Evaluation of data concerning the necessity of isoxaflutole as a herbicide to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority was requested by the European Commission to provide scientific assistance under Article 31 of Regulation (EC) No 178/2002 regarding the evaluation of data concerning the necessity of isoxaflutole as a herbicide to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, in accordance with Article 4(7) of Regulation (EC) No 1107/2009. In this context, EFSA organised a commenting phase with Member States in order to collect and validate the data submitted by the applicant. The current scientific report summarises the outcome of the evaluation of three different uses (maize, sweetcorn and poppy) in 10 Member States. The evaluation demonstrated that for two uses (maize and sweetcorn) insufficient or sufficient chemical alternatives are available, and for one use (poppy) insufficient chemical alternatives to isoxaflutole are available. The evaluation included an assessment of non-chemical methods for the presented uses. A wide range of non-chemical methods are available, however, often these methods do not have the same efficacy as chemical methods or have economic limitations. A combination of both chemical and non-chemical methods seems often possible.

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Summary

Isoxaflutole was included in Annex I to Directive 91/414/EEC on 11 July 2003 by Commission Directive 2003/68/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011 amended by Commission Implementing Regulation (EU) No 2017/841 as regards the extension of the approval period for isoxaflutole to 31 July 2018. The applicant, Bayer Crop Science, applied for renewal of approval for isoxaflutole in line with the provisions of Commission Regulation (EU) No 844/2012.

The European Food Safety Authority (EFSA) finalised the conclusion on the peer review of the pesticide risk assessment of isoxaflutole in February 2016 (EFSA, 2016a). Furthermore, EFSA finalised the peer review in light of negligible exposure data in February 2017 (EFSA, 2017a).

In 2016, during the peer review, EFSA proposed to classify isoxaflutole as carcinogenic category 2 (C2) and considering the harmonised classification as toxic for reproduction category 2 (R2) (EFSA, 2016a). A critical area of concern was identified with regard to the approval criteria of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 interim provisions for active substances that shall be considered to have endocrine disrupting properties.

The applicant Bayer Crop Science requested derogation in accordance with the provisions of Article 4(7) of Regulation (EU) No 1107/2009, submitting evidence regarding the necessity of isoxaflutole to control a serious danger to plant health which cannot be contained by other available means. In January 2016, the European Commission requested EFSA to provide scientific assistance as regards the consideration of evidence that the application of an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods. In order to address this request, EFSA set up a working group (WG) to develop a specific methodology for the assessment of herbicide active substance (a.s.). The protocol on the methodology was published on 2 August 2016 (EFSA, 2016b).

Subsequently, the applicant was requested by the European Commission to re-submit the data following the methodology developed by EFSA. On 15 December 2016, EFSA received the updated dossier provided by the applicant, consisting of a data collection set and a report (Bayer, 2016). The applicant, included claims that the use of isoxaflutole is considered essential in accordance with Article 4(7) of Regulation (EC) No 1107/2009 in relation to the uses authorised in 17 Member States (MS).

As following step, EFSA launched a commenting phase in January–March 2017 asking all MS to confirm that the uses for which the applicant requested Article 4(7) derogation are authorised, and if the use of isoxaflutole is considered essential to control a serious danger to plant health, giving clear justification for each use that is considered as essential. In addition, all MS were invited to submit information related to respective national authorisations for different crops or non-agricultural uses, evidence on resistance risk, and uses that were not covered by the applicant’s submission (e.g. minor uses).

Overall, three different uses (maize, sweetcorn and poppy) in 10 MS (Austria, France, Germany, Greece, Hungary, Italy, the Netherlands, Romania, Slovakia and the United Kingdom) were evaluated to assess the applicant’s claims or information provided by a MS (the United Kingdom) on the necessity of isoxaflutole to control a serious danger to plant health.

It can be concluded that insufficient chemical alternatives to isoxaflutole for weed control in maize are available in seven MS (Austria, Germany, Hungary, Italy, Romania, Slovakia and the United Kingdom); however, in three MS (France, Greece and the Netherlands), there are sufficient chemical alternatives. Insufficient chemical alternatives to isoxaflutole for weed control in sweetcorn are available in three MS (Greece, Italy the United Kingdom), but sufficient chemicals alternatives are available in France. Insufficient chemical alternatives to isoxaflutole for weed control in poppy are available in Hungary.

The difference in the outcome for maize can be explained by how strictly the EFSA protocol was applied by MS during the validation phase, in terms of the use of the BBCH stage (BBCH 00-13) and the weeds spectrum (grass weeds, broadleaf weeds) as a criteria for exclusion from the overall list of more than 20 herbicide a.s. Herbicides can be applied as post-emergence to control weeds that aren’t (fully) controlled by pre-emergence application. Herbicides authorised as post-emergence can be considered as alternatives for weed control. In many MS, there are post-emergence authorised herbicides containing herbicide a.s. such as mesotrione, sulcotrione and tembotrione which have the same mode of action (MoA) as isoxaflutole, and they are alternatives covering the majority of the weed spectrum of isoxaflutole. The weeds that are not controlled by mesotrione, sulcotrione and tembotrione, could be controlled with many other available alternative herbicides/mode of action.
Isoxaflutole could also be substituted with the pre-emergence authorised herbicides. MS, such as the Netherlands, France and Greece, applied a more flexible approach, which led to the conclusion that there are sufficient chemical alternatives to isoxaflutole other MS applied the protocol stricter. One MS pointed out that increased reliance on post-emergence control may increase the risk of resistance development. Additionally, without effective pre-emergence control, weed populations that need to be controlled by any post-emergence applications may be expected to be much higher, thus potentially making post-emergence control more difficult. Further discussions with MS on these issues might be useful.

Non-chemical alternatives were also evaluated for the different uses. In nine MS, up to eight non-chemical methods are available for weed control in maize. The Netherlands did not validate the information regarding non-chemical methods submitted by applicant as there are enough chemical alternatives. In four MS, up to five non-chemical methods are available for weed control in sweetcorn, and in one MS, three non-chemical methods are available for weed control in poppy.

Overall, a wide range of non-chemical methods are available; however, often these methods do not have the same efficacy as chemical methods or have economic limitations. A combination of both chemical and non-chemical methods seems often possible.
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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Isoxaflutole was included in Annex I to Directive 91/414/EEC¹ on 11 July 2003 by Commission Directive 2003/68/EC², and has been deemed to be approved under Regulation (EC) No 1107/2009³, in accordance with Commission Implementing Regulation (EU) No 540/2011⁴, amended by Commission Implementing Regulation (EU) No 2017/841⁵ as regards the extension of the approval period for isoxaflutole to 31 July 2018. Commission Implementing Regulation (EU) No 844/2012⁶ lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012⁷. Isoxaflutole is one of the active substances listed in Regulation (EU) No 686/2012.

In accordance with Article 13 of the Regulation (EU) No 844/2012, EFSA finalised a conclusion on the peer review of the pesticide risk assessment of the active substance isoxaflutole on 16 February 2016 (EFSA, 2016a) and provided its conclusion to the European Commission. Isoxaflutole was evaluated by Italy as rapporteur Member State (RMS). The RMS delivered its initial evaluation of the dossier in the Renewal Assessment Report (RAR) on 28 January 2015 (Italy, 2015). In accordance with Article 13 of the Regulation, EFSA adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 on February 2016 (EFSA, 2016a).

In 2016, during the peer review EFSA proposed to classify isoxaflutole as carcinogenic category 2 (C2)⁸ and considering the harmonised classification of isoxaflutole as toxic for reproduction category 2 (R2), a critical area of concern was identified with regard to the approval criteria of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 interim provisions for active substances that shall be considered to have endocrine disrupting properties.

Under the same mandate, EFSA was also requested by European Commission to carry out an assessment of the information submitted by Bayer Crop Science to demonstrate whether the active substance isoxaflutole can be used such that exposure to humans may be considered negligible under realistic conditions of use (EFSA, 2017a). EFSA peer review based on the risk assessment carried out by the competent authority of the RMS Italy (Italy, 2016).

Following the lack of compliance with the approval criteria set out in Annex II of Regulation (EU) No 1107/2009, the applicant Bayer Crop Science requested a derogation in accordance with the provisions of Article 4(7) of Regulation (EU) No 1107/2009, submitting evidence regarding the necessity of isoxaflutole to control a serious danger to plant health which cannot be contained by other available means. In January 2016, European Commission requested by a general mandate to EFSA to provide scientific assistance as regards the consideration of evidence that the application of an active substance is necessary to control a serious danger to plant health which cannot be contained by

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¹ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
² Commission Directive 2003/68/EC of 11 July 2003 amending Council Directive 91/414/EEC to include trifloxsystrobin, carfentrazone-ethyl, mesotrione, fenamidone and isoxaflutole as active substances, OJ L 177, 16.7.2003, p. 12–16.
³ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.9.2009, p. 1–50.
⁴ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.
⁵ Commission Implementing Regulation (EU) 2017/841 of 17 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, Ampelomyces quisqualis strain: aq 10, benalaxyl, bentazone, bifenzate, bromoxynil, carfentrazone ethyl, chlorpropham, cyazofamid, desmedipham, diquat, DPX KE 459 (fluorsulfuron-methyl), etoxazole, famoxadone, fenamidone, flumioxazine, foramsulfuron, Gliocladium catenulatum strain: j1446, imazamox, imazosulfuron, isoaxafutole, laminarin, metalaxyl-m, methoxyfenozide, milbemectin, oxasulfuron, pendimethalin, phenmedipham, pymetrozine, s-metolachlor and trifloxystrobin. OJ L 125, 18.5.2017, p. 12–15.
⁶ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, p. 26–32.
⁷ Commission Implementing Regulation (EU) No 686/2012 of 26 July 2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018. OJ L 200, 27.7.2012, p. 5–10.
⁸ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

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other available means including non-chemical methods. In order to address this request, EFSA set up a WG to develop a specific methodology for the assessment of herbicide active substances (a.s.). The protocol on the methodology was published on 2 August 2016 (EFSA, 2016b).

After publication of the EFSA protocol (EFSA, 2016a), the applicant was requested by the European Commission to re-submit the data following the methodology developed by EFSA. On 15 December 2016, EFSA received the updated dossier provided by the applicant, consisting of a data collection set and a report (Bayer, 2016). The applicant included claims that the use of isoxaflutole is considered essential in accordance with Article 4(7) of Regulation (EC) No 1107/2009 in the following Member States: Austria, Belgium, Bulgaria, Croatia, the Czech Republic, France, Germany, Greece, Hungary, Italy, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia and Spain.

On 27 January 2017, EFSA launched a 6 weeks commenting phase asking all MS to confirm that the uses for which the applicant requests Article 4(7) derogation are authorised and if the use of isoxaflutole is considered essential to control the serious danger to plant health, giving clear justification for each use that is considered as critical. In addition, all MS were invited to supplement the information provided by the applicant with information from their own MS uses also considering other uses not presented by the applicant (e.g. minor uses). During the commenting phase, Austria, France, Germany, Greece, Hungary, Italy, the Netherlands, Romania and Slovakia validated the information provided by applicant and the United Kingdom submitted new information in relation to the uses in maize and sweetcorn.

As a follow up, EFSA ensured that the methodology was consistently applied by MS and summarised the evaluation of isoxaflutole (see Appendices A and B) in the current scientific report. A final consultation process on the draft scientific report with MS was launched in May 2017.

The legal deadline to finalise the current scientific report is 14 June 2017.

2. Data and methodologies

2.1. Methodologies

The assessment was conducted in line with the methodology for the evaluation of data concerning the necessity of the application of a herbicide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods, published on 2 August 2016 (EFSA, 2016b). The submission provided by the applicant in the form of a collection data set and a report, was also in line with the EFSA methodology (EFSA, 2016b).

The role of EFSA is to act as the co-ordinator of the process, ensuring that the methodology is applied consistently and providing a scientific report on the evaluation of isoxaflutole. EFSA considered the information provided by Member States such as the full list of authorised herbicide active substances, the shortlisted a.s. and the non-chemical methods as reliable and no further research was conducted to validate these data. Thus, MS had the full responsibility for the accuracy and correctness of the data provided to EFSA to perform the assessment.

2.2. Data and information

This report presents the information contained in the applicant report on isoxaflutole (Bayer, 2016), and the additional information and data provided by MS after the commenting phase launched by EFSA in January–March 2017. Table 1 provides an overview of authorised uses of isoxaflutole to control annual broadleaved weeds and grasses in Europe. Plant protection products containing isoxaflutole alone or co-formulated with safeners, or with other herbicide a.s. are to be applied on the crop (e.g. maize) in one single application as pre-emergence to early post-emergence herbicide, except for the United Kingdom and Hungary (for poppy), where it is applied pre-emergence of the crop only. Therefore, the application time, pre-emergence to early post-emergence, will be evaluated as one application time and not separately, except for the United Kingdom, and Hungary (for poppy), where isoxaflutole is applied pre-emergence of the crop only. A total of five formulated products containing isoxaflutole are registered in Europe, and details, except for the United Kingdom, are provided in the applicant’s report (Bayer, 2016).

