

Article 50 of Regulation (EC) No 1107/2009 sets out the regulatory requirements for performing the comparative assessment of plant protection products containing candidates for substitution.

Each Member State specifies the procedures for examining the dossiers in question on its territory. In line with this, the Ministerial Order of 23 July 2015 lists the information to be submitted in the case of products containing a substance that is a candidate for substitution, as well as the analysis steps leading to the substitution or not of the use in question.

This report has been drawn up for the specific case of implementing a comparative assessment in accordance with point 50.2 of the aforementioned Regulation, i.e. for an application not concerning a product containing one or more candidates for substitution. Member States may in exceptional cases apply these general provisions when non-chemical prevention or control methods exist and are in general use in the Member State. The analytical criteria of 50.1 are then applied to compare these methods and the products concerned.

Case in question and background

This report concerns the implementation of a comparative assessment for applications for new marketing authorisations (MAs) currently being examined, as well as applications for MA renewal, following renewed approval of the active substance glyphosate with effect from 16 December 2017.

In a letter co-signed by the Ministers of Agriculture, Ecology and Health dated 18 November 2018, ANSES was asked to implement the provisions of Article 50.2 and of Annex IV of Regulation (EC) No 1107/2009.

At the same time, on 13 November 2018, INRA was commissioned by the Ministers of Ecology and Agriculture to produce a report presenting an examination of the alternatives, their uses, and the practical and economic disadvantages.

The current document has been drawn up for the use of glyphosate in arable crops, based on information from the references cited in the annex and taken from INRA/INRAE reports (INRA, 2017; INRAE, 2020), additional information provided by marketing authorisation applicants (Glyphosate Task Force (GTF2, 2019)), the analysis of the 2019 ITA inter-institute survey (ACTA¹, ARVALIS, FNAMS, ITB and Terres Inovia) (ITA survey, 2019), and the presentations and discussions of the MA Monitoring Committee at its meeting of 4 June 2020 (Minutes from the meeting of the MA Monitoring Committee meeting on 4 June 2020 (PV CSAMM)).

¹ ATCA: Network of Agricultural Technical Institutes (ITAs)

Use designation, crops concerned and use status

The uses identified in arable crops are presented in the table below, which describes the situations concerned.

Name of use ² (national catalogue)	Scope of use (crops or crop groups covered)	Status of use	Description of use
Cereals*Weed control* Before harvest	Oats, wheat, barley, rye, buckwheat, maize, rice	Major	Destruction of perennial and annual weeds before crop harvest
Protein crops* Weed control	Protein peas, field peas, field beans, lupin	Major	Destruction of perennial and annual weeds before crop harvest
Set-aside land and intermediate crops* Treatment of aerial parts* Limit growth and fruiting	Set-aside land and intermediate crops	Minor	Limitation of growth and fruiting
Flax*Weed control* During retting	Flax	Minor	Management of greening and possible grassing of fibres following uprooting and laying down of flax
Grassland*Weed control	Grassland	Major	Localised destruction of perennials and woody plants
General treatments* Weed control*Inter-row planted crops	All arable crops and seed crops	Not defined	Weed control of inter-row spaces
General treatments* Destruction of cover and regrowth in crops (new use)	Arable crops	Not defined	Weed control post-sowing and pre-emergence / Limitation or destruction of cover after sowing
General treatments* Weed control* Intercropping, set-aside land and crop destruction	Arable crops	Not defined	Destruction of plant cover, intercrops, crop regrowth, perennial, annual or woody weeds, with a view to sowing or establishing a new crop while limiting competition with weeds

Table 1 - Description of the uses in question

Among the situations described, the following uses, which were not assessed as alternatives in the INRAE report (2020), have not been included in the remainder of the analysis (see Table 2 - Situation regarding uses and continuation of the comparative assessment analysis):

- Uses in weed control before harvest on cereals and protein crops correspond to control of perennials through spot applications and concern small areas. It should also be noted that control of perennial weeds can take place at other times, particularly during intercropping;
- Uses intended to limit either grassing during the flax retting phase or growth or fruiting on set-aside land are considered to be very rare (ITA survey, 2019; PV CSAMM; PV CSAMM);
- Localised destruction of perennials and woody plants in grassland;

² Guidance note DGAL/SDQP/2015-253 of 10 March 2015. Certain uses or use designations are currently under review and will be adopted in future MA decisions.

