European Commission

Combined Draft Renewal Assessment Report prepared according to Regulation (EC) N° 1107/2009
and
Proposal for Harmonised Classification and Labelling (CLH Report) according to Regulation (EC) N° 1272/2008

GLYPHOSATE

Volume 3 – B.3 (AS)

Rapporteur Member State: Assessment Group on Glyphosate (AGG) consisting of FR, HU, NL and SE

Version History

When	What
2021/06	Initial RAR

The RMS is the author of the Assessment Report. The Assessment Report is based on the validation by the RMS, and the verification during the EFSA peer-review process, of the information submitted by the Applicant in the dossier, including the Applicant's assessments provided in the summary dossier. As a consequence, data and information including assessments and conclusions, validated and verified by the RMS experts, may be taken from the applicant's (summary) dossier and included as such or adapted/modified by the RMS in the Assessment Report. For reasons of efficiency, the Assessment Report should include the information validated/verified by the RMS, without detailing which elements have been taken or modified from the Applicant's assessment. As the Applicant's summary dossier is published, the experts, interested parties, and the public may compare both documents for getting details on which elements of the Applicant's dossier have been validated/verified and which ones have been modified by the RMS. Nevertheless, the views and conclusions of the RMS should always be clearly and transparently reported; the conclusions from the applicant should be included as an Applicant's statement for every single study reported at study level; and the RMS should justify the final assessment for each endpoint in all cases, indicating in a clear way the Applicant's assessment and the RMS reasons for supporting or not the view of the Applicant.

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B.3. DATA ON APPLICATION

The applicant's summary document that this section of the RAR builds upon (M-CA, Section 3 Further information on the active substance, Rev 1, July 2020), started with the following statement and an overview table of reports submitted:

Glyphosate is the most utilized herbicide within the European Union (EU) for agricultural and amenity use and has become an integral part of many agricultural systems including Integrated Weed Management (IWM) programs. Glyphosate is unique in the way it offers systemic control of a broad spectrum of weed species, flexible usage, and is effective against a range of weed growth stages. It is important to point out that glyphosate acts as a post-emergence herbicide and is only taken up by the green parts of already emerged plants, thus enabling precision application to detected weeds. Glyphosate's mode of action is via inhibition of an enzyme (5-enolpyruvylshikimate-3-phosphate synthase (EPSPS)) that is present only in plants, fungi, and some bacteria. The active site of the EPSPS enzyme in plants is highly conserved and accounts for glyphosate's broad-spectrum weed control.

The utility of glyphosate has made it the most comprehensively studied herbicide, reflecting its wide range of uses. Uses include weed control in agriculture, forestry, residential, industrial, and aquatic situations. Glyphosate's unique properties make it ideally suited to promote conservation tillage, which is beneficial to nutrient cycling, reducing the demand for fertilizers, water regulation, reducing soil erosion, improving functional soil biodiversity, supporting cover crop management, and improving carbon sequestration.

In addition to data requirements stated in Annex to Commission Regulation (EU) 283/2013, the high value of glyphosate for society, agriculture in general and for Conservation Agriculture in particular is presented in this document [M-CA Section 3]. *The Glyphosate Renewal Group (GRG) worked with internationally recognised weed scientists as well as with agricultural consultancy companies to provide a number of overviews and review reports that cover the areas where glyphosate adds the most value, such as Integrated Weed Management, Good Agricultural Practice, Conservation Agriculture and control of invasive and noxious weeds. Field trial reports on the use of herbicides in precision application systems in agriculture and on railways are summarized. Additionally, the publicly available report from the International Union of Railways (UIC) is included.*

The following topics are considered:

