Report from the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) in relation to the use of a kaolinitic clay as a processing aid in the process for obtaining virgin olive oil

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Abstract

It has been requested the assessment of a dossier regarding the use of a kaolinitic clay, which main component is aluminium silicate, as a processing aid in the extraction process of virgin olive oil.

Aluminium silicate or kaolin is authorized as a food additive (E 559) within the functional class of anticaking agents. Its Acceptable Daily Intake (ADI) is not specified and the use of the kaolinitic clay as a processing aid does not lead to technically avoidable residues.

Once the application dossier of the kaolinitic clay (Koliva) as a processing aid in the process of obtaining virgin olive oil has been evaluated and from the information provided by the applicant and in the doses and conditions proposed, the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) concludes that the use of the kaolinitic clay as a processing aid for the purpose mentioned does not pose a risk for the consumers' health.

Keywords

Kaolinitic clay, Koliva, E 559, processing aid, olive oil.

Introduction

The Company Agrovital Internacional S.L, with headquarters in Zaragoza, has requested authorisation for the use of a kaolinitic clay, commercially known as Koliva, as a processing aid in the extraction process of virgin olive oil. The product Koliva, which contains at least 80% of kaolinite, is manufactured by the Company, Arcillas y Feldespatos Rio Pirón S.A. Tamame, in Sayago (Zamora).

Therefore, the Executive Director of the Spanish Agency for Food Safety and Nutrition (AESAN) has asked the Scientific Committee to assess the safety of using the kaolinitic clay product (Koliva) as a processing aid in the process for obtaining virgin olive oil, considering the "Guidelines indicating the necessary documentation for the assessment of processing aids intended for use in human food" (AESAN, 2010).

Aluminium silicate or kaolin, an additive partially analogous to the product Koliva, is authorised for use as a food additive, functional category: anti-caking (E 559) (Royal Decree 142/2002 dated 1 February 2002, from the Ministry of Health and Consumer Affairs, approving the positive list of additives other than colorants and sweeteners for use in the preparation of food products, and their conditions of use) (Real Decreto, 2002), the JECFA (Joint FAO/WHO Expert Committee on Food Additives) having established an unspecified Acceptable Daily Intake (ADI) (JECFA, 1985). Therefore, in accordance with the criteria established in the above-mentioned guidelines, the aluminium silicate would be classified in situation 1: substance authorised in human food whose use is authorised *quantum satis* (no maximum level specified). In line with this situation, the applicant for the product presents information relating to the following aspects:

- Administrative data and general introduction.
- Physical and chemical characteristics.
- Technological function.

Administrative data and general introduction

1. Exact designation and commercial name

The product, with commercial name Koliva, proposed as a processing aid is kaolinitic clay with a phyllosilicate content of 99% (85% kaolinite, 7% bentonite and 7% illite) and 1% quartz. The terms montmorillonite and betonite are synonymous (EHC, 2005).

2. Intended use of the substance

Processing aid in the process for obtaining virgin olive oil.

3. Authorised uses in human food

Aluminium silicate or kaolin, a compound, the main component of which is kaolinite, is authorised as a food additive (E 559) with the functional category of anti-caking agent and under the synonym of kaolin (light or heavy).

Bentonite is authorised as a food additive (E 558) with the functional category of anti-caking agent.

The standards for the identity and purity of aluminium silicate (E 559) and for bentonite (E 558) are established in Royal Decree 1466/2009 (Real Decreto, 2009).

4. Acceptable Daily Intake

The ADI of the additive E 559 (aluminium silicate or kaolin) is not specified (JECFA, 1985). JECFA does not specify an ADI as in view of the low toxicity level, its intake does not pose a risk to health (*CODEX*, 2005).

The ADI of the additive E 558 (bentonite) has not been allocated (JECFA, 2010).

Physical and chemical characteristics

1. Composition and detailed formulation

The applicant states that the kaolinitic clay under assessment, a product commercially known as Koliva, is a purified white plastic clay consisting of kaolinite, bentonite, illite and quartz. Mineralogy composition has been verified by X-ray diffraction analysis.

Table 1 lists the composition and characteristics of kaolinitic clay (Koliva) and the requirements with which the aluminium silicate (E 559) must comply for use as a food additive.