- "Inter-row" treatments intended for all types of crops may be considered in arable crops in the case of very occasional intercropping practices, but glyphosate is not preferred in these situations due to its lack of selectivity;
- The destruction of cover and regrowth in crops is a new use.

In summary, for the continuation of the analysis and comparative assessment:

Name of use	Type	Action taken
Cereals*Weed control*Before harvest	Major	Not included in the remainder of the analysis
Protein crops*Weed control		
Set-aside land and intermediate crops*Treatment of aerial parts*Limit growth and fruiting	Minor	
Flax*Weed control*During retting	Minor	
Grassland*Weed control	Major	
General treatments*Weed control*Inter-row planted crops	Not defined	
General treatments* Destruction of cover and regrowth in crops	Not defined	
General treatments*Weed control* Intercropping, set-aside land and crop destruction	Not defined	Included in the analysis

Table 2 - Situation regarding uses and continuation of the comparative assessment analysis

Use of glyphosate for the situations described

In its 2020 report on the assessment of alternatives to glyphosate, INRAE stated that its work covered the uses of glyphosate in intercropping, based on data from the "Cultivation practices on arable crops and grassland" survey for the 2017 crop season (PK-GCP_2017), which was used to identify the crop management techniques of 17 arable crops in metropolitan France (common wheat, durum wheat, barley, triticale, rapeseed, sunflower, protein peas, forage maize, grain maize, sugar beet, potatoes, field beans, soy beans, fibre flax, linseed, mixture of grains and mixture with protein crops), as well as permanent and temporary grassland and mixed forage crops (INRAE, 2020). These data indicate that the use in intercropping, set-aside land and crop destruction is a predominant use, accounting for 98% of glyphosate applications on arable crops.

Arable crops cover 13.53 million hectares of agricultural land. The estimated area treated with glyphosate may be 2.37 million hectares, or 18.9% of the area under arable crops (excluding grassland). When used, glyphosate is mostly applied only once during the crop season (INRAE, 2020).

The main targets for glyphosate use are:

- Control of perennial weeds and regrowth for 77.8% of uses;
- Destruction of plant cover for 16.1% of uses;
- Destruction of grassland for 2.1% of uses.

Of the intercropping applications, 54% are at the pre-sowing phase (i.e. in the three weeks prior to sowing). The other half of applications take place after the harvest of the previous crop (after the harvest date and up to 3 weeks before planting the new crop) (INRAE, 2020).

Average rates of glyphosate use differ by target for all annual arable crops: the average rate of glyphosate applied per plot was 824 g/ha in 2017, which represents an annual quantity of glyphosate of 2,135 tonnes (INRAE, 2020).

Management of intercrops also emerged as the main use in the 2019 inter-institute survey (73.2% of respondents). Control of perennials is another predominant use. Today, glyphosate can be used to manage many situations: problems of resistance to herbicides, invasive species raising concerns about sanitary quality, such as jimsonweed (*Datura stramonium*), or indirect transmitters of high-stakes diseases, such as grasses that carry rye ergot (*Claviceps purpurea*) (ITA survey, 2019).

There is large variability in glyphosate use in intercropping situations according to several criteria (INRAE, 2020; INRA, 2017):