Report title	***Short description of content***	***CA data point***
The agronomic benefits of glyphosate in Europe	*Overview of a detailed technical review of several use areas, describing the situations and problems, alternative non-chemical practices and the benefits of using glyphosate*	*CA 3.1*
Socio-economic value of glyphosate	*A review of 32 individual studies, covering the local agricultural conditions in France, Hungary, The Netherlands, Sweden, Germany, Italy, Poland and UK*	*CA 3.1*
A review to assess the efficacy or socio-economic benefits of non-chemical alternatives to glyphosate for weed control in Agriculture	*A review of 56 scientific literature publications covering laboratory and greenhouse experiments, how to use a range of weed control strategies to suppress weeds and favour crop growth, Integrated Weed Management (IWM), socio-economic and user attitude aspects*	*CA 3.1*
Conservation Agriculture: Judicious Use of Glyphosate in Integrated Weed Management	*Review report covering the principles of Conservation Agriculture, soil threats in Europe, benefits of Conservation Agriculture, weed management in Conservation Agriculture and alternatives to glyphosate, including results from a survey among 1,677 farmers from 21 countries about the use of glyphosate in Europe*	*CA 3.4*
Value of Glyphosate in the Railway	*Review report covering the vegetation management on*	*CA 3.4*

Report title	***Short description of content***	***CA data point***
Industry in Europe	*tracks, sealed surfaces and unsealed surfaces, the impact of poor vegetation control and an overview of methods of chemical application and alternative weed management practices*	
Guidelines, State of the Art and Integrated Assessment of Weed Control and Management for Railways	*Report from the International Union of Railways (UIC) covering the UIC guideline for Integrated Vegetation Management, the state of the art of vegetation control in European railways and an overview of methods of weed control*	*CA 3.4*
Integrated weed management of railways and the role of glyphosate in IWM	*Review report covering the current and potential methods for vegetation control and IWM on railway tracks, sealed and unsealed surfaces*	*CA 3.4*
Test of functioning of Smart Weeding System weed detection in Railway with automatic steering of spray nozzles - evaluation of weed detection accuracy from algorithm	*Trial reports to assess and validate the performance of weed detection on railways by the Smart Weeding System spray train*	*CA 3.4*
Smart weed spray concept	*Trial reports using advanced technological opportunities for weed detection / mapping and precision application for agricultural broad acre herbicide application, to achieve a reduction in herbicide volumes while maintaining high control levels*	*CA 3.4*
*Japanese knotweed (*Fallopia japonica*)*	*Summary on key findings of peer-reviewed field-trials on the herbicide control of Japanese knotweed, focussing on the unique efficacy of late season, glyphosate-based herbicide treatments as well as discussing alternatives*	*CA 3.5*
*Key aspects on the biology, impacts and control methods of giant hogweed (*Heracleum mantegazzianum*) in Europe*	*Overview of key aspects on the biology, impacts and control methods of giant hogweed in Europe*	*CA 3.5*
*Johnsongrass (*Sorghum halepense*) control and the role of glyphosate*	*Review report covering johnsongrass distribution, biology, ecology and impacts and the integrated management of this noxious weed with an emphasis on chemical control with glyphosate*	*CA 3.5*
*Non-chemical management of couch grass (*Elymus repens*) in European agriculture*	*Report covering couch grass biology, distribution, and impacts on crop production as well as alternatives to control couch grass, which are not as effective and easy to work with as glyphosate*	*CA 3.5*

Assessment and conclusion by RMS:

The RMS agrees that glyphosate has become an important part of current practices for the control of weeds and invasive species. However, considering that glyphosate is approved and authorisations of plant protection products containing glyphosate have been evaluated according to the Uniform Principles (Regulation (EC) No 546/2011), detailed data related to efficacy is not required at this stage. Furthermore, assessments of the value of active substances, socio-economic analyses or comparisons with chemical/non-chemical alternatives are not part of the assessment of applications for (renewal of) approval of active substances under Regulation (EC) No 1107/2009.

For the above reasons, the RMS did not evaluate the reports. Most of the reports are only briefly presented in this document. Reports describing why and how glyphosate is used, have been presented in some more detail.
It is acknowledged that all reports may be of interest in a wider context.

B.3.1. USE OF THE ACTIVE SUBSTANCE

The renewal submission involves a selection of representative crop related uses. The uses in the representative GAP cover uses as pre-sowing and pre-planting in vegetables and sugar beet, post-harvest, pre-sowing and pre-planting in vegetables and sugar beet, post-emergence of weeds in orchards, vines, vegetables, railroad tracks against emerged annual, biennial and perennial weeds as well as cereal volunteers (for post-harvest, pre-sowing, pre-planting). Moreover, uses as spot treatment against invasive species and in vegetables and sugar beet against couch grass are included. For details of the representative uses, see section 1.5.1 of Vol 1 of the RAR and the List of endpoints.