9 The following isoxaflutole containing products are currently registered for use: isoxaflutole, isoxaflutole and cyprosulfamide (safener) and in co-formulation with thiencarbazone-methyl and cyprosulfamide (safener), aclonifen or flufenacet.
The data collection set validated by MS (i.e. complete list/s of authorised a.s. in the relevant Member States) and evaluated by EFSA is available as an Appendix to this scientific report (Appendix A). An overview of the shortlisting process and a summary of the shortlisted herbicide active substances for each use (crop) and MS are available as an Appendix to this scientific report (Appendix B).

### Table 1: Authorised uses of isoxaflutole in Europe

| Country      | Use/stage of application<sup>(a)</sup>                                      |
|--------------|--------------------------------------------------------------------------------|
| Austria      | Maize/BBCH 00-08 (with a safener) (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence)<sup>(b)</sup> |
| Belgium      | Maize/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence) |
| Bulgaria     | Maize/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence) |
| Croatia      | Maize/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence) |
| Czech Republic| Maize/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence) |
| France       | Maize/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence)<sup>(b)</sup>  
                 | Sweetcorn/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence)  
                 | Poppy/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence) |
| Germany      | Maize/BBCH 00-09 (pre-emergence), BBCH 10-13 (early post-emergence)<sup>(b)</sup>  |
| Greece       | Maize/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence)<sup>(b)</sup>  
                 | Sweetcorn/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence)  |
| Hungary      | Maize/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence)<sup>(b)</sup>  
                 | Poppy/BBCH 00-08 (pre-emergence) |
| Italy        | Maize/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence)<sup>(b)</sup>  
                 | Sweetcorn/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence)  |
| Netherlands  | Maize/BBCH 00-08 (pre-emergence), BBCH 09-13 (early post-emergence) |
| Poland       | Maize/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence) |
| Portugal     | Maize/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence) |
| Romania      | Maize/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence)<sup>(b)</sup>  |
| Slovakia     | Maize/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence)<sup>(b)</sup>  |
| Slovenia     | Maize/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence) |
| Spain        | Maize/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence)  
                 | Poppy/BBCH 00-08 (pre-emergence), BBCH 09-13 (with a safener) (early post-emergence)  |
| United Kingdom| Maize/BBCH 00-08 (pre-emergence)  
                 | Sweetcorn/BBCH 00-08 (pre-emergence) |

<sup>(a)</sup>: The uses proposed in the table correspond to the information provided by the applicant (Bayer, 2016) as validated by nine MS (Austria, France, Germany, Greece, Hungary, Italy, the Netherlands, Romania and Slovakia), except for the information provided by MS for the United Kingdom.

<sup>(b)</sup>: Isoxaflutole containing herbicide a.s. are authorised in Germany for BBCH 00-09 and BBCH 10-13, in Austria, France, Greece, Hungary, Italy, Romania, Slovakia for BBCH 00-08 and BBCH 09-13 with one application in the crop. This means isoxaflutole is used either before or after emergence of maize plants.

In addition, key supporting documents to this scientific report are:

- the applicant submission in the form of a Report (Bayer, 2016) and data collection set;
- the comments received on the Applicant Report (EFSA, 2017b);
- the comments received on the draft scientific report (EFSA, 2017c).

The applicant submitted the information in relation to 17 Member States (Austria, Belgium, Bulgaria, Croatia, the Czech Republic, France, Germany, Greece, Hungary, Italy, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia and Spain). Nine MS (Austria, France, Germany, Greece, Hungary, Italy, the Netherlands, Romania and Slovakia) verified the information and eight MS (Belgium, Bulgaria, Croatia, the Czech Republic, Poland, Portugal, Slovenia and Spain) did not verify the information.

<sup>10</sup> For France and poppy, no information was provided by the applicant in the excel file.
the information submitted by the applicant. Furthermore, the United Kingdom provided information for the use of isoxaflutole in maize and sweetcorn.

3. Evaluation and assessment

3.1. Maize

Table 2 summarises the number of authorised herbicide a.s. and potential chemical alternatives (shortlisted herbicide a.s.) that have the same spectrum of weed control and time of application as isoxaflutole for use in maize in Austria, France, Germany, Greece, Hungary, Italy, the Netherlands, Romania, Slovakia and the United Kingdom.

Table 2: Number of authorised and shortlisted herbicide a.s. to control weeds (annual broadleaved weeds and grasses) in maize in Austria, France, Germany, Greece, Hungary, Italy, the Netherlands, Romania, Slovakia and the United Kingdom

| Use   | Country | Authorised a.s. | Shortlisted a.s. |
|-------|---------|----------------|-----------------|
| Maize | AT      | > 20           | 1               |
| Maize | FR      | > 20           | 8               |
| Maize | DE      | > 20           | 8               |
| Maize | EL      | > 20           | 8               |
| Maize | HU      | > 20           | 0               |
| Maize | IT      | > 20           | 1               |
| Maize | NL      | > 20           | 21              |
| Maize | RO      | > 20           | 0               |
| Maize | SK      | > 20           | 4               |
| Maize | UK      | > 20           | 5               |

a.s.: active substance.

The information provided by the applicant on the necessity of isoxaflutole in maize to control a serious danger to plant health based on remaining chemical alternatives to isoxaflutole resulted in herbicide resistance (HR) strategy score of 1.5\(^{11}\) for Austria. This means that with one shortlisted herbicide a.s. thienccarbazone-methyl (B)\(^ {12}\) and one mode of action (MoA) insufficient chemical alternatives are available in Austria. In Austria, thienccarbazone-methyl is available in co-formulation with isoxaflutole as an authorised plant protection product (PPP) and controls the same weed spectrum (annual broadleaved weeds and grasses) as the substance under consideration (details are provided in Appendix B, Table B.1). Following the approach proposed by EFSA protocol (2016b), according to which, ‘if a registered product consists of two or more a.s. (a mixture\(^ {13}\)), the information should be provided for each a.s. in the mixture separately’ and the assessment is conducted for each a.s. individually. In addition, other thienccarbazone-methyl containing PPPs are registered in Austria, but with a different application time (post-emergence only) compared to the substance under consideration. In addition, Austria proposed not to shortlist PPP containing herbicide a.s. such as flufenacet, S-metolachlor and terbuthylazine. However, these herbicide a.s. were considered by other MS as alternative a.s. to isoxaflutole as criteria ‘weed spectrum’ was applied in a more generic way.

The information provided by the applicant on the necessity of isoxaflutole in maize to control a serious danger to plant health based on remaining chemical alternatives to isoxaflutole, resulted in the following shortlisted herbicide a.s. for France: aclonifen, (F3), dimethenamid-p (K3), flufenacet (K3), mesotrione (F2), pendimethalin (K1), pethoxamid (K3), S-metolachlor (K3) and thienccarbazone-methyl (B). France agreed with the shortlisted a.s. but noted that some a.s. have limitations compared to the substance under consideration (for details, see Appendix B, Table B.2). One of the shortlisted herbicide a.s., mesotrione (F2), has the same MoA as the a.s. under consideration (isoxaflutole (F2)). The protocol (EFSA, 2016b) states, that ‘if one of the shortlisted a.s. has the same MoA [and site of action] as the a.s. under consideration, withdrawal of the a.s. under consideration has no implications for

\(^{11}\) HR scores: lower to equal 6: insufficient chemical alternatives; higher than 8: sufficient chemical alternatives; between 6 and 8: intermediate situation (EFSA, 2016b).

\(^{12}\) The alphabetical coding corresponds to the mode of action group according to the Herbicide Resistance Action Committee (HRAC group) (Table 1, EFSA, 2016b).

\(^{13}\) This means an active substance which is authorised in co-formulation with another a.s. in a plant protection product.
herbicide resistance management. Consequently, justifying derogation based on a reduced number of MoAs no longer holds. This leads to the conclusion that there are sufficient chemical alternatives for maize available in France, and there is no need to calculate a HR score.

In France, aclonifen, flufenacet and thiencarbazone-methyl are herbicide a.s. which are available in co-formulation with other a.s. as an authorised PPP which control the same weed spectrum (annual broadleaved weeds and grasses) as the substance under consideration (details are provided in Appendix B, Table B.2). Following the approach proposed by EFSA protocol (2016b), according to which, 'if a registered product consists of two or more a.s. (a mixture13), the information should be provided for each a.s. in the mixture separately' and the assessment is conducted for each a.s. individually.

The information provided by the applicant on the necessity of isoxaflutole in maize to control a serious danger to plant health based on remaining chemical alternatives to isoxaflutole resulted in HR strategy score of 611 for Germany. This means that in Germany considering the herbicide a.s.: dimethenamid-p (K3), flufenacet (K3), metosulam (B), pethoxamid (K3), rimsulfuron (B), S-metolachlor (K3), terbuthylazine (C1) and thiencarbazone-methyl (B), and three MoA, insufficient chemical alternatives for suitable HR management are available.

Germany pointed out that isoxaflutole alone is not authorised in maize but only authorised in a combination with thiencarbazone-methyl. Germany proposed to use as a reference product the combination product to create the shortlist (details are provided in Appendix B, Table B.3). This is in principle in line with the approach proposed by EFSA protocol (2016b), according to which, 'if a registered product consists of two or more a.s. (a mixture13), the information should be provided for each a.s. in the mixture separately' and the assessment is conducted for each a.s. individually. Germany noted that neither isoxaflutole nor thiencarbazone-methyl are widely used active substances in maize in Germany. Based on the results of crop specific networks of survey farms, 80% of the maize growing area is treated with only 10 herbicidal active substances and both herbicides are not among them (Cramer et al., 2017). So, it will hardly be possible to argue that a herbicide containing isoxaflutole and thiencarbazone-methyl will be necessary for the German maize growing without using other specific criteria.

The information provided by the applicant on the necessity of isoxaflutole in maize to control a serious danger to plant health based on remaining chemical alternatives to isoxaflutole, resulted in the following shortlisted herbicide a.s. for Greece: dimethenamid-p (K3), flurochloridone (F1), mesotrione (F2), pendimethalin (K1), pethoxamid (K3), S-metolachlor (K3), terbuthylazine (C1), and thiencarbazone-methyl (B). One of the shortlisted herbicide a.s., mesotrione (F2), has the same MoA as the a.s. under consideration (isoxaflutole (F2)), details are provided in Appendix B, Table B.4. The protocol (EFSA, 2016b) states, that 'if one of the shortlisted a.s. has the same MoA [and site of action] as the a.s. under consideration, withdrawal of the a.s. under consideration has no implications for herbicide resistance management. Consequently, justifying derogation based on a reduced number of MoAs no longer holds'. This leads to the conclusion that there are sufficient chemical alternatives for maize available in Greece, and there is no need to calculate a HR score. Greece also noted that herbicides with post-emergence application timing could also have been considered as alternatives and shortlisted for isoxaflutole. Greece does not support the applicant’s argumentation that each of the alternative chemical methods does not cover the weed spectrum or effectiveness of isoxaflutole. However, Greece noted that each of the weeds controlled by isoxaflutole is controlled by other a.s.

