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STATEMENT OF EFSA

Statement on the validity and robustness of information provided on irradiated iron oxides[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

This scientific output, published on 27 November 2014, replaces the earlier version published on 4 July 2014*

ABSTRACT

Following a Rapid Alert System for Food and Feed (RASFF) notification concerning the use of an unauthorised irradiated colouring agent (brown iron oxide) as coatings of food supplements, the European Commission asked EFSA to assess the scientific validity and robustness of three documents i) two safety assessments from two pharmaceutical companies including information on the manufacturing process of iron oxides, and ii) one safety assessment on gamma irradiated iron oxides in food supplements provided by a consultant. According to the supplier of iron oxides and hydroxides (E 172), the aim of the ^{60}Co-gamma irradiation treatment was to eliminate microbiological contamination. Iron oxides and hydroxides (E 172) are authorised food additives in the EU. EFSA noted that the gamma irradiation of iron oxides (yellow, red, black and brown) has not been previously evaluated by other Scientific Committees dealing with foodstuffs, pharmaceutical products or cosmetics and that the irradiation doses applied to iron oxides in this particular case are higher than the doses currently authorised in the EU for "other food and food ingredients". EFSA also noted that some evidence is available in the literature demonstrating a reduction of iron(III) to iron(II) due to ^{60}Co-gamma irradiation and, that the food additive black iron oxide, as authorised in the EU, contains iron in both (II) and (III) valence states. Therefore, an increase in the content of divalent iron would not be of safety concern per se. However, EFSA also notes that the information on irradiated iron oxides provided is very limited and insufficient to substantiate the claim that iron oxides are not expected to undergo any chemical transformation upon irradiation. In order to demonstrate the chemical stability of iron oxide during the ^{60}Co-gamma irradiation treatment, EFSA recommends to carry out some further analyses.

KEY WORDS

Iron oxides, iron hydroxide, E 172, food additive, gamma irradiation, RASFF

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2 Correspondence: fip@efsa.europa.eu

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* Minor corrections to clarify the content of the output were made. The changes do not affect the contents of this statement. To avoid confusion, the original version of the statement has been removed from the EFSA Journal, but is available on request, as is a version showing all the changes made.

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SUMMARY

Following a Rapid Alert System for Food and Feed (RASFF) notification concerning the use of an unauthorised irradiated colouring agent (brown iron oxide) as coatings of food supplements, the European Commission asked EFSA to assess the scientific validity and robustness of three documents i) two safety assessments from two pharmaceutical companies including information on the manufacturing process of iron oxides, and ii) one safety assessment on gamma irradiated iron oxides in food supplements provided by a consultant. According to the supplier of iron oxides and hydroxides (E 172), the aim of the irradiation treatment (^{60}Co-gamma irradiation) was to eliminate microbiological contamination in the product.

The food additive iron oxides and hydroxides (E 172) include red iron oxide (Fe_2O_3), yellow iron oxide (FeO(OH)), black iron oxide ($FeO{\cdot}Fe_2O_3$) and brown iron oxide (a mixture of the former oxides). Each iron oxide has different physical and chemical properties and they can be used separately or as a mixture (brown iron oxide).

Iron oxides and hydroxides (E 172) are authorised food additives in the EU in entire fresh fruit and vegetables with a maximum permitted level of 6 mg/kg and according to *quantum satis* in 48 food categories (Regulation (EC) No 1333/2008). Within these food categories, iron oxides and hydroxides are authorised in food supplements supplied in a liquid form, food supplements supplied in a syrup-type or chewable form and food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms.

The three safety assessments submitted to EFSA can only be considered a hazard identification as no hazard characterisation (characterisation of the biological and toxicological dose-response relationships), no exposure assessment and no risk characterisation was included in these documents.

EFSA noted that the gamma irradiation of iron oxides (yellow, red, black and brown) has not been previously evaluated by other Scientific Committees dealing with foodstuffs, pharmaceutical products or cosmetics.

EFSA noted that the maximum irradiation doses (15-37 kGy) applied to iron oxides used as food additives are approximately two times higher than the maximum doses currently authorised in the EU for “other food and food ingredients”.