Studies submitted

Data point	EU data requirement No. 3.1/001
Report author	[redacted]
Report year	2010
Report title	The agronomic benefits of glyphosate in Europe Review of the benefits of glyphosate per market use
Report No.	Not available
Document No.	Not available
Guidelines followed in study	Not applicable
Deviations from current test guideline	Not applicable
Previous evaluation	Not previously submitted
GLP/Officially recognised testing facilities	Not applicable
Acceptability/Reliability	Not assessed since detailed data related to efficacy is not necessary for the assessment for renewal of approval of active substances under Regulation (EC) No 1107/2009 (SANCO/2012/11251 rev. 5, 22 March 2019).

Post-harvest use for perennial weed control at pre-plant of following crop
Perennial weeds including grasses like common couch (*Elymus repens*), johnsongrass (*Sorghum halepense*), bent grasses (*Agrostis* spp.), and broad-leaved species including docks (*Rumex* spp.), thistles (*Cirsium* spp.), common dandelion (*Taraxacum officinale*), sow thistles (*Sonchus* spp.) and tough to control weeds like field bindweed (*Convolvulus arvensis*), mugwort (*Artemisia vulgaris*), common horsetail (*Equisetum arvense*) can infest crops and cause yield loss.

At crop establishment, dense common couch populations strongly compete with the newly establishing crop for water, nutrients and space. In summer, perennial species have a large mass of lush green foliage, can grow to maturity above crop height and smother crops causing, in addition to yield loss, severe lodging with increased difficultly and cost of harvesting. With increased winter cropping across northern Europe, there is more pressure on farmers to establish crops in good time, particularly if ploughing. At times rainfall can make it difficult to get into fields during the autumn. Control of perennial weeds removes the absolute need to cultivate for weed control and facilitates crop establishment.

Post-harvest use for annual weed control pre-plant
Fields covered in the stubble of the previous crop or left bare before planting are often smothered by the rapid growth of volunteer crops (cereals/ oilseed rape), or weeds such as black-grass (*Alopecurus myosuroides*), wild oats (*Avena species*), brome grasses (*Bromus* spp.), rye grasses (*Lolium* spp.) that compete with the newly established crop and make selective weed control very difficult.

With the increased winter cropping of cereals and oilseed rape in a tight rotation, often using conservation tillage, there is even more risk of annual grass weed populations increasing.

Volunteer crops can smother a new crop and hinder its establishment, make harvest difficult, and reduce harvested grain quality by impurities.

Annual grasses currently represent a major challenge to combinable crops, as populations can increase after periods of poor weather with the associated poor in-crop level of control. Greater adoption of conservation tillage means good annual grass weed control is essential.

Post-plant pre-emergence
When the weather is too windy or wet to permit spraying pre-plant, or after ploughing, many growers do not spray out weeds and there is a considerable risk of annual grass and broadleaf weeds and volunteer crops establishing in the new crop.

Cultivations to establish a seedbed and even drilling can trigger weed seeds to germinate. Many crops, particularly under cool or dry conditions, can take a considerable period of 5 to 21 or more days to emerge, during which time well adapted weeds can germinate in huge numbers and quickly overwhelm arable and vegetable crops.

Some of the problems are:
- Transplanted weeds that survive a cultivation, as are already established, can quickly grow ahead of the newly planted crop competing for space, light and nutrients.
- A range of weed sizes makes timing of post-emergence sprays difficult and larger weeds are less susceptible to post-emergence herbicides so the level of weed control in crop is reduced.
- Weeds that germinate after planting can quickly smother a newly emerging crop and be difficult to control at post-emergence.
- The result is lower yields and higher weed seed return.

Orchards and Vines
Various perennial fruit crops that are grown on European farm land; of which olives are the biggest crop, are grown for many decades on the same plot of land, they can easily become infested with weeds, in particular perennial weeds, plus a wide variety of annual weeds.