The information provided by the applicant on the necessity of isoxaflutole in maize to control a serious danger to plant health based on remaining chemical alternatives to isoxaflutole, resulted in HR strategy score of 0,11 1.5 and 0 for Hungary, Italy, and Romania, respectively. This means that in Italy with one herbicide a.s.: thiencarbazone-methyl (B) and one MoA, insufficient chemical alternatives for suitable HR management are available. Hungary and Romania proposed not shortlist thiencarbazone-methyl as it is only registered in mixture with isoxaflutole. Hungary excluded this a.s. as thiencarbazone-methyl is more effective against Echinochloa crus-galli, Setaria species and Polygonum species than isoxaflutole, this means a different weed spectrum. Romania exclude this a.s. since cannot provide a satisfactory level of control on annual and perennial grasses, this means a different weed spectrum. It should be noted that other MS considered thiencarbazone-methyl as an alternative a.s. to isoxaflutole as the criteria “weed spectrum” was applied in a more generic way. In addition, it should be noted that some herbicide a.s. such as mesotrine (same MoA as isoxaflutole), pendimethalin, pethoxamid, S-metolachlor and terbuthylazine are registered for use in Hungary, Italy and Romania but were not considered to be placed on the shortlist (for details see Appendix B, Tables B.5, B.6 and B.8), whereas other, MS such as France, Greece, Germany, proposed to shortlist these a.s., particularly when considering co-formulation with other a.s.
The information provided by the applicant on the necessity of isoxaflutole in maize to control a serious danger to plant health based on remaining chemical alternatives to isoxaflutole, resulted in the following shortlisted herbicide a.s. for the Netherlands: bentazon (C3), bromoxynil (C3), clopyralid (O), dicamba (O), dimethenamid-p (K3), foramsulfuron (B), florasulam (B), fluroxypyr-methyl (O), iodosulfuron-methyl-natrium (B), mesotrione (F2), nicosulfuron (B), pendimethalin (K1), prosulfuron (B), rimsulfuron (B), S-metolachlor (K3), sulcotrione (F2), tembotrione (F2), terbutylazine (C1), thiacarbazozone-methyl (B), thifensulfuron-methyl (B) and tritosulfuron (B) (details are provided in Appendix B, Table B.9). Three of the shortlisted herbicide a.s., mesotrione (F2), sulcotrione (F2) and tembotrione (F2) have the same MoA as the a.s. under consideration (isoxaflutole (F2)). The protocol (EFSA, 2016b) states that ‘if one of the shortlisted a.s. has the same MoA [and site of action] as the a.s. under consideration, withdrawal of the a.s. under consideration has no implications for herbicide resistance management. Consequently, justifying derogation based on a reduced number of MoAs no longer holds’. This leads to the conclusion that there are sufficient chemical alternatives for maize available in the Netherlands, and there is no need to calculate a HR score.

The information provided by the applicant on the necessity of isoxaflutole in maize to control a serious danger to plant health based on remaining chemical alternatives to isoxaflutole resulted in HR strategy score of 6.11 for Slovakia. This means that considering the herbicide a.s.: flufenacet (K3), pethoxamid (K3), terbutylazine (C1) and thiacarbazozone-methyl (B), and three MoA insufficient chemical alternatives for suitable HR management are available in Slovakia. These herbicide a.s. are available in co-formulation with other a.s. as a PPP in Slovakia which control the same weed spectrum (annual broadleaved weeds and grasses) as the substance under consideration (details are provided in Appendix B, Table B.9). Following the approach proposed by EFSA protocol (2016b), according to which, ‘if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately’ and the assessment is conducted for each a.s. individually.

The information provided by the United Kingdom on the necessity of isoxaflutole in maize to control a serious danger to plant health based on remaining chemical alternatives to isoxaflutole resulted in HR strategy score of 6.11. This means that in the United Kingdom considering the herbicide a.s.: dimethenamid-p (K3), flufenacet (K3), pendimethalin (K1), pethoxamid (K3), and S-metolachlor (K3), and two MoA, insufficient chemical alternatives for suitable HR management are available (details are provided in Appendix B, Table B.10).

In nine MS, up to eight non-chemical methods are available for weed control in maize. The Netherlands did not validate the information regarding non-chemical methods submitted by applicant as there are enough chemical alternatives.

In Austria, five preventive methods such as primary tillage, crop rotation and mulching are practised (primary tillage and crop rotation: more than 50% acreage of crop; mulching up to 10% of the acreage of crop), available, but only moderate effective (e.g. primary tillage, crop rotation, mulching) or not feasible (e.g. false seedbed). One curative method, mechanical weeding, is practised (up to 10% acreage of the crop) but only moderate effective and is only feasible with restrictions. Other curative methods such hand-weeding or thermal weed control are highly effective, or moderate effective, respectively, but are not practised, and not available due to, e.g. economic limitations (hand-weeding).

In France, four preventive methods primary tillage, false seedbed, weed seed removal during harvest and crop rotation are practised (primary tillage and weed seed removal during harvest: more than 50% acreage of crop; crop rotation between 10% and 50% of the acreage of the crop, and mulching up to 10% of the acreage of crop), available, but are limited or moderate effective (e.g. false seedbed depends on climatic condition, crop rotation and mulching), except primary tillage which is highly effective. However, primary tillage (e.g. ploughing) has economic and other implications (e.g. soil dust production, erosion of soil, effect on earth worm). One curative method, mechanical weeding, is practised (up to 10% acreage of the crop) but only moderate effective and is only feasible with restrictions. Other curative methods such hand-weeding or thermal weed control are highly effective, but are not practised or only in very limited areas (e.g. organic farming) and has economic limitations, and thermal weed control is moderate effective but not practised in large areas.

In Germany, three preventive methods primary tillage, cover crop/mulching and crop rotation are practised (primary tillage and crop rotation more than 50% acreage of crop; crop cover/mulching between 10% and 50% of the acreage of the crop), and available, but are moderate effective, except for crop rotation which is highly effective. One curative method, mechanical weeding, is practised (up to 10% acreage of the crop) but only moderate effective and is only feasible with restrictions.
In Greece, five preventive methods late sowing dates, increased crop competitiveness, weed seed removal during harvest, crop cover/mulching and crop rotation are practised (crop rotation: more than 50% acreage of crop; the other methods only up to 10% of the acreage of crop), available, but only moderate effective, and are only feasible with restrictions. Two curative methods, mechanical weeding and hand weeding are practised (mechanical weeding: more than 50% acreage of crop, and hand weeding up to 10% acreage of the crop), available, but only moderate effective and mechanical weeding is only feasible with restrictions, whereas hand-weeding is not feasible.

In Hungary, two preventive methods primary tillage and crop rotation are practised (between 10% and 50% of the acreage of the crop) and feasible, but only moderate effective. Other preventive methods such as false seedbed, late sowing dates, increase crop competitiveness and crop cover/mulching are available, but only moderate effective (false seedbed, increase crop competitiveness, and crop rotation), but not practised in Hungary. One curative method, mechanical weeding, is practised (between 10% and 50% acreage of the crop) and highly effective and feasible. Hand-weeding is moderate effective, but not practised and only feasible with limitations. Thermal weed control is not practised, not available and is only moderate effective.

In Italy, five preventive methods primary tillage, false seedbed, increase crop competitiveness, cover crop/mulching and crop rotation are practised (primary tillage: more than 50% acreage of crop; false seedbed and crop rotation between 10% and 50% of the acreage of crop and increase crop competitiveness and crop/mulching up to 10% acreage of the crop), available, but only moderate effective and only limited feasible due to economic reasons (e.g. late sowing, cover crop, crop rotation), except for primary tillage and false seedbed. One curative method, mechanical weeding, is practised (between 10% and 50% acreage of the crop) but only moderate effective. Other curative methods, such thermal weed control are available, but moderate effective and not practised.

In Romania, two preventive methods primary tillage and crop rotation are practised (more than 50% acreage of crop) and available, but are moderate effective. One curative method, mechanical weeding, is practised (between 10% and 50% acreage of the crop) but only moderate effective and it is only feasible with restrictions.

In Slovakia, seven preventive methods primary tillage, false seedbed, late sowing, increase crop competitiveness, weed seed removal during harvest, cover crop/mulching and crop rotation are practised (primary tillage and crop rotation between 10% and 50% of the acreage of crop, the other methods up to 10% acreage of the crop), available, but only moderate effective and only limited feasible. One curative method, mechanical weeding, is practised (between 10% and 50% acreage of the crop) and highly effective.

In the United Kingdom, three preventive methods primary tillage, cover crop/mulching and crop rotation are practised (primary tillage and cover crop/mulching between 10% and 50% of the acreage of crop, crop rotation up to 10% acreage of the crop as forage maize in the United Kingdom is often grown in monoculture, thus restricting the use of rotation as weed management tool) and available, highly effective (except for primary tillage) and feasible (except primary tillage). One curative method, mechanical weeding, is practised (up to 10% acreage of the crop) but only moderate effective and is only feasible with restrictions.

For further details on the evaluation, see Appendices A and B.

### 3.2. Sweetcorn

Table 3 summarises the number of authorised herbicide a.s. and potential chemical alternatives (shortlisted herbicide a.s.) that have the same spectrum of weed control and time of application as isoxaflutole for use in sweetcorn in France, Greece, Italy and the United Kingdom.

| Use   | Country | Authorised a.s. | Shortlisted a.s. |
|-------|---------|----------------|-----------------|
| Sweetcorn FR | 10 | 4 |
| Sweetcorn EL | 3 | 0 |
| Sweetcorn IT | 5 | 0 |
| Sweetcorn UK | 10 | 2 |

a.s.: active substance.
The information provided by the applicant on the necessity of isoxaflutole in sweetcorn to control a serious danger to plant health based on remaining chemical alternatives to isoxaflutole resulted in the following shortlisted herbicide a.s. for France: aclonifen, (F3)\textsuperscript{12}, dimethenamid-p (K3), mesotrione (F2) and S-metolachlor (K3). France agreed with the shortlisted a.s. but noted that some a.s. have limitations compared to the substance under consideration (for details see Appendix B, Table B.11). One of the shortlisted herbicide a.s., mesotrione (F2), has the MoA as the a.s. under consideration (isoxaflutole (F2)). The protocol (EFSA, 2016b) states, that `if one of the shortlisted a.s. has the same MoA [and site of action] as the a.s. under consideration, withdrawal of the a.s. under consideration has no implications for herbicide resistance management. Consequently, justifying derogation based on a reduced number of MoAs no longer holds`; this leads to the conclusion that there are sufficient chemical alternatives for sweetcorn available in France, and there is no need to calculate a HR score.

In France, aclonifen is a herbicide a.s. which is available in co-formulation with other a.s. as an authorised PPP and it controls the same weed spectrum (annual broadleaved weeds and grasses) as the substance under consideration (details are provided in Appendix B, Table B.11). Following the approach proposed by EFSA protocol (2016b), according to which, `if a registered product consists of two or more a.s. (a mixture\textsuperscript{13}), the information should be provided for each a.s. in the mixture separately` and the assessment is conducted for each a.s. individually.

The information provided by the applicant on the necessity of isoxaflutole in sweetcorn to control a serious danger to plant health based on remaining chemical alternatives to isoxaflutole resulted in HR strategy score of 0 and 0\textsuperscript{11} for Greece and Italy, respectively. This means that in Greece and Italy there are no other alternative chemical substances available (details are provided in Appendix B, Table B.12).

The information provided by the United Kingdom on the necessity of isoxaflutole in sweetcorn to control a serious danger to plant health based on remaining chemical alternatives to isoxaflutole resulted in HR strategy score of 6\textsuperscript{11}. This means that in the United Kingdom considering the herbicide a.s.: flufenacet (K3) and pendimethalin (K1), and two MoA, insufficient chemical alternatives for suitable HR management are available (details are provided in Appendix B, Table B.13).

In four MS (France, Greece, Italy and the United Kingdom), up to five non-chemical methods are available for weed control in sweetcorn.

In France, four preventive methods such as primary tillage, false seedbed, weed seed removal during harvest, and crop rotation are practised (primary tillage and weed seed removal during harvest: more than 50% acreage of crop; crop rotation between 10% and 50% of the acreage of the crop, and mulching up to 10% of the acreage of crop), available, but are limited or moderate effective (e.g. false seedbed depends on climatic condition, and crop rotation, mulching), except primary tillage, e.g. ploughing which is highly effective. However, ploughing has economic and other implications (e.g. soil dust production, erosion of soil, effect on earth worm). One curative method, mechanical weeding, is practised (up to 10% acreage of the crop) but only moderate effective and is only feasible with restrictions. Hand-weeding is highly effective, but is not practised or only in very limited areas (e.g. organic farming) and has economic limitations and thermal weed control is moderate effective but not practised in large areas.

In Greece, five preventive methods such as late sowing dates, increased crop competitiveness, weed seed removal during harvest; crop cover/mulching and crop rotation are practised (crop rotation: more than 50% acreage of crop; the other methods only up to 10% of the acreage of crop), available, but only moderate effective, and are only feasible with restrictions. Two curative methods, mechanical weeding and hand weeding, are practised (mechanical weeding: more than 50% acreage of crop, and hand weeding up to 10% acreage of the crop), available but only moderate effective and mechanical weeding is only feasible with restrictions, whereas hand-weeding is not feasible.

In Italy, five preventive methods primary tillage, false seedbed, increase crop competitiveness, cover false seedbed and crop/mulching and crop rotation are practised (primary tillage: more than 50% acreage of crop; false seedbed and crop rotation between 10% and 50% of the acreage of crop and increase crop competitiveness and crop/mulching up to 10% acreage of the crop), available, but only moderate effective and only limited feasible due to economic reasons (e.g. cover crop, crop rotation), except for primary tillage and false seedbed. Late sowing is not considered as an alternative, as this method it is only moderate effective and feasible with restriction. Furthermore, it would imply the adoption of less productive short-cycle varieties. One curative method, mechanical weeding, is practised (between 10% and 50% acreage of the crop) but only moderate effective. Thermal weed control might be effective to control several broadleaved weeds in early stages, available, but
moderate effective, feasible with restriction as it requires at least two treatments and it is in general much more expensive than any chemical weed control, thus not practised.