Table 1. Declared composition of kaolinitic clay (Koliva) and of aluminium silicate or kaolin (E 559)

Kaolinitic clay (Koliva)	Aluminium silicate or kaolin (E 559)[a]
• Kaolinite (85% p/p): $Al_2Si_2O_5(OH)_4$	• Kaolinite: $Al_2Si_2O_5(OH)_4$[a]
	Molecular weight: 264 g/mol
• Bentonite (7% p/p): $(Al,Mg)_8(Si_4O_{10})_4\ (OH)_8 12(H_2O)$	Not less than 90% (sum of silica and aluminium oxide, after combustion)
• Illite (7% p/p): $(K,H_3O)(Al,Mg,Fe)_2(Si,Al)_4O_{10}[(OH)_2,(H_2O)]$	• Silica (SiO_2) or quartz, between 45% and 55%)
	• Aluminium oxide (Al_2O_3) between 30% and 39%
	• Alúmina (Al_2O_3) entre un 30% y un 39%
	• Potassium silicate
	• Feldspar: $K,Na,Ca,Ba,NH_4,Sr(Si,Al,B)_4O_8$[b]

[a]Royal Decree 1466/2009. [b]UNED (2000).

2. Product specifications

Table 2 includes, all the specifications (purity criteria and limits) for the authorised additive, aluminium silicate or kaolin (E 559), Koliva specifications, and the analytical tests submitted by the applicant, for comparison.

Table 2. Criteria required for the additive E 559 (Royal Decree 1466/2009), specifications for Koliva and tests submitted by the applicant for the proposed processing aid, Koliva

Purity criteria and limits		
Aluminium silicate or kaolín (E 559)	**Specifications for Koliva**	**Results Kaolinitic clay (Koliva)**
Loss during combustion: Between 10% and 14% (1,000ºC, constant weight)	Between 10% and 14% (1,000 ºC,constant weight)	13.25%
		13.41%
		13.64%
Water-soluble matter: not more than 3.0%	Not more than 0.3%	0.19%
		0.14%
		0.15%
Acid-soluble matter: not more than 2.0%	Not more than 2.0%	1.17%
		0.93%
		0.84%
Iron: not more than 5%	Not more than 3%	0.3%
		0.27%
		0.3%
Potassium Oxide (K_2O): not more than 5%	Not more than 2%	0.17%
		0.14%
		0.16%
Carbon: not more than 0.5%	Not more than 0.5%	<0.10%
		<0.10%
		<0.10%
Arsenic: not more than 3 mg/kg	Not more than 3 mg/kg	<0.25 mg/kg
		0.92 mg/kg
		1.1 mg/kg
Lead: not more than 5 mg/kg	Not more than 70 mg/kg	55 mg/kg
		67 mg/kg
		66 mg/kg
Mercury: not more than 1 mg/kg	Not more than 1 mg/kg	0.55 mg/kg
		<0.1 mg/kg
		<0.1 mg/kg
Dioxins: harmless	Harmless	0.086 pg/g WHO-TEQ*
–	Cadmium: not more than 2 mg/kg	0.04 mg/kg
		<0.03 mg/kg
		0.03 mg/kg

*WHO/TEQ: World Health Organisation toxic equivalent.

As it can be seen in Table 2, lead content is 11 times greater than that described by JECFA (1985) for aluminium silicate and it is also higher than the content established for the additive, bentonite E 558.

Royal Decree 1466/2009 refers to the dioxins in the production of the additive E 559 (aluminium silicate or kaolin) and it states that the process should not include calcination and that the dioxin level in the raw kaolinitic clay used in the production of aluminium silicate should not make it harmful to health or unsuitable for human consumption.

With respect to this point, the applicant has attached, the report of a dioxin test performed on the kaolinitic clay (Koliva) by the Mass Spectrometry Laboratory at the Barcelona Institute of Chemical and Environmental Research (CSIC), which shows that the values obtained are less than 0.086 WHO-TEQ (pg/g), sum of polychlorodibenzo-paradioxins (PCDD) polychlorodibenzofuranes (PCDF) expressed in World Health Organisation toxic equivalents (WHO-TEQ). Moreover, it should be noted that the product under assessment is extracted from a primary deposit. These are deposits with the lowest dioxin content (Schmitz et al., 2011).

Regulation (EC) No 1881/2006 (EU, 2006) establishes the maximum content of dioxins and polychlorobiphenyls similar to dioxins (PCBs) in oil at 0.75 pg/g fat WHO-PCDD/F-TEQ of dioxins. The dioxin content observed in the product, Koliva, is much lower than the maximum content established in oils.

With respect to heavy metals, the kaolinitc clay Koliva complies with the identity and purity criteria established for the additive aluminium silicate (E 559) in Royal Decree 1466/2009, except with respect to the limits for lead (Table 2).

In addition, the Koliva product complies with the arsenic criteria specified for bentonite (E 558) (not more than 2 mg/kg) but does not comply with the lead criteria (not more than 20 mg/kg).