EFSA also noted that some evidence is available in the scientific literature demonstrating a reduction of iron(III) to iron(II) due to ^{60}Co-gamma irradiation and, that the food additive black iron oxide, as authorised in the EU, contains iron in both (II) and (III) valence states. Therefore, an increase in the content of divalent iron would not be of safety concern per se. However, EFSA also notes that the information on irradiated iron oxides provided is very limited and insufficient to substantiate the claim that iron oxides are not expected to undergo any chemical transformation upon irradiation. In order to demonstrate the chemical stability of iron oxide during the ^{60}Co-gamma irradiation treatment, EFSA recommends to carry out some further analyses.

Overall, addressing the term of reference and the documents provided by the European Commission, EFSA concluded that the provided information is insufficient to fully substantiate the conclusion drawn from the provided safety assessments.

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BACKGROUND AS PROVIDED BY COMMISSION

On 10 April 2014, the Belgian Food Safety Agency issued a RASFF notification concerning the use of an unauthorized irradiated colouring agent (brown iron oxide) as coatings of e.g. food supplements. Indeed, a Belgian company notified the unauthorized irradiation of this colouring agent to their competent authorities.

This notification is based on the fact that the iron oxide supplier informed his customers that the iron oxide batches provided were ^{60}Co-gamma irradiated (with a dose of 35 kGy) for at least the past 4 years.

Iron oxide is neither contained in the EU positive list of foodstuffs authorised for irradiation treatment (Directive 1999/3/EC) nor in the list of Member State authorisations of food and food ingredients which may be treated with ionising radiation (Article 4(6) of Directive 1999/2/EC; OJ C 283/5, 24.11.2009).

The Commission received on 29/04/2014 the representatives of the two companies which are actively looking for a replacement supplier. These companies informed the Commission that they have meanwhile made internal risk assessments concluding that "food supplements containing irradiated iron oxides are safe and not injurious to human health".

The issue was addressed to all Member States at the last SCOFCAH meeting on 13/05/2014. At that meeting, the Commission committed to ask EFSA for an evaluation of these respective risk assessments.

TERMS OF REFERENCE AS PROVIDED BY COMMISSION

In accordance with Article 31 of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to assess the scientific validity and robustness of the provided information on irradiated iron oxides (safety assessments/health hazard assessment/manufacturing process). The documents (1a; 1b and 2) hereunder listed could be used as an element in the scientific and technical assistance.

- 1a) “Health Hazard Assessment” and its appendix.
- 1b) “Global Drug Safety Risk Management Assessment”.
- 2) “Gamma irradiated iron oxides in food supplements” safety assessment.

EVALUATION

1. INTRODUCTION

Iron oxides and hydroxides (E 172) are authorised as food additives in the EU in accordance with Annex II to Regulation (EC) No 1333/2008[4].

The Belgian Food Safety Agency issued a Rapid Alert System for Food and Feed (RASFF) notification concerning the use of an unauthorised irradiated colouring agent (brown iron oxide) as coatings of food supplements. This notification was based on the fact that the iron oxide supplier informed his customers that the iron oxide batches provided were ^{60}Co-gamma irradiated (with a dose of 35 kGy) for at least the past 4 years.

The use of gamma irradiation (γ-irradiation) of food using ^{60}cobalt to reduce food-borne pathogens in foods has been previously evaluated (SCF, 1986, 2003; EFSA, 2011; EFSA CEF Panel, 2011; EFSA BIOHAZ Panel, 2011).

2. LEGISLATION

Iron oxides and hydroxides (E 172) are authorised food additives in the EU in entire fresh fruit and vegetables with a maximum permitted level of 6 mg/kg and according to *quantum satis* in 48 food categories (Regulation (EC) No 1333/2008). Within these food categories, iron oxides and hydroxides are authorised in food supplements supplied in a liquid form, food supplements supplied in a syrup-type or chewable form and food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms.

Specific purity criteria on iron oxides and hydroxides have been defined in the Commission Regulation (EU) No 231/2012[5].