In the United Kingdom, three preventive methods primary tillage, cover crop/mulching and crop rotation are practised (primary tillage and cover crop/mulching between 10% and 50% of the acreage of crop). Crop rotation is practised more widely in sweetcorn than in forage maize with sweetcorn grown once every 3–4 years. One curative method, mechanical weeding, is practised (up to 10% acreage of the crop). However, a combination of all these non-chemical approaches might be expected to provide only 50–60% weed control and are only moderately effective.

For further details on the evaluation, see Appendicies A and B.

3.3. Poppy

Table 4 summarises the number of authorised herbicide a.s. and potential chemical alternatives (shortlisted herbicide a.s.) that have the same spectrum of weed control and time of application as isoxaflutole for use in poppy in Hungary.

Table 4: Number of authorised and shortlisted herbicide a.s. to control weeds (annual broadleaved weeds and grasses) in poppy in Hungary

| Use     | Country | Authorised a.s. | Shortlisted a.s. |
|---------|---------|----------------|-----------------|
| Poppy   | HU      | 5              | 0               |

a.s.: active substance.

The information provided by the applicant on the necessity of isoxaflutole in poppy to control a serious danger to plant health based on remaining chemical alternatives to isoxaflutole, resulted in HR strategy score of 011 for Hungary. This means that in Hungary there are no other alternative chemical substances available (details are provided in Appendix B, Table B.14).

In Hungry, three non-chemical methods are available for weed control in poppy. Two preventive methods, primary tillage and crop rotation are practised (between 10% and 50% of the acreage of the crop) and feasible, but only moderate effective. Other preventive methods such as false seedbed, late sowing dates, increase crop competitiveness and crop cover/mulching are available, but only moderate effective (false seedbed, increase crop competitiveness and crop rotation), but not practised in Hungary. One curative method, mechanical weeding, is practised (between 10% and 50% acreage of the crop), highly effective and feasible. Hand-weeding is moderate effective but not practised and only feasible with limitations. Thermal weed control is not practised, not available and it is only moderate effective.

For further details on the evaluation, see Appendicies A and B.

4. Conclusions

The evaluation of applicant’s claims that the use of isoxaflutole is considered essential in accordance with Article 4(7) of Regulation (EC) No 1107/2009 for each authorised use in the considered MS was evaluated following the EFSA methodology (EFSA, 2016b).

Overall, three different uses (maize, sweetcorn and poppy) in 10 MS (Austria, France, Germany, Greece, Hungary, Italy, the Netherlands, Romania, Slovakia and the United Kingdom) were evaluated to assess the applicant’s claims or information provided by a MS (the United Kingdom) on the necessity of isoxaflutole to control a serious danger to plant health.

Table 5 provides an overview of the outcome of chemical alternative substances to isoxaflutole. It can be concluded that insufficient chemical alternatives to isoxaflutole for weed control in maize are available in seven MS (Austria, Germany, Hungary, Italy, Romania, Slovakia and the United Kingdom) however for three MS (France, Greece and the Netherlands), there are sufficient chemical alternatives. Insufficient chemical alternatives to isoxaflutole for weed control in sweetcorn are available in three MS (Greece, Italy and the United Kingdom), but sufficient chemicals alternatives are available in France. Insufficient chemical alternatives to isoxaflutole for weed control in poppy are available in Hungary.

The difference in the outcome for maize can be explained by how strictly the EFSA protocol was applied by MS during the validation phase, in terms of the use of the BBCH stage (BBCH 00-13) and the weeds spectrum (grass weeds, broadleaf weeds) as a criteria for exclusion from the overall list of more than 20 herbicide a.s. Herbicides can be applied as post-emergence to control weeds that aren’t (fully) controlled by pre-emergence application. Herbicides authorised as post-emergence can be considered as alternatives for weed control. In many MS, there are post-emergence authorised
herbicides containing a.s. such as mesotrione, sulcotrione and tembotrione which have the same MoA as isoxaflutole, and are alternatives covering the majority of the weed spectrum of isoxaflutole. The weeds that are not controlled by mesotrione, sulcotrione and tembotrione, could be controlled with many other available alternative herbicides/mode of actions. Isoxaflutole could also be substituted with the pre-emergence authorised herbicides. MS such as the Netherlands, France and Greece applied a more flexible approach, which led to the conclusion that there are sufficient chemical alternatives to isoxaflutole other MS applied the protocol stricter. One MS pointed out, that increased reliance on post-emergence control may increase the risk of resistance development. Additionally, without effective pre-emergence control, weed populations that need to be controlled by any post-emergence applications may be expected to be much higher, thus potentially making post-emergence control more difficult. Further discussions with MS on these issues might be useful.

Non-chemical alternatives were also evaluated for the different uses. In nine MS, up to 8 non-chemical methods are available for weed control in maize. The Netherlands did not validate the information regarding non-chemical methods submitted by applicant as there are enough chemical alternatives. In four MS, up to five non-chemical methods are available for weed control in sweetcorn and three non-chemical methods are available for weed control in poppy in one MS.

Overall, a wide range of non-chemical methods are available, however, often these methods do not have the same efficacy as chemical methods or have economic limitations. A combination of both chemical and non-chemical methods seems often possible.

Table 5: Outcome of the evaluation of applicant’s claims on the necessity of isoxaflutole to control a serious danger to plant health according to Article 4(7) of Regulation (EC) No 1107/2009 for three different uses (crop) in ten Member States

| Crop     | Country | Authorised a.s. | Shortlisted a.s. | Score | Results |
|----------|---------|-----------------|------------------|-------|---------|
| Maize    | AT      | > 20            | 1                | 1.5   | Insufficient |
| Maize    | FR      | > 20            | 8                | n.a.  | Sufficient  |
| Maize    | DE      | > 20            | 8                | 6     | Insufficient |
| Maize    | EL      | > 20            | 8                | n.a.  | Sufficient  |
| Maize    | HU      | > 20            | 0                | 0     | Insufficient |
| Maize    | IT      | > 20            | 1                | 1.5   | Insufficient |
| Maize    | NL      | > 20            | 21               | n.a.  | Sufficient  |
| Maize    | RO      | > 20            | 0                | 0     | Insufficient |
| Maize    | SK      | > 20            | 4                | 6     | Insufficient |
| Maize    | UK      | > 20            | 5                | 6     | Insufficient |
| Sweetcorn| FR      | 10              | 4                | n.a.  | Sufficient  |
| Sweetcorn| EL      | 3               | 0                | 0     | Insufficient |
| Sweetcorn| IT      | 3               | 0                | 0     | Insufficient |
| Sweetcorn| UK      | 10              | 2                | 6     | Insufficient |
| Poppy    | HU      | 5               | 0                | 0     | Insufficient |

a.s.: active substance.
n.a. = not applicable. There is no need to calculate HR scores as one of the shortlisted herbicide a.s. has the same MoA as the a.s. under consideration.

5. Recommendation

A critical step in the evaluation is the development of the shortlisted herbicide active substances based on the selection criteria ‘spectrum of weed control’ and ‘time of application’. A drop-down list for these two selection criteria should be provided in the data collection form to facilitate a consistent assessment.

If the EFSA protocol is strictly applied by MS, this means to use the BBCH stage (BBCH 00-13) and the weeds spectrum (grass weeds, broadleaf weeds) as a criteria for exclusion, none or few herbicide a.s. can be shortlisted. However, it would be useful to analyse a subset of data, e.g. herbicides that can be applied as post-emergence to control weeds that aren’t fully controlled by pre-emergence application and post-emergence herbicides could be considered as alternatives for weed control. Such an evaluation would reflect better the situation (including non-chemical methods). Further discussions with MS on this subject might be useful.
Evaluation of data on isoxaflutole to control a serious danger to plant health

References

Austria, 2017. Validated excel on isoxaflutole prepared by the Member State Austria in the framework of a derogation to Art. 4(7) of Regulation (EC) No 1107/2009, January–March 2017. Available online: www.efsa.europa.eu

Bayer, 2016. Report on isoxaflutole submitted in the context of Article 4(7) of Regulation (EC) No 1107/2009. December 2016. Documentation made available to EFSA by the European Commission.

Cramer F, Kahlenbeck H and Zwerger P, 2017. Perspektiven für den Pflanzenschutz in Mais. Mais 44, 8–11.

EFSA (European Food Safety Authority), 2016a. Conclusion on the peer review of the pesticide risk assessment of the active substance Isoxaflutole. EFSA Journal 2016;14(3):4416, 115 pp. https://doi.org/10.2903/j.efsa.2016.4416

EFSA (European Food Safety Authority), 2016b. Protocol for the evaluation of data concerning the necessity of the application of herbicide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods. EFSA supporting publication 2016:13(8): EN-1060, 18 pp. https://doi.org/10.2903/sp.efsa.2016.en-1060

EFSA (European Food Safety Authority), Brancato A, Brocca D, Chiusolo A, Court Marques D, Crivellente F, De Lentdecker C, De Maglie M, Egsmove M, Erdos Z, Fait G, Ferreira L, Goumenou M, Greco L, Istance F, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Magrans JO, Medina P, Miron I, Nougadere A, Padovani L, Parra Morte JM, Pedersen R, Reich H, Sacchi A, Santos M, Serafimova R, Stanczak A, Sturma J, Tarazona J, Terron A, Vagenende B, Verani A and Villamar-Bouza L, 2017a. Conclusion on the peer review of the pesticide risk assessment for the active substance isoxaflutole in light of negligible exposure data submitted. EFSA Journal 2017;15(2):4731, 12 pp. https://doi.org/10.2903/j.efsa.2017.4731

EFSA (European Food Safety Authority), 2017b. Compilation of comments received on the Applicant Report from Pesticide Member State Competent Authorities during the evaluation of data concerning the necessity of isoxaflutole to control a serious danger to plant health. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2017c. Compilation of comments received on the draft scientific report from Pesticide Member State Competent Authorities during the evaluation of data concerning the necessity of isoxaflutole to control a serious danger to plant health. Available online: www.efsa.europa.eu

France, 2017. Validated excel on isoxaflutole prepared by the Member State Netherlands in the framework of a derogation to Art. 4(7) of Regulation (EC) No 1107/2009, January–March 2017. Available online: www.efsa.europa.eu

Germany, 2017. Validated excel on isoxaflutole prepared by the Member State Netherlands in the framework of a derogation to Art. 4(7) of Regulation (EC) No 1107/2009, January–March 2017. Available online: www.efsa.europa.eu

Greece, 2017. Validated excel on isoxaflutole prepared by the Member State Netherlands in the framework of a derogation to Art. 4(7) of Regulation (EC) No 1107/2009, January–March 2017. Available online: www.efsa.europa.eu

Hungary, 2017. Validated excel on isoxaflutole prepared by the Member State Netherlands in the framework of a derogation to Art. 4(7) of Regulation (EC) No 1107/2009, January–March 2017. Available online: www.efsa.europa.eu

Italy, 2015. Renewal assessment report (RAR) on the active substance isoxaflutole prepared by the rapporteur Member State, Italy, in the framework of Commission Implementing Regulation (EU) No 844/2012, revised in January 2016. Available online: www.efsa.europa.eu

Italy, 2016. Addenda to Volume 3 of the Renewal Assessment Report (RAR) (dietary and non-dietary) on the active substance isoxaflutole prepared by the rapporteur Member State Italy according to the Draft Technical Guidance Document on assessment of negligible exposure of an active substance in a plant protection product under realistic conditions of use (points 3.6.3 to 3.6.5, and 3.8.2 of Annex II of Regulation (EC) No 1107/2009; SANCO-2014-12096), November 2016. Available online: www.efsa.europa.eu

Italy, 2017. Validated excel on isoxaflutole prepared by the Member State Netherlands in the framework of a derogation to Art. 4(7) of Regulation (EC) No 1107/2009, January–March 2017. Available online: www.efsa.europa.eu

Netherlands, 2017. Validated excel on isoxaflutole prepared by the Member State Netherlands in the framework of a derogation to Art. 4(7) of Regulation (EC) No 1107/2009, January–March 2017. Available online: www.efsa.europa.eu

Romania, 2017. Validated excel on isoxaflutole prepared by the Member State Netherlands in the framework of a derogation to Art. 4(7) of Regulation (EC) No 1107/2009, January–March 2017. Available online: www.efsa.europa.eu

Slovakia, 2017. Validated excel on isoxaflutole prepared by the Member State Slovakia in the framework of a derogation to Art. 4(7) of Regulation (EC) No 1107/2009, January–March 2017. Available online: www.efsa.europa.eu

United Kingdom, 2017. Validated excel on isoxaflutole prepared by the Member State Netherlands in the framework of a derogation to Art. 4(7) of Regulation (EC) No 1107/2009, January–March 2017. Available online: www.efsa.europa.eu
Abbreviations

a.s. active substance
BBCH growth stages of mono- and dicotyledonous plants
DAR Draft Assessment Report
HR Herbicide Resistance
HRAC Herbicide Resistance Action Committee
IPM Integrated Pest Management
MoA Mode of Actions
MS Member State
PPP plant protection product
RAR Renewal Assessment Report
RMS Rapporteur Member State
WG Working Group
Appendix A – Data collection set

Validated Excel files submitted by MS (Austria, 2017; France, 2017; Germany, 2017; Greece, 2017; Hungary, 2017; Italy, 2017; Netherlands, 2017; Romania, 2017; Slovakia, 2017 and United Kingdom, 2017) and evaluated by EFSA can be found in the online version of this output (‘Supporting Information’ section): https://10.2903/j.efsa.2017.4894.
### Appendix B – Shortlisted herbicide active substances

Overview of the shortlisting process and final shortlisted herbicide active substances in relation to each use (crop) and Member State.