- ⇒ farm size: the proportion of glyphosate-treated areas is around 14% for farms with less than 150 ha of utilised agricultural land (UAL), around 23% for those with between 150 and 350 ha of UAL and almost 40% for those with more than 350 ha of UAL, a trend confirmed by the inter-institutional survey (ITA survey, 2019);
- ⇒ previous crops, in the case of use for destroying regrowth. Glyphosate is used more often after soy bean (41% of cases), rapeseed and durum wheat (32%) crops, and in only 1% of cases after beet;
- ⇒ soil characteristics: plots with hydromorphic soils are treated more often with glyphosate (24.6%) than plots with non-hydromorphic soils (17.4%) (INRAE, 2020). Indeed, in the event of a wet winter and early spring, the use of glyphosate may become indispensable if there is high rainfall or on soils sensitive to excess water where tillage is not possible during these periods. The objective is then to destroy weeds and cover in situations where herbicide use is authorised during intercropping, but also to be able to destroy temporary grassland (INRA, 2017);
- ⇒ and according to the tillage strategy, with direct sowing plots being treated with glyphosate to a greater extent than ploughed plots (85.9% of the area treated in the case of direct sowing, compared with 39.3% in the case of simplified cultivation techniques, and 7.6% in the case of systematic ploughing). The proportion of ploughed areas treated with glyphosate decreases with increased ploughing frequency, which can be explained by the contribution of ploughing to weed control in general, particularly with intercrops (due to burial of part of the seed stock).

Examination of non-chemical alternatives under Article 50.2

1. Identification of non-chemical alternatives in general use

1.a. Are non-chemical methods of prevention or control available for the claimed uses?

The contributions were analysed and provided the following answers to the question posed.

Response:

- **Yes**, for the situations identified below (1.b.);
- **No**, in the following situations of technical deadlock:
 - control of invasive plants or perennial weeds where mechanical solutions fail to limit their growth (INRA, 2017);
 - mandatory (regulated) control of certain weeds (ragweed, creeping thistle, etc.) or destruction of crop regrowth in the event of control of regulated pests (PV CSAMM) (e.g. potato regrowth for control of nematodes or quarantine bacteria);

- the practice of conservation agriculture, which is based on a strategy of minimum tillage, permanent or quasi-permanent plant cover, crop diversification and a longer growing season (INRAE, 2020). These practices aim to take advantage of plant cover (to combat erosion, limit runoff and addition of organic matter, even nitrogen for cover including legumes) and soil biological activity (which is disturbed by tillage, ploughing in particular), which contributes to the mineralisation of organic nitrogen, with macrofauna activity also having a pivotal role. Today, only 1.7% of farmers use conservation agriculture (INRAE, 2020), although this practice is steadily increasing throughout the world, and in France in particular.

1.b. If so, which ones? Are they in general use?

Strategies exist that enable herbicide use to be avoided for the long-term management of weeds and their seed stocks on a given plot, mainly those developed by organic farmers.

They incorporate a series of methods combining both cultivation practices (long rotations) and mechanical operations (ploughing and tillage). However, they require a total reorganisation of the farm, sector and markets and cannot therefore be scaled up immediately for national production (PV CSAMM).

Alternative techniques exist for mechanically destroying weeds in intercrops in a given situation (ITA survey, 2019; INRA, 2017; INRAE, 2020). These are mechanical methods such as:

- rolling and shredding of plants;
- shallow tillage (less than 15 cm deep) using different types of tools: stubble cultivators, cultivators, weeders, hoes, harrows, etc.;
- deep tillage without turning over the soil, using various implements such as subsoilers, soil looseners, rotary spaders, spading machines, tine or disc cultivators, etc.;
- or ploughing (deep tillage that turns over the soil).

These mechanical methods can be combined with cultivation methods such as:

- ⇒ creating a false seedbed;
- ⇒ grazing of cover;
- ⇒ shifting sowing dates;
- ⇒ changing crop rotations and their management;
- ⇒ introducing set-aside land to destroy perennials.

Combining the identified mechanical and cultivation methods (deep tillage without turning over the soil, shallow tillage, changing crop rotation, false seedbeds, etc.) could in the medium term enable the development of new strategies to reduce weeds, particularly in the context of conservation agriculture. However, to date, this type of alternative strategy cannot be considered to be in general use, according to the analysis of practices carried out on this series of techniques by INRA/INRAE (2017, 2020).

With respect to the tillage and weed control practices characterised by INRAE (2017, 2020), the only strategy considered to be in general use for the long-term management of weeds and their seed stocks in a given plot is the implementation of tillage strategies with an increased frequency of ploughing operations (deep tillage that turns over the soil) on a plot, given the strong correlation shown between this frequency and that of glyphosate use.