There are two Directives regulating the irradiation of food at EU level: Directive 1999/2/EC[6] and Directive 1999/3/EC[7]. Besides the irradiation of foodstuffs listed in Directive 1999/3/EC (so far only "dried aromatic herbs, spices and vegetable seasonings" at the maximum overall average absorbed radiation dose of 10 kGy), irradiation of a number of foodstuffs is also temporarily admitted in certain Member States until a new Directive establishes an updated Community list. Foodstuffs and doses temporarily admitted at Member States level have been published by the Commission[8].

3. IRON OXIDES AND HYDROXIDES (E 172)

There are 16 known iron oxides either oxides, hydroxides and oxide-hydroxides. The iron oxides are composed of iron (Fe) together with O and/or OH. In most compounds iron is in the trivalent state (Fe^{3+}); three compounds contain Fe^{2+} (Cornell and Schwertmann, 2003).

The food additive iron oxides and hydroxides (E 172) include red iron oxide (Fe_2O_3), yellow iron oxide (FeO(OH)), black iron oxide ($FeO{\cdot}Fe_2O_3$) and brown iron oxide (a mixture of the former oxides). Each iron oxide has different physical and chemical properties and they can be used separately or as a mixture (brown iron oxide).

[4] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008.

[5] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p 1-295.

[6] Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation. OJ L 66, 13.3.1999, p 16.

[7] Directive 1999/3/EC of the European Parliament and of the Council of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation. OJ L 66, 13.3.1999, p 24.

[8] Official Journal of the European Union, C 283, volume 52. 24 November 2009. List of Member States' authorisations of food and food ingredients which may be treated with ionising radiation, OJ C 283, 24.11.2009, p 5.

Table 1 summarises the chemical information for the food additive iron oxides (yellow, red and black).

Table 1: Iron oxides and hydroxides (E 172) (Commission Regulation (EU) No 231/2012[9])

Chemical Name	Chemical formula	Molecular weight (g/mol)	CAS Registry Number	Colouring Index (CI) Number	EINECS Number	Synonyms
Iron oxide yellow: hydrated ferric oxide, hydrated iron (III) oxide	$FeO(OH)\cdot H_2O$	106.87 (monohydrate)	51274-00-1	77492	257-098-5	CI Pigment Yellow 42 and 43
Iron oxide red: anhydrous ferric oxide, anhydrous iron (III) oxide	Fe_2O_3	159.70	1309-37-1	77491	215-168-2	CI Pigment Red 101 and 102, Pigment Brown 6, Pigment Brown 7
Iron oxide black: ferrous ferric oxide, iron (II, III) oxide	$FeO\cdot Fe_2O_3 = Fe_3O_4$	231.55	1317-61-9	77499	235-442-5	CI Pigment Black 11

4. ASSESSMENT OF THE INFORMATION

The European Commission asked EFSA to assess the scientific validity and robustness of three documents i) two safety assessments from two pharmaceutical companies including information on the manufacturing process of iron oxides, and ii) one safety assessment on gamma irradiated iron oxides in food supplements provided by a consultant. In the limited amount of time for the response to the assistance request, EFSA did not conduct a thorough literature search and based this assessment on a limited data set. However, a literature search in Web of Science and SciFinder databases[10] resulted in no peer-reviewed scientific articles or scientific evaluations on the irradiation of iron oxides to be used in foodstuff, cosmetics and pharmaceutical products.

A workflow on the manufacturing process of yellow, red, black and brown iron oxides was provided to EFSA. According to the supplier of iron oxides and hydroxides (E 172), the aim of the irradiation treatment (^{60}Co-gamma irradiation) was to eliminate microbiological contamination in the product. The irradiation process is not indicated in the manufacturing processes as, according to the manufacturer, the gamma irradiation is a post-treatment after the final packaging step[11]. Yellow iron oxide is produced synthetically from a ferrous salt. Red iron oxide is produced by calcination of yellow iron oxide. The black iron oxide is produced via chemical synthesis using a precipitation processes in which yellow iron oxide and red iron oxide are the raw materials. Brown iron oxide is produced through a blending process of yellow, red and black iron oxides.