**Table B.1:** Shortlisted herbicide active substances with information on MoA according to HRAC, herbicide application time and targeted weed spectrum having similar characteristics to isoxaflutole and authorised in plant protection products for *maize* in *Austria*

| Herbicide authorised<sup>a</sup> | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|---------------------------------|------------|-------------------------|---------------|------------------------------------------------------------------|
| Aclonifen                       | F3         | BBCH 00-09              | Annual broadleaved weeds and very limited on grasses | AT: Early post-emergence of maize not covered<br>EFSA: Different application time (pre-emergence (EM)) compared to the substance under consideration (pre- and post-EM). A.s. is proposed not to be shortlisted |
| Dimethenamid-p                  | K3         | BBCH 00-16              | Annual broadleaved weeds and grasses | AT: (a) Only registered in annual dicotyledonous weeds + *Sorghum* species (solo formulation); dimethenamid is a grass control a.s., key broadleaf weeds are not sufficiently covered; (b) a mixture (dimethenamid + pendimethalin is registered in annual mono- and dicotyledonous weeds, but only pre-EM). A.s. is proposed not to be shortlisted<br>EFSA: Different application time (pre-EM) compared to the substance under consideration (pre- and post-EM) |
| Flufenacet<sup>b</sup>          | K3         | BBCH 00-16              | Annual broadleaved weeds and grasses | AT: Only registered in mixtures with terbuthylazine against annual dicotyledonous weeds and ECHCG, SETSS, DIGSS, PANSS; Flufenacet is a grass control a.s., key broadleaf weeds are not sufficiently controlled<br>EFSA: According to EFSA protocol (2016), ‘if a product consist of two or more a.s.,… the assessment is conducted for each a.s.’ EFSA proposes to shortlist this a.s.<br>AT: Results of the individual assessment indicate that flufenacet is mainly grass control a.s. and target broadleaf weeds are not sufficiently controlled. Thus this a.s. should not be shortlisted<br>EFSA remains with its earlier position related to the shortlist in line with the EFSA protocol (2016) which defines the target spectrum in a more generic way (e.g. grasses, broadleaved weeds). However, EFSA accepts the proposal from AT to remove these substances from the shortlist as MS have the possibility to provide a ‘justified’ shortlist |
| Glyphosate                      | G          | Pre-sowing              | Annual broadleaved weeds and grasses | AT: Different application time (pre-sowing). Thus, this a.s. is proposed not to be shortlisted |
| Pendimethalin                   | K1         | BBCH 00-13              | Annual broadleaved weeds and very limited on grasses | AT: (a) Only registered in annual dicotyledonous weeds + ECHCG, *Poa annua* (solo formulation); there is no registration for further grass weeds; (b) a mixture (dimethenamid + pendimethalin is registered in annual mono- and dicotyledonous weeds, but only pre-EM). A.s. is proposed not to be shortlisted |
| Pethoxamid                      | K3         | BBCH 00-16              | Annual broadleaved weeds and grasses | AT: (a) Solo formulation is registered in annual mono- and dicotyledonous weeds; according to the data presented by the applicant, key broadleaf weeds are not as effectively controlled as with isoxaflutole; A.s. is proposed not to be shortlisted |
| Herbicide authorised(a) | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|-------------------------|------------|-------------------------|---------------|----------------------------------------------------------------------------------|
| S-Metolachlor           | K3         | BBCH 00-18              | Annual and perennial grasses | AT: (a) Only registered in Sorghum species (solo formulation); (b) a mixture (S-metolachlor + terbuthylazine) is registered in annual dicotyledonous weeds, Sorghum species and Poa annua in pre-and post-emergence application; S-metolachlor is a grass control a.s., only limited broadleaf weeds are covered  
EFSA: According to EFSA protocol (2016), ‘if a product consist of two or more a.s.,... the assessment is conducted for each a.s.’ EFSA proposes to shortlist S-metolachlor and terbuthylazine  
AT: Results of the individual assessment indicate that S-metolachlor is mainly grass control a.s. and target broadleaf weeds are not sufficiently controlled. Thus, this a.s. should not be shortlisted |
| Terbuthylazine(b)       | C1         | BBCH 00-18              | Annual broadleaved weeds and grasses | AT: (a) Only registered in mixtures with other a.s.; a mixture (flufenacet + terbuthylazine) is registered in annual dicotyledonous weeds and ECHCG, SETSS, DIGSS, PANSS from BBCH 00-16; terbuthylazine does not sufficiently control Sorghum species; therefore, it cannot be shortlisted; (b) another mixture (S-metolachlor + terbuthylazine) is registered in annual dicotyledonous weeds and ECHCG, SETSS, DIGSS, PANSS and Poa annua (pre-and post-emergence); terbuthylazine does not sufficiently control Sorghum species  
EFSA: According to EFSA protocol (2016), ‘if a product consist of two or more a.s., the assessment is conducted for each a.s.’ EFSA proposes to S-metolachlor and terbuthylazine  
AT: Results of the individual assessment indicate that terbuthylazine does not sufficiently control Sorghum species. Thus, this a.s. should not be shortlisted  
EFSA remains with its earlier position related to the shortlist in line with the EFSA protocol (2016) which defines the target spectrum in a more generic way (e.g. grasses, broadleaved weeds). However, EFSA accepts the proposal from AT to remove these substances from the shortlist as MS have the possibility to provide a ‘justified’ shortlist |
| Thiencarbazone-methyl(b) | B          | BBCH 00-18              | Annual broadleaved weeds and grasses | AT: 1 product in mixture with isoxaflutole-is currently registered for pre- or post-emergence of maize. AT proposes excluding thiencarbazone from the shortlist, because the risk of resistance to HRAC B is considered high on global and national level (more details in the excel file)  
EFSA: The HRAC group (= resistance risk) is taken into account in the calculation of the HR score. The a.s. is already classified as ‘high’ risk. Therefore, this a.s. is proposed to be shortlisted in line with the approach proposed in the EFSA protocol (2016) ‘if a product consists of two or more a.s., the assessment is conducted for each a.s.’  
AT: In addition, 3 other thiencarbazone containing product is registered in mixture with other a.s. (e.g. tembotrione, iodosulfuron, foramsulfuron), but only post-emergence is covered  
EFSA: Different application time (post-EM only) compared to the substance under consideration (pre- and post-EM). Thus, tembotrione, iodosulfuron, foramsulfuron)- are proposed not to be shortlisted |
### Table B.2: Shortlisted herbicide active substances with information on MoA according to HRAC, herbicide application time and targeted weed spectrum having similar characteristics to isoxaflutole and authorised in plant protection products for maize in France

| Herbicide authorised<sup>(a)</sup> | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|----------------------------------|------------|-------------------------|---------------|---------------------------------------------------------------------------------|
| Isoxaflutole<sup>(c)</sup>       | F2         | BBCH 00-08, BBCH 09-13  | Annual broadleaved weeds and grasses |                                                                                |
| **1** Aclonifen<sup>(b)</sup>    | F3         | BBCH 00-09               | Annual broadleaved weeds and very limited on grasses | FR: May be aggressive for maize in some soils and climate conditions. A partial solution but not the solution. This a.s. is proposed to be shortlisted, as it controls a good part of the weed spectrum, but has some limitation compared to the substance under consideration |
| **2** Dimethenamid-p             | K3         | BBCH 00-16               | Annual broadleaved weeds and grasses | FR: Not the same spectrum of weed and limitation due to leaching for substance active in sandy or loamy soils. However, this a.s. is proposed to be shortlisted although is a medium solution |
| **3** Flufenacet<sup>(b)</sup>   | K3         | BBCH 00-15               | Annual broadleaved weeds and grasses | FR: Not the same spectrum of weed and limitation due to leaching for substance active in sandy or loamy soils. However, this a.s. is proposed to be shortlisted although is a medium solution |
| Glyphosate                       | G          | Pre-sowing-BBCH 00       | Annual broadleaved weeds and grasses | FR: Not possible practical use in France without tolerant maize (GM maize), or intercrop use only. Thus, a.s. is proposed not to be shortlisted, although is a medium solution |
| **4** Mesotrione                 | F2         | BBCH 00-13/14, BBCH 13-19| Annual broadleaved weeds and grasses | FR: Nearly same spectrum but mainly post sowing use. This a.s. is proposed to be shortlisted, although is a medium solution |
| **5** Pendimethalin              | K1         | BBCH 00-16               | Annual broadleaved weeds and very limited on grasses | FR: May be aggressive for maize in some soils and climate conditions. A partial solution but not the solution. This a.s. is proposed to be shortlisted as it controls a good part of the weed spectrum, but has some limitation compared to the substance under consideration |
| **6** Pethoxamid                 | K3         | BBCH 00-16               | Annual broadleaved weeds and grasses | FR: Not the same spectrum of weed and limitation due to leaching for substance active in sandy or loamy soils. However, this a.s. is proposed to be shortlisted, although is a medium solution |
| **7** S-Metolachlor              | K3         | BBCH 00-13               | Annual and perennial grasses | FR: Not the same spectrum of weed and limitation due to leaching for substance active in sandy or loamy soils. However, this a.s. is proposed to be shortlisted, although is a medium solution |
| **8** Thiencarbazone-methyl<sup>(b)</sup> | B          | BBCH 00-13               | Annual broadleaved weeds and grasses | FR: In the shortlist but with large number of weeds uncontrolled rapidly, is a solution but for a short time due to reason of practicality, resistance or efficacy. EFSA: This a.s. is proposed to be shortlisted as the HRAC group (= resistance risk) is taken into account in the calculation of the HR scores. The a.s. is already classified as ‘high’ risk |

**HRAC**: Herbicide Resistance Action Committee; **BBCH**: growth stages of mono- and dicotyledonous plants.

(a): The bold indicates the active substance (a.s.) shortlisted.

(b): a.s. is only authorised in co-formulation with other a.s.

(c): In AT, isoxaflutole is registered as isoxaflutole and cyprosulfamide (safener).
Herbicide authorised\(^{(a)}\) | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist
--- | --- | --- | --- | ---
Isoxaflutole\(^{(c)}\) | F2 | BBCH 00-08, BBCH 09-13 | Annual broadleaved weeds and grasses | 

HRAC: Herbicide Resistance Action Committee; BBCH: growth stages of mono- and dicotyledonous plants.

\(^{(a)}\): The bold indicates the active substance (a.s.) shortlisted.

\(^{(b)}\): a.s. is only authorised in co-formulation with other a.s.

\(^{(c)}\): In FR, isoxaflutole is registered as isoxaflutole, isoxaflutole and cyprosulfamide (safener), as well as in co-formulated with thiencarbazone-methyl and cyprosulfamide (safener) and aclonifen.

