

# Revised safe intake for 3-MCPD in vegetable oils and food

EFSA's experts have used an updated scientific approach to reassess the possible long-term adverse effects of the food processing contaminant 3-MCPD on the kidney and male fertility.

Consumption levels of 3-MCPD in food are considered safe for most consumers but there is a potential health concern among high consumers in younger age groups. In the worst case scenario, infants receiving formula only may slightly exceed the safe level.

## Updated 2016 opinion

The chemical 3-monochloropropane diol (3-MCPD) and related substances called 3-MCPD esters are food processing contaminants found in some processed foods and vegetable oils, mainly palm oil. 3-MCPD and its esters are formed unintentionally in these foods, in particular during oil refining processes.

EFSA's expert panel on contaminants first assessed the [potential risks of 3-MCPD](#) in 2016 together with another food processing contaminant called glycidyl fatty acid esters (GE). EFSA concluded that GE are a concern for public health because they are genotoxic and carcinogenic, i.e. they can damage DNA and cause cancer.

The European Commission is finalising [new EU legislation](#) aimed at reducing GE levels in vegetable oils and food.

The current update is for 3-MCPD and its esters only and EFSA's previous assessment of GE has not changed.

## Why has EFSA updated its assessment of 3-MCPD?

Prof Christer Hogstrand, who chaired the scientific group that developed the 2016 opinion and the update, said: "EFSA decided to review its assessment after the UN's Joint FAO/WHO Expert Committee on Food Additives [JECFA] subsequently established a different safe level – tolerable daily intake or TDI.

"In the meantime EFSA updated the method we used to calculate our previous TDI – what's called the [benchmark dose \(BMD\) approach](#).

"The panel applied the revised method to its reassessment of 3-MCPD and, as a result, it has increased its previous safe level two and a half fold."

### 3-MCPD Tolerable Daily Intake (TDI) in µg/kg bw\*

EFSA 2017	2.0
JECFA 2016	4.0

*\*Micrograms per kilogram of body weight*

## **Potential risks for the kidney and male fertility**

Prof Hogstrand added: “We checked again the data concerning effects on development and reproduction, particularly on male fertility as these were highlighted by JECFA.

“We calculated the levels at which possible adverse effects on the kidney and on male fertility could occur. The updated TDI is protective for both types of effects.”

## **Technical differences, same overall conclusions**

EFSA’s new TDI is closer to JECFA’s TDI. EFSA and JECFA used the same toxicological data but different BMD modelling techniques. Despite these technical differences, both bodies came to the same overall conclusions on the possible adverse effects of 3-MCPD and the level of concern for public health.

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## **[Statement following the working dinner between President Juncker and Polish Prime Minister Morawiecki](#)**

The following joint statement was issued by President Jean-Claude Juncker and Prime Minister Mateusz Morawiecki following their working dinner in Brussels on 9 January 2017:

*“The Prime Minister of Poland and the President of the European Commission had a wide ranging and constructive discussion this evening. They continued the conversation which began at their first meeting in the margins of the December 2017 European Council.*

*They addressed a broad range of issues of common interest. These issues included the future of the European Union, the Polish position within the European Union as well as EU policies on the internal market, the digital single market, energy and migration.*

*The Prime Minister and the President also had a detailed discussion of questions related to the Rule of Law.*

*They agreed that they will meet again to pursue the discussion with a view to*

*making progress by the end of February.*

*The dinner took place in a friendly atmosphere.”*

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## **ESMA delays publication of double volume cap data**

Since 3 January, ESMA has been performing an analysis of the quality and completeness of the data received from trading venues to perform DVC calculations. Based on the analysis performed, ESMA realised that the publication would have resulted in a biased picture covering only a very limited number of instruments and markets.

ESMA is aware of the legal obligation to apply the DVC from January 2018. However, as the publication of the calculations triggers other legal obligations in terms of transparency waivers' suspensions related to dark trading, initiating the new regime based on the insufficient data ESMA has received is not appropriate at this stage

It expects that the actions initiated to bridge this information gap, involving working with national competent authorities (NCAs) and trading venues to address data quality and submission issues, will allow for publication in March.

### **Incomplete data provided by trading venues**

The DVC requires all trading venues listing a particular equity (or equity like) instrument to provide data on trading activity for the complete previous year. A failure to provide this information leads to incompleteness in the relevant data for that instrument.

While ESMA's systems are functioning and ready to receive data, a large proportion of trading venues have yet to provide complete data. ESMA expected to receive data for around 30,000 instruments in the context of the DVC mechanism, on the basis of the data collected for the transitional transparency calculations for equity and equity-like instruments. ESMA has received files from 75% of trading venues. However, this resulted, in most cases, in only partial delivery of the information needed i.e. data delivered by only some, but not all, venues trading an instrument, or data not covering the entire 12-month period from January to December 2017 that is relevant for the DVC calculations in January 2018.

