The Regulation bears the official name of *"Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC"*. According to its Article 1, the Regulation sets maximum levels for pesticide residues in or on food and feed of "plant and animal origin". Since calcium or calcium carbonate is neither a food of plant nor of animal origin, Regulation (EC) No 396/2005 does not apply to this and other mineral substances.
This element is further argued in Annex II.

- *Food additives legislation (Regulation (EU) No 231/2012)*

In the case of food additives, the specifications of Regulation (EU) No 231/2012 must be observed. The Annex of this regulation specifies that EtO shall not be used for sterilisation of food additives.

- *Marketability versus safety of food*

The regulations on pesticides (Regulation (EC) No 396/2005) and on additives (Regulation (EU) No 231/2012) concern the marketability of food. If a MRL according to Regulation (EC) No 396/2005 is exceeded for a type of goods listed in Annex I, the product is not marketable. According to Article 19 of Regulation (EC) No 396/2005, a processing and mixing ban applies to raw materials that are not marketable. This has to be evaluated, however, always taking Article 20 of that Regulation on processing factors into account.

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However, a food that is not marketable is not automatically "unsafe" in the sense of Art. 14 of the EU General Food Law ("GFL", Regulation (EC) No 178/2002). Such a classification requires an additional, independent, comprehensive and individual assessment of the specific (end) product consumed.

Importantly, as mentioned above, analytical data quantifying or determining no traces of EtO in the (end) product, but only in the ingredients used, cannot lead *per se* to the assessment of an unsafe product in terms of Article 14 of the GFL Regulation. This is in clear contrast with what is suggested in the "Legal considerations" of the Annex of the EC report of the 04/10/2021 meeting[17].

While it is true that final products manufactured from non-complying ingredients (in terms of Reg. 396/2005 or Reg. 231/2012) are non-complying themselves, they are NOT automatically also unsafe. This is especially true if the contaminant, even if it has CMR properties, cannot be detected in the final product. This absence of quantifiable – in any case of detectable – amounts of the contaminant totally deprive the factual basis for an assessment as unsafe under the rules of Article 14 of the GFL Regulation, which always have to meet the proportionality test, and must always be based on relevant, proven facts to be legal in the very terms of the overreaching rule-of-law principle that lays the very foundation of European Union law.

This is also in line with the scientific definition of risk as the product of hazard and exposure:

*Risk = hazard * exposure*

If there is no trace of EtO in the (end) product, the exposure is null and therefore so is the risk.

This is even more crucial for cases where there have been no findings of proper EtO at all, but just of 2-CE, which does not justify any Article 14 measures especially if findings of it in the end product stay below the LOQ. For the end products that show traces above the LOQ, the additional, independent, comprehensive and individual assessment of the specific (end) product consumed will lead to products being still safe under the comparison by toxicological approaches like the "intake of low concern" under an MoE approach (see above). This is especially true for food products, such as food supplements, that are consumed in very low absolute quantities.

This element is further argued in Annex II.

[17] https://ec.europa.eu/food/system/files/2021-10/rasff_ethylene-oxide-incident_e410_crisis-coord_20211004_sum.pdf @ p. 7 bottom / p. 8 top

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Conclusions

In light of the above, we urge the Commission to review the detection method calculation of EtO residues establishing two different MRLs for EtO and 2-CE, and at the same time to engage in a solid risk assessment of 2-CE.

Based on the current scientific findings, we ask that the Commission adopts a more proportionate approach that would, at the same time, guarantee the safety of consumers and prevent an enormous waste of products which are not contaminated with EtO.

EHPM is engaging liaising with researchers and universities to conduct a scientific study on the possible sources of 2-CE other than EtO contamination. We will be glad to present any additional findings to the Commission in due time.

Trusting that the EHPM reasoned statement will help the discussion around this major crisis for the whole food sector, we sincerely confirm our availability to constructively cooperate towards the shared objective to promote a healthy, innovative and prosperous Europe.