**Table B.3:** Shortlisted herbicide active substances with information on MoA according to HRAC, herbicide application time and targeted weed spectrum having similar characteristics to isoxaflutole and authorised in plant protection products for **maize in Germany**

| Herbicide authorised\(^{(a)}\) | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|---|---|---|---|---|
| 1 Dimethenamid-p | K3 | BBCH 00-09 | Annual broadleaved weeds and grasses | DE: Herbicides containing dimethenamid-p solo are not suitable to replace the mixture isoxaflutole/thiencarbazone but in combination with terbuthylazine yes EFSA: According to protocol (EFSA, 2016b), ‘if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately’. Thus, this a.s. is proposed to be shortlisted |
| 2 Flufenacet\(^{(b)}\) | K3 | BBCH 00-09, BBCH 10-14 | Annual broadleaved weeds and grasses | DE: Only registered in mixtures with metosulam to control cockspur grass, annual dicotyledonous weeds EFSA: According to protocol (EFSA, 2016b), ‘if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately’. A.s. is proposed to be shortlisted |
| 3 Metosulam\(^{(b)}\) | B | BBCH 00-09, BBCH 10-14 | Annual broadleaved weeds and grasses | DE: Only registered in mixtures with flufenacet to control cockspur grass, annual dicotyledonous weeds EFSA: According to protocol (EFSA, 2016b), ‘if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately’. A.s. is proposed to be shortlisted |
| 4 Pethoxamid | K3 | BBCH 00-14 | Annual broadleaved weeds and grasses | DE: Herbicides containing pethoxamid solo are not suitable to replace the mixture isoxaflutole/thiencarbazone but in combination with terbuthylazine yes EFSA: According to protocol (EFSA, 2016b), ‘if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately’. Thus, this a.s. is proposed to be shortlisted |
| 5 Rimsulfuron | B | BBCH 10-16 | Annual broadleaved weeds and grasses | DE: Because of high resistance a.s. is proposed not to be shortlist EFSA: The HRAC group (= resistance risk) is taken into account in the calculation of the HR score. The a.s. is already classified as “high” risk. Thus, this a.s. should be shortlisted |
| 6 S-Metolachlor | K3 | BBCH 00-09 | Annual and perennial grasses | DE: Herbicides containing S-metolachlor solo are not suitable to replace the mixture isoxaflutole/thiencarbazone but in combination with terbuthylazine yes EFSA: According to protocol (EFSA, 2016b), ‘if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately’. Thus, this a.s. is proposed to be shortlisted |
## Table B.4: Shortlisted herbicide active substances with information on MoA according to HRAC, herbicide application time and targeted weed spectrum having similar characteristics to isoxaflutole and authorised in plant protection products for maize in Greece

| Herbicide authorised<sup>(a)</sup> | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|-----------------------------------|------------|-------------------------|---------------|----------------------------------------------------------------------------------|
| Terbuthylazine<sup>(b)</sup>      | C1         | BBCH 00-09, BBCH 10-14  | Annual broadleaved weeds and grasses | DE: Herbicides containing terbuthylazine solo are not suitable to replace the mixture isoxaflutole/thiencarbazone but in combination with dimethenamid-P or S-metolachlor yes. EFSA: According to protocol (EFSA, 2016b), 'if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately'. Thus, this a.s. is proposed to be shortlisted. |
| Thiencarbazone-methyl<sup>(b)</sup> | B          | BBCH 00-09, BBCH 10-13  | Annual broadleaved weeds and grasses | DE: It is correct that isoxaflutole is only available in a mixture with thiencarbazone. It might be also correct that according to EFSA (2016b) protocol 'the full information should be provided for each a.s. in the mixture separately'. But this makes no sense for answering the question if the active under evaluation is necessary for an essential use. As the authorised product is a combination of both actives, one active alone could not solve the given problem. EFSA: This a.s. is proposed to be shortlisted to be consistent with the protocol and within the overall assessment. |
| Isoxaflutole<sup>(c)</sup>        | F2         | BBCH 00-08, BBCH 09-13  | Annual broadleaved weeds and grasses | HRAC: Herbicide Resistance Action Committee; BBCH: growth stages of mono- and dicotyledonous plants. <br>(a): The bold indicates the active substance (a.s.) shortlisted. <br>(b): a.s. is only authorised in co-formulation with other a.s. <br>(c): In DE, isoxaflutole is registered only in co-formulation with thiencarbazone either at BBCH 00-08 (pre-EM) or BBCH 09-13 (post-EM). It is not allowed to use isoxaflutole for both application times. |
### Table B.5: Shortlisted herbicide active substances with information on MoA according to HRAC, herbicide application time and targeted weed spectrum having similar characteristics to isoxaflutole and authorised in plant protection products for maize in Hungary

| Herbicide authorised\(^{(a)}\) | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|---|---|---|---|---|
| **8** Thiencarbazone-methyl\(^{(b)}\) | B | BBCH 00-13 | Annual broadleaved weeds and grasses | EL: No. A.s. is registered in EL only in mixtures with isoxaflutole. EFSA: According to protocol (EFSA, 2016), 'if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately'. Thus, this a.s. is proposed to be shortlisted, to be consistent with the protocol and within the overall assessment. |
| Isoxaflutole\(^{(c)}\) | F2 | BBCH 00-08, BBCH 09-13 | Annual broadleaved weeds and grasses | |

HRAC: Herbicide Resistance Action Committee; BBCH: growth stages of mono- and dicotyledonous plants.
(a): The bold indicates the active substance (a.s.) shortlisted.
(b): a.s. is only authorised in co-formulation with other a.s.
(c): In EL, isoxaflutole is registered as isoxaflutole, isoxaflutole and cyprosulfamide (safener) as well as in mixtures with thiencarbazone-methyl and cyprosulfamide (safener).
(d): Commission Implementing Regulation (EU) 2017/244 of 10 February 2017 concerning the non-renewal of approval of the active substance linuron, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 36, 11.2.2017, p. 54-56.
### Table B.6: Shortlisted herbicide active substances with information on MoA according to HRAC, herbicide application time and targeted weed spectrum having similar characteristics to isoxaflutole and authorised in plant protection products for maize in Italy

| Herbicide authorised<sup>(a)</sup> | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|----------------------------------|------------|-------------------------|---------------|----------------------------------------------------------------------------------|
| Aclonifen                        | F3         | BBCH 00-09              | Annual broadleaved weeds and very limited on grasses | IT: Its activity spectrum is incomplete and not overlapping the one of isoxaflutole. A.s. is proposed not to be shortlisted |
| Clomazone                        | F3         | BBCH 00-12              | Annual broadleaved weeds and grasses                  | IT: Its activity spectrum is incomplete and not overlapping the one of isoxaflutole. A.s. is proposed not to be shortlisted |
| Dimethenamid-p                   | K3         | BBCH 00-16              | Annual broadleaved weeds and grasses                  | IT: Its activity spectrum is incomplete and not overlapping the one of isoxaflutole. A.s. is proposed not to be shortlisted |
| Diquat                           | D          | Pre-sowing to BBCH 00   | Annual and perennial broadleaved weeds and grasses    | IT: Its activity spectrum is incomplete and not overlapping the one of isoxaflutole. A.s. is proposed not to be shortlisted |

HRAC: Herbicide Resistance Action Committee; BBCH: growth stages of mono- and dicotyledonous plants.

<sup>(a)</sup>: The bold indicates the active substance (a.s.) shortlisted.

<sup>(b)</sup>: a.s. is only authorised in co-formulation with other a.s.

<sup>(c)</sup>: In HU, isoxaflutole is registered as isoxaflutole and cyprosulfamide (safener) as well as in mixtures with thiencarbazone-methyl and cyprosulfamide (safener).

<sup>(d)</sup>: Commission Implementing Regulation (EU) 2017/244 of 10 February 2017 concerning the non-renewal of approval of the active substance linuron, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 36, 11.2.2017, p. 54-56.

### Table B.6: Shortlisted herbicide active substances with information on MoA according to HRAC, herbicide application time and targeted weed spectrum having similar characteristics to isoxaflutole and authorised in plant protection products for maize in Italy

| Herbicide authorised<sup>(a)</sup> | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|----------------------------------|------------|-------------------------|---------------|----------------------------------------------------------------------------------|
| Pethoxamid                      | K3         | BBCH 00-13              | Some annual broadleaved weeds and annual grasses    | HU: No control of key broadleaved weeds ABUTH, AMBEL, CHEAL, POLPE/POLLA, and XANST. Pethoxamid cannot replace isoxaflutole to control broadleaved weeds. Thus, a.s. is proposed not to be shortlisted |
| S-Metolachlor                   | K3         | BBCH 00-13              | Annual grasses                                    | HU: No control on broadleaved weeds, e.g. ABUTH, AMARE, AMACH, CHEAL AMBEL, POLPE, POLLA, SOLNI. Thus, a.s. is proposed not to be shortlisted |
| Terbuthylazine                   | C1         | BBCH 00-16              | Annual broadleaved weeds                          | HU: No grass control and key broadleaved weeds are not enough effective controlled. Nowadays authorised dose in Hungary is only maximum 750 g/ha active ingredient which is not comparable with isoxaflutole. Thus, a.s. is proposed not to be shortlisted |
| Thiencarbazone-methyl<sup>(b)</sup> | B       | BBCH 00-13              | Annual broadleaved weeds and grasses              | HU: This a.s. is only registered in mixture with isoxaflutole pre-emergence and early post-emergence EFSA: According to protocol (EFSA, 2016b), ‘if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately’. Thus, this a.s. is proposed to be shortlisted HU: Thiencarbazone-methyl is more effective against Echinochloa crus-galli, Setaria species and Polygonum species than isoxaflutole. Thus thiencarbazone-methyl is proposed not to be shortlisted EFSA remains with its earlier position related to the shortlist in line with the EFSA protocol (2016) which defines the target spectrum in a more generic way (e.g. grasses, broadleaved weeds). However, EFSA accepts the proposal from HU to remove these substances from the shortlist as MS have the possibility to provide a ‘justified’ shortlist |
| Isoxaflutole<sup>(c)</sup>      | F2         | BBCH 00-08, BBCH 09-13  | Annual broadleaved weeds and grasses              | HRAC: Herbicide Resistance Action Committee; BBCH: growth stages of mono- and dicotyledonous plants. (a): The bold indicates the active substance (a.s.) shortlisted. (b): a.s. is only authorised in co-formulation with other a.s. (c): In HU, isoxaflutole is registered as isoxaflutole and cyprosulfamide (safener) as well as in mixtures with thiencarbazone-methyl and cyprosulfamide (safener). (d): Commission Implementing Regulation (EU) 2017/244 of 10 February 2017 concerning the non-renewal of approval of the active substance linuron, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 36, 11.2.2017, p. 54-56. |
**Herbicide authorised**<sup>(a)</sup>  | **HRAC group**  | **Application time (crop)**  | **Weed spectrum**  | **Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist** |
--- | --- | --- | --- | --- |
Flufenacet  | K3  | BBCH 00-16  | Annual broadleaved weeds and grasses  | IT: Its activity spectrum is incomplete and not overlapping the one of isoxaflutole. A.s. is proposed not to be shortlisted |
Linuron  | C2  | BBCH 00-09  | Annual broadleaved weeds and grasses  | EFSA: Accordingly with Commission Implementing Regulation (EU) No 2017/244<sup>(d)</sup>, linuron received a non-approval of renewal in February 2017. Thus, a.s. cannot be shortlisted |
Mesotrione  | F2  | BBCH 00-13/BBCH 14-19  | Annual broadleaved weeds and grasses  | IT: Its activity spectrum is incomplete and not overlapping the one of isoxaflutole. A.s. is proposed not to be shortlisted |
Pendimethalin  | K1  | BBCH 00-13  | Annual broadleaved weeds and very limited on grasses  | IT: Its activity spectrum is incomplete and not overlapping the one of isoxaflutole. A.s. is proposed not to be shortlisted |
Pethoxamid  | K3  | BBCH 00-16  | Annual broadleaved weeds and grasses  | IT: Its activity spectrum is incomplete and not overlapping the one of isoxaflutole. A.s. is proposed not to be shortlisted |
S-Metolachlor  | K3  | BBCH 00-13  | Annual and perennial grasses  | IT: Its activity spectrum is incomplete and not overlapping the one of isoxaflutole. A.s. is proposed not to be shortlisted |
Sulcotrione  | F2  | BBCH 00-09/BBCH 12-18  | Annual broadleaved weeds and some grasses  | IT: Its activity spectrum is incomplete and not overlapping the one of isoxaflutole. A.s. is proposed not to be shortlisted |
Terbuthylazine  | C1  | BBCH 00-16  | Annual broadleaved weeds and grasses  | IT: Its activity spectrum is incomplete and not overlapping the one of isoxaflutole. A.s. is proposed not to be shortlisted |
**1 Thiencarbazone-methyl**<sup>(b)</sup>  | B  | BBCH 00-18  | Annual broadleaved weeds and grasses  | IT: Its activity spectrum is incomplete and not overlapping the one of isoxaflutole. A.s. is proposed not to be shortlisted |
Isoxaflutole<sup>(c)</sup>  | F2  | BBCH 00-08, BBCH 09-13  | Annual broadleaved weeds and grasses  | EFSA: According to protocol (EFSA, 2016b), ‘if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately’. Thus, this a.s. is proposed to be shortlisted |