Illite, with a minority presence in kaolinitic clay, is a phyllosilicate from the group of micas for which there are no signs indicating toxicity *per se* and which, in the conditions of use proposed by the applicant, would be eliminated during the centrifugal process together with the solid waste or pomace.

The applicant indicates that, although the lead content is high, the metal is encapsulated, forming part of the crystalline structure of the clay and in no case it is bioavailable, so it does not pass to the oil during the process of obtaining virgin olive oil. To demonstrate this hypothesis, the applicant has provided the analytic results for the determination of lead in the oil after treatment with the kaolinitic clay, together with the results for the lead content in the oil control (obtained without treatment). These tests were carried out as part of a efficiency study performed by the experimental oil mill (laboratory and pilot plant) at the Instituto de la Grasa de Sevilla (CSIC).

In this study, besides other determinations, arsenic, copper, iron and lead contents in oil samples from *Arbequina* and *Picual* olives in the laboratory tests and *Picual* olives in the pilot test were analyzed. In both tests, olives at two different stages of ripening were used. Table 3 gives the results obtained for arsenic, copper, iron and lead in the control samples (samples not treated with any processing aid) and in samples in which a concentration, within the maximum dose requested (2%) and up to 2.5% of kaolinitic clay (Koliva), has been used.

Table 3. Arsenic, copper, iron and lead contents in control oils and oils obtained with kaolinitic clay (Koliva)

Scale	Laboratory								Pilot	
Oil	***Arbequina* 2**		***Picual* 1**			***Picual* 2**			***Picual***	
Metal (mg/kg)	**Control**	**Koliva 2%**	**Control**	**Koliva 2%**	**Koliva 2.5%**	**Control**	**Koliva 2%**	**Koliva 2.5%**	**Control**	**Koliva 2%**
Arsenic	<0.020	<0.020	<0.020	<0.020	<0.020	<0.020	<0.020	<0.020	<0.024	<0.021
									<0.020	<0.022
Copper	<0.050	<0.050	<0.050	<0.050	<0.050	<0.050	<0.050	<0.050	<0.050	<0.050
									<0.050	<0.050
Iron	<0.600	<0.600	1.2	<0.600	<0.600	<0.600	<0.600	<0.600	<0.600	<0.600
									<0.600	<0.600
Lead	0.008	0.01	0.01	<0.006	<0.006	0.006	0.008	0.009	0.014	0.013
									0.013	0.013

Arsenic, copper, iron and lead contents in oils obtained by using the processing aid Koliva (table 3) are below the limits established by the Technical and Sanitary Regulations of Edible Vegetable Oils, approved by Royal Decree 308/1983 dated 25 January (Real Decreto, 1983). The results prove that oils obtained using the processing aid Koliva had lead contents similar to those obtained using talc (authorized processing aid).

3. Process for obtaining kaolinitic clay

The processing aid is obtained using the following sequence of production for the washed clay obtained from the deposit:

1. Feed to a chopper.
2. Wet processing: fragmentation on contact with water and hydrocyclonation in various successive stages. Screening and storage in thickener tank in which the kaolinitic clay to be used in the manufacture of the processing aid is concentrated.
3. Filtration and extrusion of resultant clay slabs.
4. Drying of clay slab after fragmentation in a mixer-extruder and obtaining of dry clay *pellets*.
5. Silage of loose product.
6. Milling of loose product.
7. Packaging.

Technological function

According to the applicant, the kaolinitic clay (Koliva) is added at the stage prior to the beating of the olive paste. The objective is that during the beating phase, drops of oil partially released during milling bond with the larger drops as a result of movement, temperature, the action of the processing aid and time, thus facilitating the process for separating the solid from the liquid. The kaolinitic clay residue remaining in the oil, due to its high specific weight (2.6 g/cm^3) is easily eliminated in the centrifugal process together with the solid waste or pomace.

1. Level of use requested

As stated by the applicant, the maximum dose requested for use is 2 % with respect to the weight of the olive paste.

2. Justification for use, interest and efficiency

Virgin olive oil, as established in Regulation (EC) No 1513/2001 (EU, 2001), is the oil obtained using solely mechanical or other physical procedures, in conditions that do not result in modification of the oil, and the use of chemical or biochemical action processing aids is not permitted.

The efficiency study was performed by the experimental oil mill at the Instituto de la Grasa de Sevilla (CSIC), and is based on the comparison of the results obtained in the following situations:

- Control: oil obtained without the use of treatment.
- Treatment of the olive paste with talc in varying concentrations, a processing aid authorised by the Order dated 13 January 1986 (Orden de 13 enero de 1986) with similar characteristics to the processing aid under assessment.
- Treatment of the olive paste with kaolinitic clay (Koliva) in varying concentrations.