About the EHPM:
EHPM was created in 1975 and represents and supports approximately 1,600 health-product manufacturers, distributors and suppliers in 14 European Countries, the majority of which are Small and Medium Size Enterprises (SMEs).
As the EU trade association for the food supplement sector, EHPM proactively and constructively engages with the EU Institutions to contribute to the development of a fair European regulatory framework for the sector.
Through our member associations EHPM aims to provide consumers with safe, science-based, high-quality products as well as accurate and helpful information about their nutritional value and use.

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ANNEX I: Further analytical considerations

- **Technical analytical considerations and the role of 2-chloroethanol in products**

EHPM acknowledges that the report of the EC technical meeting held on the 4th of October 2021[18] clarified the applicability of MRLs for different products.
Regulation (EC) No 396/2005 specifies that marketable food should comply with the limit of 0.1 ppm of EtO+2-CE residues expressed as EtO, with some specific exceptions.
Despite the information provided by stakeholders and FBOS, in the aforementioned report the EC states that "While there is information from stakeholders suggesting that 2-chloro-ethanol (2-CE), the metabolite of EtO, might not be present due to the use of EtO, but to other sources, such as natural occurrence or as process contaminant, sufficient proof of the presence of 2-CE through such mechanisms is still to be provided".
Actually, documents issued from some specialised laboratories[19] underlined that test methods used to quantify EtO level as sum of EtO and 2-CE could not distinguish 2-CE from EtO conversion and from other sources and this may lead to improper conclusions as regards EtO level in analysed products when only 2-CE (and not EtO) is found. This is the case of many food supplements and minerals that are known not to undergo fumigation with EtO. Indeed, in many products with 2-CE above MRL, the use of EtO seems very unlikely, as this is not necessary from a technical and economic point of view.

- The presence of traces of 2-CE in raw materials and end products has been recently linked to the use or natural presence of chlorine derivatives in the manufacturing process.
- In particular:
    - chemical and cleaning agents authorised within the EU may result in containing 2-CE[20];
    - 2-CE may result as a metabolite of the reaction between hypochlorites (present for example in detergents and drinking water) and unsaturated fatty acids of natural products[21];
    - chlorine reactive derivatives, from used water or detergents, in presence of ethoxylates or ethylene glycols could result in 2-CE[22].

[18] https://ec.europa.eu/food/system/files/2021-10/rasff_ethylene-oxide-incident_e410_crisis-coord_20211004_sum.pdf @ p. 8, middle and bottom
[19] Statement: Possible pathways of formation of 2-chloroethanol in calcium carbonate (English version of statement dated September 20th, 2021), Lach & Bruns Partnerschaft Consulting Chemists, 27th September 2021
[20] Ibid. ref 4
[21] Ibid. ref 7
[22] Ibid. ref 6, 9

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A recent test reported in the Statement of Lach & Bruns on the "*Possible pathways of formation of 2-chloroethanol in calcium carbonate"* of the 27th of September 2021 showed that minerals (i.e. calcium carbonate) processed without cleaning agents but with pure water only were always found to be 2-CE-free.

Finally, it should be noticed that 2-CE could naturally occur in food matrices. Indeed, ethylene is a plant hormone, commonly found in detectable traces in many plant derivatives and in high amount in climacteric fruits[23]. It is therefore plausible that naturally occurring ethylene combined to chlorine results in 2-CE traces synthesis.

[23] https://doi.org/10.1093/fqsafe/fyz042

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ANNEX II: Further legal observations

- **Applicability of Regulation (EC) No 396/2005**

As far as Reg. 396/2005 sets MRLs for plant and animal-based foods, which then are used in processed and composite final products like food supplements, it has to be respected that the application of processing factors according to Article 20 of that Regulation is essential, especially where the food samples analysed are highly concentrated extracts. This is in fact the case in many food supplements, leading even to double-digit processing factors — e.g., after extraction with supercritical CO2 — compared to the fresh plants that are the real subject of the MRLs in Reg. 396/2005. A finished product — or an ingredient, particularly a plant extract — however cannot be "unsafe" under Reg. 178/2002 (General Food Law / "GFL" Regulation) if it does not show even a *non-conformity* to Reg. 396/2005, taking its Article 20 into account.