Name of use	Non-chemical methods	Description	General use?	Sources
Weed control of intercrops and set-aside land Crop destruction	Tillage strategy based on an increased ploughing frequency	Ploughing defined as deep tillage that turns over the soil	Yes	(INRAE, 2020) (ITA survey, 2019)
	Strategy of changing cultivation practices combined with mechanical methods	Increased use of false seedbeds, grazing of cover, later sowing, modified crop rotations Introduction of set-aside land to destroy perennials Deep tillage without turning over the soil, shallow tillage	No	(ITA survey, 2019; INRAE, 2020)

Table 3 - Non-chemical alternatives and situation regarding their use

2. Consideration of major practical or economic disadvantages

For each of the non-chemical prevention or control alternatives in general use, the practical and economic disadvantages were examined to identify whether the obstacles to making them available to all the farmers concerned could be considered to be major, and to set out the specific conditions for substituting glyphosate use by this alternative.

In this analysis, only one situation was identified.

Use in General treatments*Weed control*Intercropping, set-aside land and crop destruction

Intensified deep tillage is an alternative to the use of glyphosate in intercropping, which represents the bulk of the uses.

Do the identified non-chemical alternatives in general use have major practical or economic disadvantages?

Non-chemical methods in general use: case of tillage with increased ploughing frequency	
Practical disadvantages compared to chemical weed control	<p>Disadvantages related to the environment:</p> <ul style="list-style-type: none"> - difficulties tilling shallow stony soils (INRAE, 2020); - difficulty tilling and ploughing soils sensitive to excess water (hydromorphic and/or clayey), for destroying an intermediate crop or regrowth shortly before planting a crop in spring under wet conditions (high rainfall), given the limited number of days available for mechanical operations before sowing; - soil erosion risk in the event of a sharp increase in tillage and periods of bare soil (INRAE, 2020) in areas where there is a high erosion risk (INRA, 2017); - tillage less feasible on steep slopes (ITA survey, 2019; INRAE, 2020); - disruption of soil biological activity and increase in greenhouse gases (INRA, 2017), nitrate management (INRAE, 2020). <p>Disadvantages in terms of the effectiveness of operations:</p> <ul style="list-style-type: none"> - effectiveness uncertain on dicotyledonous species (ITA survey, 2019). <p>Disadvantages related to management of the farm:</p> <ul style="list-style-type: none"> - tillage offers slower and less practical solutions for "difficult" weeds and plots with high weed pressure (INRAE, 2020; ITA survey, 2019);

<p>Practical disadvantages compared to chemical weed control</p>	<ul style="list-style-type: none"> - an increased number of tillage operations that could lead to organisational difficulties, due to the need to coordinate labour and equipment requirements over a limited period of time, for example in the case of large farms with a large area to be sown within a short time window (INRAE, 2020; PV CSAMM); - more time spent on operations, with difficulties related to availability and training of a qualified workforce (INRAE, 2020); - difficulties related to changes in practices that require a reorganisation of work (INRAE, 2020); - difficulties accessing investment financing for equipment upgrades (INRAE, 2020); - complexity of implementing tillage requiring solid knowledge: many types of tillage operations each needing specific tools, and which need to be adapted according to the plot's soil conditions and weed flora (INRAE, 2020); - crop rotation changes that may be necessary in some cases, in order to spread tillage over a longer period, or when a crop can no longer be planted due to a lack of sufficiently effective weed control options (INRAE, 2020); - the particular case of direct sowing strategies: the reintroduction of tillage and ploughing in systems where there is currently no tillage at all (direct sowing under plant cover) calls into question this agronomic strategy and its environmental benefits (INRA, 2017).
<p>Economic disadvantages compared to chemical weed control</p>	<ul style="list-style-type: none"> - additional labour costs (INRAE, 2020) due to the increase in the number of tillage operations (INRA, 2017); - additional costs due to the cost of mechanisation and the need for specific tillage and ploughing equipment (INRAE, 2020; ITA survey, 2019); this is a major initial investment that can be difficult for farms in a challenging financial position; - additional cost due to extra fuel consumption; → <u>Overall additional average annual cost</u> estimated to be €80/ha (areas under direct sowing) and less than €10/ha (areas currently under occasional ploughing or with higher ploughing frequencies) (INRAE, 2020). - costs related to the transition phase from one practice to another, including learning and reorganisation of activities, and errors due to a lack of experience with the new practice (INRAE, 2020). Economic impact related to crop rotation changes and the incidence of constraints relating to days available for tillage (INRAE, 2020).
<p>Uncertainties</p>	<ul style="list-style-type: none"> - possible increase in herbicide use in crops if conditions prevent the necessary tillage from being carried out (ITA survey, 2019); - compatibility with the National Low-Carbon Strategy (SNBC)³, Ministry of Ecological and Inclusive Transition (MTES, February 2020), particularly in terms of the impact on greenhouse gas production (no quantified data) related to the increased number of passes: higher fuel consumption of between 1.84 L/ha and 30.55 L/ha depending on initial tillage practices (INRAE, 2020); - sufficient availability of suitable equipment, which depends on agro-equipment companies having enough supply capacity to meet increased demand in the short term.