Data completeness is required to undertake the DVC calculations. In this respect, ESMA only received complete data for approximately 650 instruments, i.e. around 2% of the expected total. Additionally, the set of 650 instruments for which complete data is available only encompasses relatively

illiquid instruments, which have a limited amount of dark trading. This fact would have rendered a publication at this point in time largely inconsequential. The DVC IT system is more complex compared to the other MiFID II IT systems that ESMA is running. Moreover, ESMA acknowledges that trading venues only had limited time to compute and submit all data as the relevant reporting period only closed on 31 December 2017 and the data had to reach ESMA by close of business on 5 January 2018.

### **ESMA's preparations for applying the DVC mechanism**

ESMA finalised its IT system for the DVC and opened it for the submission of data by trading venues and national competent authorities to ESMA on the 16 October 2017, more than two months in advance of the MiFID II/MiFIR 3 January 2018 application date. ESMA informed trading venues and NCAs about the system specifications by publishing those specifications and organising workshops for trading venues. The system is globally operating as designed and is performing calculations based on the data received as envisaged.

### **Next steps**

ESMA, to ensure a timely publication of DVC data, is already engaging with NCAs and trading venues to close the gaps in reporting as soon as possible. ESMA has analysed the data and is aware of which venues have so far not succeeded in submitting an adequately complete set of data and will address them first to improve the completeness of the available dataset.

ESMA believes that the initial technical and reporting problems leading to this delay can be overcome within the next few weeks. To achieve this, ESMA and the NCAs are depending, and relying, on good cooperation from trading venues to be able to operate the DVC mechanism as envisaged by the co-legislators.

In March, ESMA intends to publish the data covering the previous periods in order to ensure the full application of the DVC as of January 2018.

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## **[Discours par Michel Barnier au Trends Manager de l'année 2017](#)**

Prime Minister,

Ladies and gentlemen,

Allow me in turn to wish you all the best for this new year.

2018 will be a decisive year for the negotiations that I am leading and for many of your businesses.

Charles Michel is well aware of this and I would like to personally thank him, and his government, for his vigilant support and his personal confidence in these negotiations.

I would also like to thank the Roularta group and the editors of Trends and Trends-Tendances for inviting me to speak here.

And I'm happy to be doing so in Belgium, which has long had close commercial and political ties with the United Kingdom.

There was a time when England's prosperity depended on the wool trade, particularly with Flanders. A reduction in the supply of English or Scottish wool yarn could threaten the jobs of thousands of Flemish artisans.

And some centuries later, it was an Englishman, William Cockerill, who imported the first machines for spinning wool to Verviers, in 1799, and then the steam engine to Seraing, making Liège the starting point for the industrial revolution on the Continent.

Today the UK is still an important partner for your country, representing 7 % of Belgian trade in goods.

But, at the same time, 68 % of your trade is with the other Member States of the European Union. Almost 10 times more!

What makes our European economies strong is the Single Market. The British know this well, since it was the main reason why they joined the EEC in 1972.

Our Single Market will still have 440 million consumers and 22 million businesses after the UK's departure.

Beyond facilitating trade between us, it helps our businesses succeed in international competition, thanks to our collective negotiating power and our rules and standards, which are often adopted worldwide.

This is why, in these negotiations, one of my main concerns is to maintain the integrity of the Single Market, which is our common good – and is not, and will not be negotiable.

But naturally, alongside this home market, the UK will remain an important market for many of you, and I understand the concern which is expressed here and throughout Europe about the consequences of Brexit, which we did not want.

Since day one, I have asked – and I have asked myself – three questions. And it is in the answer to these three questions that we will see the form of our future relationship.

I – Does the UK want an orderly withdrawal or a disorderly withdrawal and is it ready to assume the immediate consequences of its decision to leave the European Union?

We have obtained a positive answer to this first question. On 8 December we

reached an agreement with the UK that represents a significant step towards an orderly withdrawal.

In other words, the risk of a disorderly withdrawal has receded, even though we must remain prepared for all options.

This agreement addresses the three most urgent subjects of these negotiations:

1) Citizens' rights, which is our priority and that of the European Parliament. There are 30 000 Belgians in the UK and 27 000 British citizens in Belgium. In all, 4.5 million people are involved. Our agreement guarantees their rights for their lifetime.

2) Ireland, whose unique situation calls for specific solutions to prevent the return of a hard border.

3) Finally, with regard to the financial settlement, all the commitments undertaken by the 28 will be honoured by the 28.

On the basis of our Joint Report, the European Council agreed that 'sufficient progress' had been made to begin discussions on a possible transition period and on the framework for our future relationship.

This is the subject of my second question.

II – What kind of future relationship does the UK want with the European Union?

We don't yet have the answer to this question. However, we can proceed by deduction, based on the Union's legal system and the UK's red lines. By officially drawing these red lines, the UK is itself closing the doors, one by one.

The British government wants to end the free movement of persons, which is indivisible from the other three freedoms. It has therefore indicated its intention of leaving the Single Market.