In this context, it has to be noted that Article 18 (2) (a) of Reg. 396/2005 prohibits any authority action "*prohibit[ing] or imped[ing] the placing on the market […] within their territories of the products covered by Annex I on the grounds that they contain pesticide residues provided (a) such products comply with paragraph 1 and Article 20* […]".

Therefore, the position stated in the Annex to the EC report of the Meeting on EtO of 04/10/2021[24] as regards Article 20 of the MRL Regulation is unconvincing when it states: "*While the Commission recognises that for processed/composite products, Article 20 of the MRL Regulation may apply, it takes the view that, under the circumstances of the present incident, in which the substance is classified as CMR and there is a clear trace to the use of non-compliant ingredients, Article 20 (and Article 18(2) MRL Regulation) cannot be interpreted as removing the possibility of withdrawing or recalling the products, if such food cannot be considered safe within the meaning of Article 14 of the GFL (regarding its unsafety, see above).*"

The problem with this statement, however, relates not only with the interpretation and application of Articles 18 (2) and 20 of the MRL Regulation "removing the possibility" of withdrawal / removal measures under the GFL Regulation, but first and foremost with the correct interpretation and application of Article 14 (7) and (8), especially the dualism of these to paragraphs of Article 14, of the GFL Regulation. The real problem lies, however, in the suggestion that any finding of EtO or even of "2-CE only" would directly lead to an "unsafe" food in the sense of Article 14 of the GFL Regulation. — see discussion of this aspect below.

[24] https://ec.europa.eu/food/system/files/2021-10/rasff_ethylene-oxide-incident_e410_crisis-coord_20211004_sum.pdf @ p. 7 et seq.

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- **Marketability versus safety of food**

As to the deliberations on page 8 of the "Legal considerations" annexed to the EC report of the 04/10/2021 Meeting[25], it has to be pointed out that Articles 18 (2) and 20 of the MRL Regulation are still binding provisions to assess legal conformity of final products as to the aspect of food safety in the contaminants field, and that compliance to all MRL provisions by a final product must be a clear indication of a product's safety — unless the additional, independent, comprehensive and individual assessment of the specific (end) product consumed proves the unsafety *in spite of* MRL compliance.

In this context, the reasoning on the bottom of page 8 / top of page 9 of the "Legal considerations"[26] fails to convince because:

- The fact of EtO being CMR a) does give no legal grounds for cases of "2-CE only", b) is not conclusive of a final product with EtO below LOQ (or even LOD) being unsafe, taking into account the "intake of low concern"/ MoE approach;
- The safety / unsafety distinction has to be made primarily on a specific product's own properties, not on other, unrelated products, and while many products on the market may contain E410, this does NOT mean that it could be presumed all (or most) of these additives would be contaminated (especially, the effectiveness on market control activities against EtO contaminated additives in the market could be expected to minimise overall market exposure to EtO in the short term);
- "deliberate and/or avoidable use" of EtO is NOT a legitimate aspect of assessing food safety under the Article 14 rule, as it is toxicologically totally irrelevant where a given amount of the substance is originating from; apart from that, market reality shows that in many cases, EtO has NOT been deliberately or avoidably been used (cf. cases of minimal amounts of EtO being due to shipping containers of Asian origin being fumigated too recently before loading, etc.); additionally, this argument does not hold in cases of "2-CE only", especially taking into account the possible other sources of 2-CE apart from EtO (see above);
- it is not correct, as the "Legal considerations" suggest, that "there are still grounds to believe that the presence of the substance/metabolite is due to deliberate use as a disinfectant" — where it is not just speculative presumption of deliberate use, this is (see above) still a nonconformity issue, not a food safety issue, and especially is invalid in cases of "2-CE only" findings, and in cases outside the E410 issue (like plant extracts, minerals like calcium carbonate — see above).

[25] ibid. p. 8, middle and bottom
[26] ibid.

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