Table 4 - Disadvantages of alternatives in general use

³ SNBC - points A2 and A4: With regard to agriculture, priority A2 stipulates reducing CO₂ emissions associated with fossil fuel consumption and developing the use of renewable energies, and priority A4 stipulates stopping the current release of carbon from agricultural soils and reversing the trend, in connection with the "4 per 1000, soils for food security and climate" initiative.

Note:

- the transition costs have not been taken into account in the estimate of the overall additional average annual cost (INRAE, 2020). The additional costs included only relate to the phase of proficient use of the new practices: additional costs due to increases in fuel, labour and mechanisation expenditure (i.e. investment costs, renewal, maintenance and depreciation of equipment);
- unlike the situations analysed in arboriculture or viticulture, tillage does not have a negative effect on yield due to a lack of control of flora in the event that glyphosate is phased out (INRAE, 2020).

In view of the information presented in Table 4, it seems that the non-chemical alternative identified in general use consisting of tillage with increased ploughing frequency may have practical and economic disadvantages compared to chemical weed control.

Insofar as the use of tillage enables effective weed control without a need for glyphosate, if the following crop is planted early enough after this tillage has taken place, **these disadvantages will not be considered to be major**, except in cases where tillage cannot be carried out, mainly in wet spring conditions in hydromorphic soils.

3. Consideration of minor uses and management of resistance

Is the use concerned:	Yes/No	Justify
by a minor use situation?	No	General treatments are not concerned by the minor/major distinction.
by management of resistance?	Not applicable	As it concerns non-chemical alternatives for prevention and control, an analysis of the chemical diversity of the active substances is not appropriate.

Table 5 - Minor uses and resistance

4. Risk comparison

Are the identified alternatives significantly safer for human or animal health or the environment?

Regulation (EC) No 1107/2009 stipulates that the identified alternatives are significantly safer if a significant difference in risk has been established between the substitutable product and these alternatives for the use in question. Annex IV to this Regulation sets out the methodology for carrying out this risk comparison.

This annex gives the following indications:

"The properties of the active substance and plant protection product, and the possibility of exposure of different population subgroups (professional or non-professional users, bystanders, workers, residents, specific vulnerable groups or consumers) directly or indirectly through food, feed, drinking water or the environment shall be taken into account [*by the competent authorities*]. Other factors such as the stringency of imposed restrictions on use and prescribed personal protective equipment shall also be considered. For the environment, if relevant, a factor of at least 10 for the toxicity/exposure ratio (TER) of different plant protection products is considered a significant difference in risk."

This shows that the idea of Regulation (EC) No 1107/2009 really is to assess and compare plant protection products. All the application guidance documents concern plant protection products, whether the active substance is a chemical or a micro-organism.

Although non-chemical alternative methods are cited in the Regulation, no method is given for assessing the risks associated with their use.

ANSES does not therefore have the tools or validated methodology needed for conducting an assessment to determine whether the non-chemical alternatives are significantly safer for human or animal health or the environment than a plant protection product.