The three safety assessments submitted to EFSA can only be considered a hazard identification as no hazard characterisation (characterisation of the biological and toxicological dose-response relationships), no exposure assessment and no risk characterisation was included in these documents.

[9] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012.

[10] Keywords: iron oxides and gamma irradiation; timespan 1970-2014.

[11] Personal communication by a manufacturer to EFSA, 25th June 2014.

Within the information provided to EFSA, it is indicated that the maximum irradiation doses for yellow, red and black iron oxide are 15-20 kGy, 35-37 kGy and 33-35 kGy, respectively. The irradiation dose applied for the brown iron oxide was not provided. In a further personal communication to EFSA, it is indicated that "brown iron oxides are treated with irradiation in the same manner and to the same dosage levels as per the other iron oxides"[12]. EFSA noted that these irradiation doses are up to approximately two times higher than the upper limits authorised in the EU for "other food and food ingredients"[13] and considered in the EFSA opinion on the efficacy and microbiological safety of irradiation (EFSA, 2011). No data supporting the use of these high irradiation doses for the microbiological safety were provided by the manufacturer, nor any reason for applying different irradiation dose to iron oxides.

The provided safety assessments stated that "food supplements containing irradiated iron oxides are safe and not injurious to human health" based on the following considerations:

- "Gamma irradiation did not render the iron oxide radioactive". EFSA agreed with this statement and acknowledged that, in the previous EFSA opinion on the chemical safety of irradiation of food, it was stated that "None of the radiation techniques described induces at the specified energy levels measurable amounts of radioactivity (Diehl, 1995; Terry and McColl, 1992; WHO, 1994), therefore the natural content of radioactivity of food is not affected by these ionizing radiations" (EFSA CEF Panel, 2011).

- "A number of articles have reviewed the potential and actual use of irradiation for ingredient used in pharmaceutical and cosmetic products" (Prince and Welt, 1971; Chang et al.,1974; Hangay, 1978; Jacobs, 1995; Katušin-Ražem et al., 2003; Howard, 2010; Hasanain et al., 2014). EFSA noted that none of the references provided[14] refer to iron oxides and that gamma irradiation of iron oxides (yellow, red, black and brown) has not been evaluated in any previous assessment on the safety of irradiated iron oxides to be used in foodstuff, cosmetics and pharmaceutical ingredients.

- "That no evidence of untoward health effects in humans for irradiated iron oxides has been identified in the literature". EFSA noted that no scientific evidence has been submitted to support this statement.

- "No radiolytic by-products or residues in the iron oxide additive, no safety risk to the consumer is conceivable". EFSA noted that no scientific evidence has been submitted to support this statement.

- "The irradiation affects the photochromic properties of iron oxides which are otherwise chemical stable". EFSA noted that there is contradictory information on this issue in the provided information. The manufacturer stated "confirmed that the chemical, physical and colour parameters noted in the respective certificate of analysis remained within specifications in spite of the gamma irradiation treatment" whilst in another document it is mentioned "as far as we know there is no measurable physical or chemical change of properties of irradiated iron oxide pigments". In addition, following a further request for clarifications by EFSA on the colour of each of the irradiated oxides after the irradiation process, it was stated that the analyses were carried out some years ago and they would need re-confirmation[12]. EFSA noted that in the literature (Plötze et al., 2003; Gotic et al., 2007; Bank et al., 2008; Gotic et al., 2009) the reduction of iron(III) to iron(II) associated with gamma irradiation is demonstrated, including a dose within the same dose range as the ones used by industry.

[12] Personal communication to EFSA by a manufacturer, 25th June 2014.

[13] Official Journal of the European Union, C 283, volume 52. 24 November 2009. List of Member States' authorisations of food and food ingredients which may be treated with ionising radiation, OJ C 283, 24.11.2009, p 5.