The study was performed under laboratory conditions and at the pilot plant.

Laboratory test

Arbequina and *Picual* olives were used at two different stages in the ripening process. The characteristics of the olives used in the test (maturity index, humidity and volatile matter content, total oil content over dry and wet matter, partial oil content) were studied and a comparison was made of a control sample, samples treated with talc and samples treated with kaolinitic clay (Koliva) in an interval of between 0.3% and 2.5%. Different parameters were determined: yield, oil quality characteristics, organoleptic profile, composition of fatty acids and of sterols, total sterols, erythrodiol and uvaol.

The applicant provides the mentioned efficiency study which indicates that the use of kaolinitic clay (Koliva) improves the phase separation in the elaboration process, thereby increasing the quantity of aqueous phase produced. In addition, there is, with respect to the control, an increase in the yield of oil extracted of up to 0.7 points in the case of the *Arbequina* variety and up to 2.2 points in the *Picual* variety.

The composition in methyl esters of fatty acids (%), sterols (%), erythrodiol and uvaol (%) and total sterols (mg/kg) content in the oil is unchanged (Table 4). No differences are observed in the quality, degree of acidity, peroxide index, absorbance at 270 and 232 nm, stability, colour and organoleptic characteristics between the oil obtained using kaolinitic clay (none of the doses used in an interval between 0.3% and 2.5%), and the control.

The optimum dose of kaolinitic clay was determined to be between 2% and 2.5% with respect to the weight of the olive paste.

Table 4. Composition in methyl esters (%), sterols (%), erythrodiol and uvaol (%) and total sterols (mg/kg) in the oil obtained from the *Picual* olive at two different stages of the ripening process, without processing aid, using talc (2%) and kaolinitic clay (2 and 2.5%). Laboratory test

Sterolic composition (%)	**Control**	**Talc 2%**	**Koliva 2%**	**Koliva 2.5%**	**Methyl esters (%)**	**Control**	**Talc 2%**	**Koliva 2%**	**Koliva 2.5%**
Cholesterol	0.1	0.2	0.1	0.2	Myristic	0.00	0.00	0.01	0.00
	0.2	0.2	0.1	0.3		0.00	0.00	0.00	0.00
Brassicasterol	0.0	0.0	0.0	0.0	Palmitic	11.8	11.9	12.0	11.8
	0.0	0.0	0.0	0.0		9.5	9.4	9.6	9.5
24-methylene	0.2	0.2	0.2	0.2	Palmitoleic	1.1	1.1	1.2	1.1
cholesterol	0.1	0.1	0.1	0.1		0.7	0.7	0.7	0.7
Campesterol	3.2	3.2	3.2	3.1	Margaric	0.1	0.1	0.0	0.1
	3.3	3.3	3.3	3.3		0.1	0.1	0.1	0.1
Campestanol	0.1	0.1	0.1	0.2	Margaroleic	0.1	0.1	0.1	0.1
	0.1	0.1	0.1	0.1		0.1	0.1	0.1	0.1
Stigmasterol	0.5	0.5	0.5	0.7	Stearic	3.4	3.4	3.4	3.4
	0.6	0.7	0.7	0.7		3.1	3.1	3.1	3.1
Clerosterol	1.0	1.0	1.0	1.0	Oleic	76.2	76.2	76.1	76.2
	1.0	0.9	1.0	0.9		80.3	80.3	80.0	80.3
ß-sitosterol	85.3	85.2	85.3	85.5	Linoleico	5.8	5.8	5.8	5.8
	86.8	86.9	86.5	86.7		4.9	4.9	4.9	4.9
Sitostanol	0.6	0.6	0.5	0.6	Linolenic	0.6	0.6	0.6	0.6
	0.6	0.6	0.7	0.7		0.7	0.7	0.7	0.7
Delta-5-	7.5	7.5	7.5	7.3	Arachic	0.4	0.4	0.4	0.4
avenasterol	6.4	6.2	6.4	6.3		0.4	0.4	0.4	0.4
Delta-5,24-	0.6	0.6	0.6	0.4	Eicosanoic	0.2	0.2	0.2	0.2
stigmastadienol	0.3	0.3	0.5	0.3		0.2	0.3	0.3	0.3
Delta-7-	0.4	0.4	0.5	0.3	Behenic	0.1	0.1	0.1	0.1
stigmastadienol	0.3	0.3	0.3	0.3		0.1	0.1	0.1	0.1
Delta-7-	0.5	0.5	0.5	0.5	Lignoceric	0.1	0.1	0.1	0.1
avenasterol	0.3	0.4	0.3	0.3		0.1	0.1	0.0	0.1
Erytrodiol + Uvaol	1.7	1.8	1.4	1.7					
	1.7	1.7	1.2	1.8					
Total (mg/kg)	1,258	1,257	1,249	1,267					
sterols	1,360	1,369	1,351	1,368					

Test at pilot plant

A dose of kaolinitic clay of 2% with respect to the olive paste was used for the extraction of virgin olive oil from *Picual* olives at only one stage in the ripening process.

