Approval of an extraction agent with a 100% certified plant origin

Regulatory Review is a regular column featuring updates on regulatory matters concerning oils- and fats-related industries.

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The European Food Safety Authority (EFSA) just approved the use of a new biobased solvent for food extraction, paving the way for the substitution of the petrochemical solvents widely used for the food and feed production.

On March 14th, 2022, The Minafin Group eagerly announced that the EFSA has released a positive opinion for the use of methyloxolane as extraction agent for food processing. Thus, the use of methyloxolane under the approved production conditions has been identified as safe for consumers and the environment. We see this as a positive step for the safety and sustainability of the food production in Europe. By unlocking the opportunity to substitute petrochemicals for a plant-based extraction agent in food processes, petroleum residues in the whole food chain can be eliminated.

This technology brings to the food and feed market a 100% renewable and safe extraction solution for oils, plant proteins and natural ingredients. This breakthrough and award-winning innovation is biobased, safer for human health, and has a ten times lower CO_2 impact than the currently used petrochemical solvents.

HOW DID IT START?

The method for producing the molecule, methyloxolane, was developed in the 2000s. Our product has been used in the pharmaceutical industry since 2007. However, the study of its application as an extraction agent began in 2012. At the time a thesis conducted in France, named Anne-Gaelle Sicaire, was part of a collaboration between a laboratory in Bordeaux, the Institut des Corps Gras and the Eco-Extraction laboratory of the University of Avignon. Sicaire showed that among the 10 bio-solvents that had been studied in comparison with hexane

(such as ethanol, ethyl acetate, and limonene) methyloxolane was the only one that produced equivalent yields. In 2017, we verified that the extraction worked on a wide variety of seeds and substrates. We invested in additional studies to determine that our solution was innocuous on humans and animals.

It would take us 10 years, from 2012 to 2022, to develop the extraction application. Finally, we filed our application for food approval in December 2019 with the European Commission. With the positive opinion in March, it will now take 6 months to have the European law updated and our product fully approved for food.

PERMITTED EXTRACTION AGENTS IN EUROPE

Twenty solvents are currently authorized in the European Parliament's Directive 2009/32/CE for processing foodstuff (Table 1). Most of these chemicals are derived from petroleum. Methyloxolane is the only extraction agent permitted in food applications that is 100% certified carbon from plant origin, a first since the Directive was first issued in 2009. Except for the addition of dimethyl ether (a dossier reviewed by EFSA in 2015), the toxicological database of approved extraction agents has

TABLE 1. The 20 solvents which are currently approved for use in the Directive 2009/32/CE.

Name	Origin	At 20°C	Comments	Note in the 2009/32/CE
Propane	Petrochemical	Gas		
Butane	Petrochemical	Gas		
Ethyl acetate	Petrochemical or biobased	Liquid		
Ethanol	Petrochemical or biobased	Liquid		
Carbon dioxide	Petrochemical	Gas	Greenhouse Gas	
Acetone	Petrochemical	Liquid		The use of acetone in the refining of olive-pomace oil is forbidden.
Nitrous oxide	Mineral or biobased	Gas	Greenhouse Gas	
Hexane	Petrochemical	Liquid		The term 'hexane' means a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64°C and 70°C. The combined use of hexane and ethyl methyl ketone is forbidden.
Methyl acetate	Petrochemical or biobased	Liquid		
Ethyl methyl ketone	Petrochemical	Liquid		The level of n-hexane in this solvent should not exceed 50 mg/kg. The combined use of hexane and ethyl methyl ketone is forbidden.
Dimethyl ether	Petrochemical	Gas		
Dichloromethane	Petrochemical	Liquid		
Methanol	Petrochemical	Liquid		
2-propanol	Petrochemical	Liquid		
Diethyl ether	Petrochemical	Gas		
Cyclohexane	Petrochemical	Liquid		
1-butanol	Petrochemical	Liquid		
2-butanol	Petrochemical	Liquid		
1-propanol		Liquid		
1,1,1,2-tetrafluoroethane		Gas		
Methyloxolane	Biobased only	Liquid		

not been reviewed or updated by EFSA since the Directive was issued in 2009. We hope that this review will occur soon as the review of the food additives authorized prior to 2009 has just been completed. We think it is important for public authorities to regularly ask the manufacturers of the substances used in food processing to update their toxicological database and bibliography to consider the latest inputs of science as is regularly done for pesticides, and food and feed additives.

WHAT IS METHYLOXOLANE?

Methyloxolane is a bio-based product upcycled from sugar cane bagasse**,** the fibrous by-product remaining after the sugar has been extracted from the cane. It can be fully mixed with lipids. It is particularly well-adapted for vegetable oil extraction and other defatting processes. This property is rare for a bio-based solvent. Ethanol for instance is not naturally miscible with lipids.

HOW METHYLOXOLANE IMPROVE FOOD PROCESSING?

Oil and protein-rich food make up half of our diet. We consume an average of 130 grams of lipids and 50 to 70 grams of protein every day. Oil in food production is essential and present in many everyday foods, spreads, chocolate bars, chips, sweet and savory cakes, meats, cold meats, and ready meals.

Today, the production of vegetable oil and protein-rich plant products relies on hexane extraction, a technique which was optimized in the 1950s in large industrial processing facilities. Its use results in the presence of hexane residues in our food. However, with one exception, hexane is forbidden in organic food.