[14] The Reid and Fanaras (1990) study was not available to EFSA, however, EFSA noted that other available publications in the literature (Reid and Wilson, 1993; Reid, 1995; Reid, 1998) do not refer to the irradiation of iron oxides.

- Therefore, a change in the valence state of iron, during the gamma irradiation treatment of iron oxides (yellow, red black and brown iron oxides contain iron(III)), cannot be precluded. If the valence state changes, then the chemical composition, the bonding and the structure around the iron atom will change too.

- "Iron oxide additive represents a small fraction of the total product". EFSA noted that in these assessments, it was considered that irradiated iron oxides are only used as food additives in the coating of food supplements. Further information on the composition of the coating of the food supplements was provided to EFSA[15]. Based on this information, EFSA calculated a theoretical exposure scenario[16], assuming that irradiated iron oxides are only used in food supplements, that results in an intake up to 0.074 mg iron oxide/kg bw/day. However, EFSA noted that iron oxides and hydroxides (E 172) are authorised in 46 food categories.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

EFSA noted that the gamma irradiation of iron oxides (yellow, red, black and brown) has not been previously evaluated by EFSA or other Scientific Committees dealing with foodstuffs, pharmaceutical products or cosmetics.

EFSA noted that the maximum irradiation doses applied to iron oxides to be used as food additives are up to approximately two times higher than the doses currently authorised for "other food and food ingredients".

EFSA also noted that some evidence is available in the peer-reviewed scientific literature demonstrating a reduction of iron(III) to iron(II) due to ^{60}Co-gamma irradiation and, that the food additive black iron oxide, as authorised in the EU, contains iron in both (II) and (III) valence states. Therefore, an increase in the content of divalent iron would not be of safety concern per se. However, EFSA also notes that the information on irradiated iron oxides provided is very limited and insufficient to substantiate the claim that iron oxides are not expected to undergo any chemical transformation upon irradiation.

Overall, addressing the term of reference and the documents provided by the European Commission, EFSA concluded that the provided information is insufficient to fully substantiate the conclusion drawn from the provided safety assessments.

RECOMMENDATIONS

In order to demonstrate the chemical stability of the yellow iron oxide ($FeO(OH)\cdot H_2O$), red iron oxide (Fe_2O_3), black iron oxides ($FeO\cdot Fe_2O_3$) and brown iron oxide (mixture of the previous mentioned iron oxides) during the ^{60}Co-gamma irradiation treatment, EFSA recommends to carry out some comparative analyses on the iron oxides before and after the irradiation (same batch before and after irradiation) using appropriate methods of analysis, including ^{57}Mössbauer spectroscopy and FT-IR spectroscopy as well as colour analysis.

Depending on the results of such studies, additional data may be needed to demonstrate the safety of the use of irradiated iron oxides as food additives.

DOCUMENTATION PROVIDED TO EFSA

1. "Health Hazard Assessment" and its appendix (five pages). Submitted by the European Commission, 23rd May 2014.

[15] Addendum: EFSA request for clarifications. Submitted to EFSA on 25th June 2014.

[16] Considering a capsule of 1 g of food supplements per day and taking into account a body weight of 70 kg for the European adult population (EFSA Scientific Committee, 2012)

2. "Global Drug Safety Risk Management Assessment" safety assessment (two pages). Submitted by the European Commission, 23rd May 2014.

3. "Gamma irradiated iron oxides in food supplements" safety assessment (nine pages). Submitted by the European Commission, 23rd May 2014.

4. A workflow on the manufacturing process of iron oxides (one page). Submitted by the European Commission, 23rd May 2014.

5. Addendum: EFSA request for clarifications. Submitted to EFSA on 25th June 2014.

6. Personal communication to EFSA by a manufacturer. Submitted to EFSA on 25th June 2014.

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GLOSSARY AND ABBREVIATIONS

ANS	Scientific Panel on Food Additives and Nutrient Sources added to Food
BIOHAZ	Scientific Panel on Biological Hazards
CEF	Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
RASFF	Rapid alert system for food and feed
SCF	EU Scientific Committee on Food
SCOFCAH	Standing Committee on the Food Chain and Animal Health