The British government wants to recover its independence to negotiate international agreements. It has therefore confirmed its intention of leaving the Customs Union.

The UK no longer wishes to recognise the jurisdiction of the Court of Justice of the European Union, which guarantees the application of our common rules.

It follows that the only model possible is a free trade agreement, which could obviate the need for trade barriers, such as customs duties, and could facilitate customs procedures and product certification.

This will of course be adapted to the specificities of the relationship between the EU and the UK, in the same way that our agreement with Canada is not identical to our agreements with Korea or Japan.

But one thing is clear: a free trade agreement, however ambitious, cannot include all the benefits of the Customs Union and the Single Market.

For example, with regard to financial services, a free trade agreement may include provisions on regulatory cooperation – as is the case with Japan. This regulatory cooperation may also take the form of a regular dialogue like the one we have with the United States.

But we have never given up our regulatory autonomy.

The regulatory framework we have constructed as a Union of 28, including the United Kingdom, learning from the financial crisis, is extremely precise. We have developed a single rulebook and more integrated European supervision, which guarantee financial stability, protection for investors, market integrity and a level playing field.

A country leaving this very precise framework and the accompanying supervision gains the ability to diverge from it but by the same token loses the benefits of the Internal Market. Its financial service providers can no longer enjoy the benefits of a passport to the Single Market nor those of a system of generalised equivalence of standards.

This is not a question of punishment or revenge; we simply want to remain in charge of our own rules and the way in which they are applied. As it seeks to regain its decision-making autonomy, the United Kingdom must respect ours.

Where allowed by our legislation, we will be able to consider some of the United Kingdom's rules as equivalent using a proportionate and risk-based approach, in particular for financial stability, which will remain our main concern.

Let us not have short memories: the financial crisis was not that long ago. It cost us a lot and it destroyed value and millions of jobs, creating an unprecedented social crisis.

Ladies and gentlemen,

We are waiting for the United Kingdom to confirm, over the coming months, that we are working towards an ambitious free trade agreement and to tell us in which other areas it would like to cooperate.

From our point of view, we think that in addition to trade, our partnership should include security, defence and foreign policy, as well as justice and home affairs and include some sectors such as aviation and fisheries.

Whatever the exact framework of our future relationship – which will be the subject of a political declaration in October when we finalise our withdrawal agreement – we must allow businesses and public administrations the time to prepare themselves for it.

This is the aim of the transition period requested by the United Kingdom, for which the Commission proposed to the Member States a period of 21 months, from the withdrawal of the United Kingdom on 29 March 2019 to

31 December 2020.

That said, the real transition period has already started. My responsibility is to tell you the truth.

A trading relationship with a country that does not belong to the European Union will never be frictionless. Take VAT statements, for example. Or imports of live animals and products of animal origin, which are subject to systematic checks at the border of the EU when they arrive from third countries.

For the port of Zeebrugge, which I visited a couple of months ago with Minister-President Geert Bourgeois and for which the United Kingdom is the main market, maintaining such extremely efficient organisation requires methodological preparation.

It is therefore important that all businesses clearly analyse their exposure to the United Kingdom and are ready to adapt their logistical channels, supply chains and contractual clauses, including in the financial services sector.

Ladies and gentlemen,

With regard to this clarification that we are expecting from the United Kingdom, I would like to raise one last question.

III Does the United Kingdom want to stay close to the European regulatory model or to distance itself from it?

This is an important decision because the European regulatory framework is underpinned by key societal choices that are dear to us: our social market economy, health protection, food security, and fair and effective financial regulation.

There will be no ambitious partnership without common ground on fair competition, State aid, guarantees against tax dumping and social and environmental standards. I know that Marianne Thyssen, like President Juncker, the European Parliament and the Member States, is being particularly vigilant in this respect.

Because for the first time in the history of our trade relations, it is not a question of encouraging regulatory convergence but of managing divergence.

This question is equally important from a political point of view since the future agreements with the United Kingdom will most likely be mixed agreements which, in addition to the approval of the European Parliament, will require ratification by the 27 national parliaments and doubtless some regional parliaments too.

Ladies and gentlemen,

We have worked together in a united way for a year now. Together we will ask these questions. And together, at 27, we will continue to advance.



We need this unity in these negotiations. But we especially need it to reform Europe and to overcome the challenges of today:

- by building, alongside the Banking Union, a real Capital Markets Union;
- by investing together in research, innovation and technology. That is the point of the Juncker plan.
- by continuing to build a 'global Europe', which is preparing to offer our businesses new opportunities to export to Australia and New Zealand.
- by also building a European defence, in keeping with the wishes of the European Commission, by proposing a European Defence Fund and Permanent Structured Cooperation.

As Prime Minister Charles Michel said last week in Trends/Tendances, we need leaders who give Europe the political impetus. It is the time for a new resolve and this new resolve is more important than Brexit

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