**Table B.7:** Shortlisted herbicide active substances with information on MoA according to HRAC, herbicide application time and targeted weed spectrum having similar characteristics to isoxaflutole and authorised in plant protection products for maize in the Netherlands

| Herbicide authorised<sup>(a)</sup>  | HRAC group  | Application time (crop)  | Weed spectrum  | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
--- | --- | --- | --- | --- |
1 Bentazone  | C3  | Post-emergence  | Annual weeds  | NL: Inclusion for application against annual weeds, pre- and post-emergence of the crop. A.s. is proposed to be shortlisted |
2 Bromoxynil  | C3  | Post-emergence  | Annual weeds  | NL: Inclusion for application against annual weeds, pre- and post-emergence of the crop. A.s. is proposed to be shortlisted |
3 Clopyralid  | O  | Post-emergence  | Broadleaved weeds  | NL: Inclusion for application against annual weeds, pre- and post-emergence of the crop. A.s. is proposed to be shortlisted |
4 Dicamba  | O  | Post-emergence  | Broadleaved weeds  | NL: Inclusion for application against annual weeds, pre- and post-emergence of the crop. A.s. is proposed to be shortlisted |

HRAC: Herbicide Resistance Action Committee; BBCH: growth stages of mono- and dicotyledonous plants.
(a): The bold indicates the active substance (a.s.) shortlisted.
(b): a.s. is only authorised in co-formulation with other a.s.
(c): In IT, isoxaflutole is registered as isoxaflutole, isoxaflutole and cyprosulfamide (safener) as well as co-formulated with thiencarbazone-methyl and cyprosulfamide (safener), aclonifen and flufenacet.
(d): Commission Implementing Regulation (EU) 2017/244 of 10 February 2017 concerning the non-renewal of approval of the active substance linuron, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 36, 11.2.2017, p. 54-56.
| Herbicide authorised(a) | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|------------------------|------------|-------------------------|---------------|---------------------------------------------------------------------------------|
| 5 Dimethenamid-p K3    | Pre- and post-emergence | Annual weeds | NL: Inclusion for application against annual weeds, pre- and post-emergence of the crop. A.s. is proposed to be shortlisted |
| 6 Florasulam B         | Post-emergence | Annual broadleaved weeds | NL: Inclusion for application against annual weeds, pre- and post-emergence of the crop. A.s. is proposed to be shortlisted |
| 7 Fluroxypyr-mepityl O | Post-emergence | Broadleaved weeds | NL: Inclusion for application against annual weeds, pre- and post-emergence of the crop. A.s. is proposed to be shortlisted |
| 8 Foramsulfuron(b) B   | Post-emergence | Annual weeds | NL: Inclusion for application against annual weeds, post-emergence of the crop. A.s. is proposed to be shortlisted |
| 9 Iodosulfuron-methyl-natrium(b) B | Post-emergence | Annual weeds | NL: Inclusion for application against annual weeds, post-emergence of the crop. A.s. is proposed to be shortlisted |
| 10 Mesotrione F2 Post-emergence | Annual broadleaved weeds, DIGSA and ECHCG | NL: Inclusion for application against annual weeds, post-emergence of the crop. Authorised pre- and post-emergence against annual weeds as part of a mixture. EFSA: According to protocol (EFSA, 2016b), ‘if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately’. A.s. is proposed to be shortlisted |
| 11 Nicosulfuron B      | Post-emergence | Weeds | NL: Inclusion for application against weeds, post-emergence of the crop. A.s. is proposed to be shortlisted |
| 12 Pendiethalin K1 Pre- and post-emergence | Annual weeds | NL: Inclusion for application against annual weeds, pre- and post-emergence of the crop. A.s. is proposed to be shortlisted |
| 13 Prosulfuron B       | Post-emergence | Broadleaved weeds | NL: Inclusion for application against broadleaved weeds, post-emergence of the crop. A.s. is proposed to be shortlisted |
| 14 Rimsulfuron B       | Post-emergence | Weeds | NL: Inclusion for application against weeds, post-emergence of the crop. A.s. is proposed to be shortlisted |
| 15 S-Metolachlor K3 Pre- and post-emergence | Annual weeds | NL: Inclusion for application against annual weeds, post-emergence of the crop |
| 16 Sulcotrione F2 Post-emergence | Annual broadleaved weeds | NL: Inclusion for application against annual broadleaved weeds, post-emergence of the crop. A.s. is proposed to be shortlisted |
| 17 Tembotrione F2 Post-emergence | Annual weeds | NL: Inclusion for application against annual weeds, post-emergence of the crop. A.s. is proposed to be shortlisted |
| 18 Terbuthylazine(b) C1 Pre- and post-emergence | Annual broadleaved and grasses | NL: Authorised pre- and post-emergence against annual weeds as part of a mixture. EFSA: According to protocol (EFSA, 2016b), ‘if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately’. Thus, this a.s. is proposed to be shortlisted |
| 19 Thiencarbazone-methyl(b) B | Post-emergence | Weeds | NL: Inclusion for application against weeds, post-emergence of the crop. A.s. is proposed to be shortlisted |
| 20 Thifensulfuron-methyl B | Post-emergence | Annual broadleaved weeds | NL: Inclusion for application against annual broadleaved weeds, post-emergence of the crop. A.s. is proposed to be shortlisted |
| 21 Tritosulfuron B Post-emergence | Broadleaved weeds | NL: Inclusion for application against broadleaved weeds, post-emergence of the crop. A.s. is proposed to be shortlisted |
Table B.8: Shortlisted herbicide active substances with information on MoA according to HRAC, herbicide application time and targeted weed spectrum having similar characteristics to isoxaflutole and authorised in plant protection products for *maize* in Romania

| Herbicide authorised(a) | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|------------------------|------------|-------------------------|---------------|----------------------------------------------------------------------------------|
| Isoxaflutole           | F2         | Pre- and post-emergence | Annual weeds  |                                                                                  |
| Dimethenamid-p K3      | BBCH 00-16 | Annual broadleaved weeds and annual grasses | RO: Dimethenamid being a specific product against grasses cannot replace isoxaflutole on some important broadleaves as: *Xanthium strumarium* (XANST), *Polygonum* sp. (POLSS), *Chenopodium album* (CHEAL), *Amaranthus retroflexus* (AMARE) and *Abutilon theophrasti* (ABUTH). A.s. is proposed not to be shortlisted |
| Diquat D               | Pre-sowing to BBCH 00 | Annual and perennial broadleaved weeds and grasses | RO: In October 2016, the EU Commission proposed a non-renewal of the approval of the active substance diquat. A vote for non-renewal is expected in 2017. EFSA: Different application time (pre-sowing) compared to the substance under consideration (pre- and post-EM). Thus, based on the application time, this a.s. is proposed not to be shortlisted |
| Flumioxazin E BBCH 00-09 | Annual broadleaved weeds | RO: Flumioxazin has no control on grasses, and consequently cannot be an alternative to some important grasses weeds for Romania: *Sorghum halepense* (SORHA) from seeds, *Setaria pumila* (SETPU) and *Echinochloa crus-galli* (ECHCG). Also, on some important dicots, isoxaflutole ensure a better and consistent efficacy, for example *Xanthium strumarium* (XANST and POLSS). As flumioxazin has a R1B harmonised classification, in case of a renewal of approval, a very restrictive re-authorisation of the products is foreseen. We do not consider the restrict uses can replace Isoxaflutole. A.s. is proposed not to be shortlisted |
| Glyphosate G           | Pre-sowing | Annual and perennial broadleaved weeds and grasses | RO: Non-selective herbicide used in intercropping before sowing or emergence of maize. Foliar burn down activity, no control on new germination of grasses and broadleaved weeds during the vegetative growth of the crop. EFSA: Different application time (pre-sowing) compared to the substance under consideration (pre- and post-EM). Thus, this a.s. is proposed not to be shortlisted |
| Linuron C2 BBCH 00-09  | Annual broadleaved weeds and annual grasses | EFSA: Accordingly with Commission Implementing Regulation (EU) No 2017/244(c), linuron received a non-approval of renewal in February 2017. Thus, a.s. cannot be shortlisted |
| Mesotrione F2 BBCH 00-13/14-19 | Annual broadleaved weeds and some annual grasses | RO: Mesotrione does not meet isoxaflutole efficacy on the most important grasses for Romania: *Sorghum halepense* (SORHA), *Setaria* sp. (SETSS), *Echinochloa crus-galli* (ECHCG), *Digitaria ischaemum* (DIGIS), and cannot replace isoxaflutole on the grasses segment. Isoxaflutole cannot be replaced on *Xanthium stramonium* (XANST), *Portulaca oleracea* (POROL), *Stellaria media* (STEME) by mesotrione due to low efficacy. Thus, a.s. is proposed not to be shortlisted |

HRAC: Herbicide Resistance Action Committee.
(a): The bold indicates the active substance (a.s.) shortlisted.
(b): a.s. is only authorised in co-formulation with other a.s.
(c): In NL, isoxaflutole is registered as isoxaflutole.
| Herbicide authorised<sup>a</sup> | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|--------------------------------|------------|-------------------------|---------------|------------------------------------------------------------------------------------|
| Pendimethalin<sup>b</sup> | K1         | BBCH 00-16              | Annual broadleaved weeds and very narrow spectrum on grasses | RO: Pendimethalin cannot replace isoxaflutole due to the inconsistency of efficacy on grasses, and lower efficacy on broadleaves weeds Xanthium stramonium (XANST), Polygonum persicaria (POLPE), Polygonum laphatiformi (POLL), Chenopodium album (CHEAL), Amaranthus retroflexus (AMARE). Thus, a.s is proposed not to be shortlisted |
| Pethoxamid | K3         | BBCH 00-16              | Annual grasses and some broadleaved weeds | RO: Pethoxamid being a grasses product cannot replace isoxaflutole on some important broadleaves as: Xanthium strumarium, (XANST), Polygonum persicaria (POLPE), Polygonum laphatiformi (POLL), Chenopodium album (CHEAL) and Abutilon theophrasti (ABUTH). Thus, a.s is proposed not to be shortlisted |
| S-Metolachlor | K3         | BBCH 00-13              | Annual and perennial grasses and some broadleaved weeds | RO: S-Metolachlor is a product which works against grasses, but cannot be considered as a replacer for isoxaflutole on broadleaves weeds Xanthium stramanium (XANST), Polygonum persicaria (POLPE), Polygonum laphatiformi (POLL), Chenopodium album (CHEAL), Amaranthus retroflexus (AMARE), Amaranthus sp. (AMASS). Thus, a.s is proposed not to be shortlisted |
| Terbuthylazine | C1         | BBCH 00-16              | Annual broadleaved weeds and grasses | RO: Terbuthylazine has less efficacy on grass weeds, and also some important broadleaves are not controlled (AMARE, CHEAL, DATST, POLPE/POLLA, XANST), and from this point of view cannot be alternative to replace isoxaflutole. Thus, a.s is proposed not to be shortlisted |
| Thiencarbazone-methyl<sup>b</sup> | B          | BBCH 00-13              | Annual broadleaved weeds and grasses | RO: Thiencarbazone cannot provide a satisfactory level of control on annual grasses like: Digitaria sanguinalis (DIGSA) and Setaria verticillata (SETVE) and perennial grasses like: Sorghum halepense (SORHA). It is only used in pre-emergence to early post-emergence in mixture with isoxaflutole. Thus, this proposal is proposed not to be shortlisted. EFSA: According to protocol (EFSA, 2016b), ‘if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately’. Thus, this proposal is proposed not to be shortlisted. RO: Thiencarbazone-methyl is registered with isoxaflutole in the same time due to a better activity of thiencarbazone-methyl on annual grasses and Polygonaceae species. Thus, thiencarbazone-methyl is proposed not to be shortlisted. EFSA remains with its earlier position related to the shortlist in line with the EFSA protocol (2016) which defines the target spectrum in a more generic way (e.g. grasses, broadleaved weeds). However, EFSA accepts the proposal from RO to remove this a.s from the shortlist as MS have the possibility to provide a ‘justified’ shortlist |
| Isoxaflutole<sup>c</sup> | F2         | BBCH 00-08, BBCH 09-13 | Annual broadleaved weeds and grasses | |

HRAC: Herbicide Resistance Action Committee; BBCH: growth stages of mono- and dicotyledonous plants.
(a): The bold indicates the active substance (a.s.) shortlisted.
(b): A.s. is only authorised in co-formulation with other a.s.
(c): In RO, isoxaflutole is registered as isoxaflutole and cyprosulfamid (safener) as well as in co-formulation with thiencarbazone-methyl and cyprosulfamid (safener) and terbuthylazine.
(d): Commission Implementing Regulation (EU) 2017/244 of 10 February 2017 concerning the non-renewal of approval of the active substance linuron, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 36, 11.2.2017, p. 54–56.