Hexane is indispensable today. About 20% of vegetable oil production depends on hexane-based solvent extraction. The production of long-life, high-protein feed depends on solvent-aided extraction of the oil. Beside the extraction of major oilseed crops such a soya bean, sunflower, rapeseed, cotton seed, and palm kernels, hexane is also used for the production of natural extracts such as hop extract, annatto extract, and omega 3 rich oils.

The use of large quantities of hexane has a negative impact on the environment, because of the large amount of emissions into the atmosphere. Each year, food extraction plants release 700,000 tons of hexane in the air, which contributes air pollution (hexane is classified as hazardous pollutant in the US) and to the transfer of non-renewable carbon to the atmosphere. The replacement of hexane using methyloxolane will significantly reduce the environmental impact of these parts of the food and feed industries.

WHAT ARE THE MAIN USES IN FOOD APPLICATIONS?

Methyloxolane dissolves lipids and so the main application is in the processing of oilseeds and grains. In addition to the extraction of valuable lipophilic natural pigments, flavors, fragrances, and bioactives from a wide range of natural sources. The Minafin Group is currently scaling-up production of EcoXtract®, an innovative and patented extraction system using methyloxolane in such food-based extraction applications.

WHAT ARE THE MAIN BENEFITS OF METHYLOXOLANE FROM A FOOD SAFETY PERSPECTIVE?

Consumers are generally unaware that hydrocarbon solvents are used in food processing as they are categorized as “processing aids” and are exempt from labelling. However, residues are unavoidable and widespread, particularly in foods that contain vegetable oils or plant protein concentrates. At Minafin Group, we advocate for transparent labelling about the use of safe extraction agents in food applications. EFSA’s positive opinion on methyloxolane relates to a full application dossier including state-of-the-art scientific studies performed under OECD standards. The opinion confirms the safety of the product for food applications. These studies combined with a 15-year background of methyloxolane use to manufacture pharmaceutical actives ensures a high level of protection for the consumer. In addition, methyloxolane is a naturally occurring molecule found in our close environment. For instance, it is naturally produced by a yeast living on human skin, known as Malassezia furfur. It was also identified in mother’s milk samples in 1982, long before any commercial production of product started at the beginning of the 21st century.

ORGANIC LABELING?

The EFSA positive opinion will support the methyloxolane dossier for an organic certification. The use of the product is already approved by COSMOS label to produce organic cos-

metic ingredients. Minafin Group will apply for this recognition in the coming weeks for food and feed applications.

WHAT ARE THE MAIN BENEFITS OF METHYLOXOLANE FROM AN ENVIRONMENTAL PERSPECTIVE?

As a science-led company dedicated to developing and commercializing breakthrough bio-based solutions, we are committed to building a fossil carbon-free world through the replacement of petrochemicals used in the food value chain. Reducing our dependence on petroleum derivatives is our day-to-day mission. Due to its plant origin, the carbon emissions from the production of methyloxolane is less than 200 g CO_2 per kg, 90% less than an average petrochemical solvent.

Because it is upcycled from agricultural byproducts, the production of methyloxolane does not require additional land. Land use being the foremost direct cause of biodiversity loss with the largest relative global impact. The superior performance of EcoXtract® solution as a lipophilic solvent, enables high extraction yields which maximizes oil production from a given quantity of oilseed and reduces the protein food waste.

WHAT IS THE IMPACT ON THE GLOBAL FOOD SUPPLY?

All cumulated food waste represents roughly one-third of the food production in the world. In the oilseeds industry, food waste represents 20% of the total production. We must act upon the current global situation where one out of nine people are hungry or undernourished and 2,37 billion people did not have access to enough safe and nutritious food in 2020.

According to Wageningen University, the limited application of oilseed residues, like rapeseed press cake, results in 26 Megatons of global protein losses annually. Implementation of this protein source is limited because conventional oilseed processing by mechanical press is optimized for oil extraction only and often reduces protein functionality.

Using methyloxolane in an extraction process, results in a 33% increase of the oil yield compared with mechanical processing alone and renders a high quality well-defatted long-lasting protein-rich residue which can be used for feed or for food application. Reducing food losses and waste is essential in a world where the number of people affected by hunger has been slowly on the rise since 2014, and multiple tons of edible food are lost and/or wasted every day. Globally, around 14% of food produced is lost between harvest and retail, while an estimated 17% of total global food production is wasted (11% in households, 5% in the food service and 2% in retail).

Methyloxolane offers a bio-based option to food ingredient producers committed to limiting the use of processing aids derived from petroleum sources, particularly those that use vegetable oil and high-protein co-products of oilseeds. Therefore, methyloxolane eliminates petroleum residues across the food chain.

The European approval of this extraction agent is a major boost to the safety and sustainability of food processing in Europe. Thanks to EFSA's positive opinion, issued on March 15th this year, methyloxolane will be admitted soon to the list of permitted food extraction agents described in the Directive 2009/32/CE. You can access the full EFSA's opinion here: https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2022.7138.

WHAT'S NEXT?

We have prepared the patent filing for the US, Canada and Australia; other countries will follow. In Europe, the Directive 2009/32/EC be amended by the end of the year. We have already been working with our partners and customers to prepare the adaptation of their process to methyloxolane in their industrial plants. Our aim is to bring our extraction solution to the market to allow ingredient producers to offer a safer and more sustainable products to their customers. We will also apply in the coming months for recognition for use in organic processing.

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