5. Summary table

Can the use of glyphosate be substituted by an alternative non-chemical method?	Yes / No	Justify
General treatments*Weed control* Intercropping, set-aside land and crop destruction	No	⇒ Technical deadlocks identified in the following situations: <ul style="list-style-type: none"> - Conservation agriculture and farms practising direct sowing; - Control of perennial weeds and invasive plants; - Mandatory regulated control ⇒ Identified alternatives not considered to be in general use: change in cultivation practices combined with mechanical methods ⇒ Identified alternatives considered to be in general use: strategy based on increased ploughing frequency <ul style="list-style-type: none"> ⇒ For these alternatives, the practical disadvantages are considered to be major in the following case: <ul style="list-style-type: none"> - Spring crop planted after summer or early autumn ploughing in hydromorphic soils
	Yes	⇒ Identified alternatives considered to be in general use: strategy based on increased ploughing frequency <ul style="list-style-type: none"> ⇒ For these alternatives, practical or economic disadvantages were identified, but are not considered to be major in cases other than those listed above

General conclusion

Among all the uses of glyphosate in arable crops, the main use analysed was in intercropping.

For this use, situations of technical deadlock were identified for which tillage is a difficult alternative to implement:

- regarding exceptional situations where regulated control has to be implemented, for uses in intercropping, **substitution is not adopted**. It is therefore not proposed to apply any restrictions on use;
- regarding control of perennial and invasive weeds, they can be managed in the situations described below.

The non-chemical alternative to glyphosate identified was the implementation of tillage strategies based on increased ploughing frequency. Insofar as they can be considered practices in general use and do not have any major practical disadvantages in situations where deep ploughing is carried out in summer or autumn for the planting of a winter crop, or a spring crop on soils with good draining capacity, **the substitution of glyphosate by this non-chemical alternative can be considered**.

On the other hand, this substitution cannot be total insofar as major practical disadvantages were identified, mainly in the case of spring crops planted after summer or early autumn ploughing on hydromorphic soils.

With regard to conservation agriculture and plots where only shallow tillage is carried out, in view of the practical and economic disadvantages identified, it seems difficult to prohibit the use of glyphosate without a transitional period to allow new strategies to be developed. Indeed, today, the levers for achieving the ecosystem services offered by crop diversity, permanent cover and minimal soil disturbance, without the use of a systemic pesticide, have yet to be identified (INRAE, 2020). It seems necessary to maintain the possibility of using glyphosate on these plots.

However, a **reduction in the maximum application rate** could be considered, which would avoid the substance being used systematically and cover situations with high infestation levels or soil and climate conditions that are unfavourable for tillage (APAD, 2020). This limitation in the rate of glyphosate use could be part of a weed management strategy in combination with other non-chemical tools, including tillage (excluding ploughing), rolling and mulching of plants in intercrops and/or crops, or the use of modified agronomic practices (e.g. shifted sowing dates or longer rotations).

For the selected uses, it is proposed to reduce the maximum annual quantity of glyphosate to 1,080 g of active substance per ha, leading to a 62.5% reduction in the maximum annual quantity of glyphosate not to be exceeded per ha (2,880 g/ha), in accordance with the Opinion to MA holders of 8 October 2004.

Authorisations would therefore be granted for uses with a favourable conclusion after assessment.

Uses	Maximum rate and conditions of use
General treatments* Weed control* Intercropping, set-aside land and crop destruction	Product rate to be calculated according to the glyphosate content of the product based on a maximum rate of 1,080 g of glyphosate per hectare
	<u>Conditions of use:</u> Do not apply when ploughing has taken place prior to crop establishment, with the exception of spring crops planted after summer or early autumn ploughing on hydromorphic soils. Do not exceed the annual rate of 1,080 g of glyphosate per hectare.
	Product rate to be calculated according to the glyphosate content of the product based on a maximum rate of 2,880 g per hectare (see glyphosate opinion of 8 October 2004⁴)
	Only as part of regulated control.

⁴ Opinion to all holders of marketing authorisations for commercial products containing glyphosate (or N-(phosphonomethyl)glycine), French Official Journal No. 235 of 8 October 2004

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