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Table B.9: Shortlisted herbicide active substances with information on MoA according to HRAC, herbicide application time and targeted weed spectrum having similar characteristics to isoxaflutole and authorised in plant protection products for maize in Slovakia

| Herbicide authorised(a) | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|-------------------------|------------|--------------------------|---------------|----------------------------------------------------------------------------------|
| Dimethenamid-p          | K3         | BBCH 00-16               | Annual broadleaved weeds and grasses | SK: Dimethenamid-p weed spectrum is very different with isoxaflutole. Dimethenamid-p is authorised only for pre-emergent application. A.s. is proposed not to be shortlisted |
| 1 Flufenacet(b)         | K3         | BBCH 00-15               | Some annual broadleaved weeds and grasses | SK: Flufenacet is registered in maize only with active substance terbuthylazine. Flufenacet should not be on shortlist because weed spectrum is very different than isoxaflutole. EFSA: According to protocol (EFSA, 2016), ‘if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately’ Thus, this a.s. is proposed to be shortlisted |
| Glyphosate              | G          | Pre-sowing or pre-emergence | Annual broadleaved weeds and grasses | SK: Isoxaflutole is also authorised for early post-emergent application in Slovakia. Glyphosate is authorised for pre-emergent application in maize in Slovakia. Therefore, glyphosate should not be on shortlist. EFSA: different application time (pre-sowing) compared to the substance under consideration (pre- and post-EM). Thus, this a.s. is proposed not to be shortlisted |
| Linuron                 | C2         | BBCH 00-09               | Annual broadleaved weeds and grasses | EFSA: Accordingly with Commission Implementing Regulation (EU) No 2017/244(d), linuron received a non-approval of renewal in February 2017. Thus, a.s. cannot be shortlisted |
| Mesotrione              | F2         | BBCH 00-13/BBCH 14-19    | Annual broadleaved weeds and some grasses | SK: Mesotrione should not be on shortlist because weed spectrum is different than isoxaflutole. Thus, a.s. is proposed not to be shortlisted |
| Pendimethalin           | K1         | BBCH 00-16               | Annual broadleaved weeds and very narrow spectrum on grasses | SK: Pendimethalin should not be on shortlist because weed spectrum is different than Isoxaflutole. Thus, a.s. is proposed not to be shortlisted |
| 2 Pethoxamid(b)         | K3         | BBCH 00-16               | Annual grasses and some broadleaved weeds | SK: Pethoxamid is registered in maize only with active substance terbuthylazine. Pethoxamid should not be on shortlist because weed spectrum is different than isoxaflutole. EFSA: According to protocol (EFSA, 2016b), ‘if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately’. Thus, this a.s. is proposed to be shortlisted |
| S-Metolachlor           | K3         | BBCH 00-13               | Annual and perennial grasses and some broadleaved weeds | SK: S-Metolachlor should not be on shortlist because weed spectrum is very different than isoxaflutole. Thus, a.s. is proposed not to be shortlisted |
| 3 Terbuthylazine(b)     | C1         | BBCH 00-16               | Annual broadleaved weeds and grasses | SK: Terbuthylazine is authorised in Slovakia only with active substances bromoxynil, dimethenamid-p, flufenacet, mesotrione, S-metolachlor and pethoxamid. Single active substance Terbuthylazine is not authorised in Slovakia. Terbuthylazine should not be on shortlist because weed spectrum is different than isoxaflutole. EFSA: According to protocol (EFSA, 2016b), ‘if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately’. Thus, a.s. is proposed to be shortlisted |
### Table B.10:
Shortlisted herbicide active substances with information on MoA according to HRAC, herbicide application time and targeted weed spectrum having similar characteristics to isoxaflutole and authorised in plant protection products for maize in the United Kingdom

| Herbicide authorised<sup>(a)</sup> | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|-----------------------------------|------------|--------------------------|---------------|-----------------------------------------------------------------------------------|
| 4 Thiencarbazone-methyl<sup>(b)</sup> | B          | BBCH 00-13               | Annual broadleaved weeds and grasses | SK: Thiencarbazone-methyl is not authorised single in Slovakia. It is authorised only mixture with foramsulfuron, iodosulfuron-methyl Na in PPP MAISTER POWER and with Isoxaflutole in PPP ADEGO SC. MAISTER POWER and ADEGO SC have different weed spectrum than isoxaflutole. Therefore, thiencarbazone should not be on shortlist. EFSA: According to protocol (EFSA, 2016b), 'if a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately'. Thus, this a.s. is proposed to be shortlisted. |
| Isoxaflutole<sup>(c)</sup>         | F2         | BBCH 00-08, BBCH 09-13   | Annual broadleaved weeds and grasses | |

HRAC: Herbicide Resistance Action Committee; BBCH: growth stages of mono- and dicotyledonous plants.

<sup>(a)</sup>: The bold indicates the active substance (a.s.) shortlisted.

<sup>(b)</sup>: A.s. is only authorised in co-formulation with other a.s.

<sup>(c)</sup>: In SK, isoxaflutole is registered as isoxaflutole and cyprosulfamide (safener) as well as in co-formulation with thiencarbazone-methyl and cyprosulfamide (safener).

<sup>(d)</sup>: Commission Implementing Regulation (EU) 2017/244 of 10 February 2017 concerning the non-renewal of approval of the active substance linuron, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 36, 11.2.2017, p. 54-56.
### Table B.12:
Shortlisted herbicide active substances with information on MoA according to HRAC, herbicide application time and targeted weed spectrum having similar characteristics to isoxaflutole and authorised in plant protection products for sweetcorn in Italy

| Herbicide authorised<sup>(a)</sup> | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|-----------------------------------|------------|------------------------|---------------|--------------------------------------------------------------------------------|
| Isoxaflutole<sup>(c)</sup>        | F2         | BBCH 00-08 (pre-EM)    | Annual broadleaved weeds and grasses |                                                                                  |

HRAC: Herbicide Resistance Action Committee; BBCH: growth stages of mono- and dicotyledonous plants.

(a): The bold indicates the active substance (a.s.) shortlisted.
(b): A.s. is only authorised in co-formulation with other a.s.
(c): In UK, isoxaflutole is only authorised in co-formulation with flufenacet.

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### Table B.11:
Shortlisted herbicide active substances with information on MoA according to HRAC, herbicide application time and targeted weed spectrum having similar characteristics to isoxaflutole and authorised in plant protection products for sweetcorn in France

| Herbicide authorised<sup>(a)</sup> | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|-----------------------------------|------------|------------------------|---------------|--------------------------------------------------------------------------------|
| Aclonifen<sup>(b)</sup>           | F3         | BBCH 00-09             | Annual broadleaved weeds and very limited on grasses | FR: May be aggressive for maize in some soils and climate conditions. A partial solution but not the solution. This a.s. is proposed to be shortlisted as it controls a good part of the weed spectrum, but has some limitation compared to the substance under consideration |
| Dimethenamid-p                     | K3         | BBCH 00-16             | Annual broadleaved weeds and grasses | FR: Not the same spectrum of weed and limitation due to leaching for substance active in sandy or loamy soils. However, this a.s. is proposed to be shortlisted although it is a medium solution |
| Mesotrione                         | F2         | BBCH 00-13/14, BBCH 13-19 | Annual broadleaved weeds and grasses | FR: Nearly same spectrum but mainly post sowing use. This a.s. is proposed to be shortlisted, although it is a medium solution |
| S-Metolachlor                      | K3         | BBCH 00-13             | Annual and perennial grasses | FR: Not the same spectrum of weed and limitation due to leaching for substance active in sandy or loamy soils. However, this a.s. is proposed to be shortlisted, although it is a medium solution |
| Isoxaflutole<sup>(c)</sup>         | F2         | BBCH 00-08, BBCH 09-13 | Annual broadleaved weeds and grasses |                                                                                  |

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### Table B.12:
Shortlisted herbicide active substances with information on MoA according to HRAC, herbicide application time and targeted weed spectrum having similar characteristics to isoxaflutole and authorised in plant protection products for sweetcorn in Italy

| Herbicide authorised<sup>(a)</sup> | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|-----------------------------------|------------|------------------------|---------------|--------------------------------------------------------------------------------|
| Diquat                            | D          | Pre-sowing to BBCH 00   | Annual and perennial broadleaved weeds and grasses | IT: Diquat is a non-selective herbicide and is considered to have an inadequate weed spectrum for the application in pre-sowing EFSA: Different application time (pre-sowing) compared to the substance under consideration (pre- and post-EM). Thus, this a.s. is proposed not to be shortlisted |
| Isoxaflutole<sup>(b)</sup>        | F2         | BBCH 00-08, BBCH 09-13 | Annual broadleaved weeds and grasses |                                                                                  |

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HRAC: Herbicide Resistance Action Committee; BBCH: growth stages of mono- and dicotyledonous plants.

(a): The bold indicates the active substance (a.s.) shortlisted.
(b): In IT, isoxaflutole is registered as isoxaflutole, isoxaflutole and cyprosulfamide (safener), as well as in co-formulated with thiencarbazone-methyl and cyprosulfamide (safener), and aclonifen.
(c): In FR, isoxaflutole is registered as isoxaflutole, isoxaflutole and cyprosulfamide (safener), as well as in co-formulated with thiencarbazone-methyl and cyprosulfamide (safener), and aclonifen.
Table B.13: Shortlisted herbicide active substances with information on MoA according to HRAC, herbicide application time and targeted weed spectrum having similar characteristics to isoxaflutole and authorised in plant protection products for sweetcorn in the United Kingdom

| Herbicide authorised \(^{(a)}\) | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|-------------------------------|------------|-------------------------|---------------|----------------------------------------------------------------------------------|
| Flufenacet \(^{(b)}\)         | K3         | BBCH 00                  | Annual broadleaved weeds and grasses | UK: Similar timing but weed not spectrum not entirely the same as isoxaflutole. Flufenacet alone does not give effective control of AMARE, CHEAL, POLPE/POLLA. However, this a.s. is proposed to be shortlisted |
| Pendimethalin \(^{(c)}\)      | K1         | BBCH 00-14               | Annual broadleaved weeds and grass POANN only | UK: Similar timing but weed not spectrum not entirely the same as isoxaflutole - limited grass weed activity but does control CHEAL, SOLNI, POLPE. However, this a.s. is proposed to be shortlisted |
| Isoxaflutole \(^{(c)}\)       | F2         | BBCH 00-08 (pre-EM)      | Annual broadleaved weeds and grasses | |

HRAC: Herbicide Resistance Action Committee; BBCH: growth stages of mono- and dicotyledonous plants.
(a): The bold indicates the active substance (a.s.) shortlisted.
(b): A.s. is only authorised in co-formulation with other a.s.
(c): In UK isoxaflutole is only authorised in co-formulation with flufenacet.

Table B.14: Shortlisted herbicide active substances with information on MoA according to HRAC, herbicide application time and targeted weed spectrum having similar characteristics to isoxaflutole and authorised in plant protection products for poppy in Hungary

| Herbicide authorised \(^{(a)}\) | HRAC group | Application time (crop) | Weed spectrum | Justification by MS or EFSA for inclusion or non-inclusion of a.s. on the shortlist |
|-------------------------------|------------|-------------------------|---------------|----------------------------------------------------------------------------------|
| Chlorotoluron                 | C2         | BBCH 00-08, BBCH 16     | Some broadleaved weeds and annual grasses | HU: Low weed spectrum in poppy. A.s. is proposed not to be shortlisted |
| Clomazone                     | F3         | BBCH 00-08               | Some broadleaved weeds and some annual grasses | HU: No control on key annual grasses: DIGSA and ECHCG and broadleaved weeds: BUTH, AMASS and CHESS. A.s. is proposed not to be shortlisted |
| Isoxaflutole \(^{(b)}\)       | F2         | BBCH 00-08 (pre-EM)      | Annual broadleaved weeds and grasses | HU: Isoxaflutole is only registered as pre-emerging application (BBCH 00-08) for poppy in Hungary |

HRAC: Herbicide Resistance Action Committee; BBCH: growth stages of mono- and dicotyledonous plants.
(a): The bold indicates the active substance (a.s.) shortlisted.
(b): In HU, isoxaflutole is registered as isoxaflutole and cyprosulfamide (safener).