The results of this study indicate that treatment with kaolinitic clay (Koliva) led to an increase in the industrial yield of approximately 0.5 points, in comparison with the control. In the pomace pastes, the average oil content with respect to dry material decreased in the samples treated with clay in comparison with the control samples.

The analytical results show that there are no significant differences between the control oil and the oil obtained with the kaolinitic clay (Koliva) with respect to the composition of methyl esters of fatty acids (%), sterols (%), erythrodiol and uvaol (%) and total sterols (mg/kg) (Table 5).

Table 5. Composition in methyl esters (%), sterols (%), erythrodiol and uvaol (%) and total sterols (mg/kg) in the oil obtained from the *Picual* olive without processing aid (control) and using talc (2%) or kaolinitic clay (2%). Pilot assay

Sterolic composition (%)	**Control**	**Talc 2%**	**Koliva 2%**	**Methyl esters (%)**	**Control**	**Talc 2%**	**Koliva 2%**
Cholesterol	0.2	0.2	0.2	Myristic	0.0	0.0	0.0
Brassicasterol	0.0	0.0	0.0	Palmitic	9.3	9.3	9.3
24-methylene cholesterol	0.1	0.1	0.1	Palmitoleic	0.7	0.7	0.7
Campesterol	3.5	3.5	3.5	Margaric	0.1	0.1	0.1
Campestanol	0.1	0.2	0.2	Margaroleic	0.1	0.1	0.1
Stigmasterol	0.6	0.6	0.6	Stearic	3.4	3.4	3.4
Clerosterol	1.1	1.0	1.0	Oleic	81.1	81.1	81.0
ß-sitosterol	88.7	89.0	89.3	Linoleic	4.1	4.1	4.1
Sitostanol	1.0	0.9	0.9	Linolenic	0.6	0.6	0.6
Delta-5-avenasterol	3.8	3.8	3.7	Arachic	0.4	0.4	0.4
Delta-5,24-stigmastadienol	0.4	0.4	0.4	Eicosanoic	0.3	0.3	0.3
Delta-7-stigmastadienol	0.4	0.3	0.3	Behenic	0.1	0.1	0.1
Delta-7-avenasterol	0.3	0.2	0.2	Lignoceric	0.1	0.1	0.1
Erythrodiol + Uvaol	1.4	1.3	1.1				
Total sterols (mg/kg)	1,102	1,129	1,101				

In view of the results obtained, the product can be assumed to be chemically inactive. In addition, the safety data sheet submitted by the applicant shows that the product under assessment is an inert and stable preparation.

The tests performed in the laboratory and at the pilot plant show that for all the parameters studied, (quantity of oil obtained, oil quality and composition), the results obtained with talc are similar to those obtained using kaolinitic clay (Koliva).

Nevertheless, queries have been raised concerning the situation produced due to the permanence of the kaolinitic clay in the pomace, especially with respect to the processes involved in its industrial exploitation: drying, extraction and subsequent refining.

The pomace oil is extracted by the dried pomace contacts with hexane, a non-polar solvent in which the kaolinitic clay is totally insoluble, and therefore it should not be present in the extracted oil.

With respect to heavy metals, the applicant claims that corrosive polar protic solvents are used instead of non-polar solvents for the extraction of heavy metals.

The use of non-polar solvents to obtain oil from the pomace is based on the similarity of the solvent to the oil to be extracted. The studies submitted show that the use of kaolinitic clay in the process to extract olive oil does not leave any contaminants in the oil, and therefore, it can be assumed that this would not occur with the use of a compound of similar characteristics, such as hexane.

With respect to the dioxins, their content in the kaolinitic clay is far below the established limits. Thus, it is possible to estimate that, as in virgin olive oil, no safety issues arise in pomace oil.

Conclusions of the Scientific Committee

The Scientific Committee, having assessed the application to use kaolinitic clay (Koliva) as a processing aid in the procedure for obtaining virgin olive oil, concludes that, based on the information provided by the applicant and in the doses and conditions proposed, the use of the kaolinitic clay under assessment as a processing aid in the procedure for obtaining virgin olive oil does not pose a risk for the consumers' health.

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