In the first 3-5 years of establishment of a new vineyard or olive orchard, the vines and trees are most susceptible to weed competition and weed interference affects harvest and reduces productivity.

Some of the problems are:
- Weed competition for water and nutrients, and for light in the early 3-5 years after planting.
- Weeds reduce crop yield and impair crop quality.
- Reduced ground heat radiation and increased frost risk in orchards/ vineyards.
- Weeds around young trees provide cover for rodents that damage the young bark/ stems and such girdling can kill young, establishing plants.

Amenity and industrial weed control
Open spaces can be rapidly colonised by weeds from wind-blown seed. Less disturbance means bigger and more numerous weeds that spread seed rapidly to neighbouring land.

Weeds rapidly colonise new plantings of ornamentals or trees on bare sites, and if existing perennial weeds and grass vegetation is not cleared before planting, it can severely hamper establishment.

Some of the problems are:
- Weeds and invasive plants compete with ornamental and tree plantings for light, moisture and nutrients.
- Establishment and growth of new trees and shrubs will be stunted, affecting amenity improvement.

Railway track vegetation management
Railway track vegetation management was discussed in several more recent summaries (see section 3.4).

Invasive and noxious weed control
Some exotic species introduced to gardens across Europe have been very well adapted to local conditions and thrived to the extent that they are now classified as invasive species. They have colonised well beyond gardens to roadsides, watercourses, arable land, industrial land, waste land, hardstandings and around buildings such that they threaten drainage, building stability and damage roads and paths. These include Japanese knotweed (*Fallopia japonica*), Himalayan balsam (*Impatiens glandulifera*), pampas grass (*Cortaderia selloana*), rhododendron (*Rhododendron ponticum*) and Australian swamp stonecrop (*Crassula helmsii*).

Other weeds, classified as noxious are a nuisance through explosive seed production and spread resulting in potential human and livestock damage. These include docks (*Rumex* spp.), thistles (*Cirsium* spp.) and common ragwort (*Senecio jacobaea*).

Some of the problems are:

- Invasive weeds are often very vigorous and form dense stands and populations that out compete or cover native vegetation.
- Blocking drainage channels that increases flood risk.
- Damage to hard surfaces like roads and pavement, foundations of buildings and even floors by growth of Japanese knotweed.
- Human hazard: common ragweed (*Ambrosia artemisiifolia*) is a potent allergen causing hay fever across continental Europe. Giant hogweed sap is very irritating to human skin and eyes causing blistering and photo-sensitization.
- Risk: Obscured sight-lines on roads by large vegetation growth can cause traffic accidents.
- Damages pastures and decreases in farm productivity by docks and thistles.
- Invasive plants taken off site are classified as controlled waste and need a specially licensed and approved contractor and site for disposal, so costs can be very high.

Assessment and conclusion by RMS:
In the summary of [redacted] (2010) in document M-CA Section 3, the applicant focussed on the representative uses. This approach was also followed in the RMS' short summary above. [redacted] (2010) described also areas of use of glyphosate not included in the representative uses, e.g.:
- Pre-harvest perennial weed control in arable crops and grassland,
- Harvest management / crop desiccation in combinable crops,
- Crop desiccation in grain maize and sunflower,
- Grassland management and weed control,
- Forestry and Christmas trees.

See also section 3.5 on existing uses of glyphosate.

As indicated by its title, the report ([redacted] 2010) focussed on describing benefits of using glyphosate, e.g., in comparison with alternative methods to control weeds.

Detailed evaluation of efficacy and alternatives is not necessary for the assessment of applications for renewal of approval of active substances under Regulation (EC) No 1107/2009). Therefore, those aspects of the report are not presented above, and the report is only briefly presented. However, the report also presented a relevant overview of situations in which glyphosate is used.

Data point	EU data requirement No. 3.1/002
Report author	[redacted]
Report year	2020
Report title	Socio-economic value of glyphosate A review of EU studies assessing the value of glyphosate to the agriculture industry
Report No.	Not available
Document No.	Not available
Guidelines followed in study	Not applicable
Deviations from current test guideline	Not applicable
Previous evaluation	Not previously submitted
GLP/Officially recognised testing facilities	Not applicable
Acceptability/Reliability	Not assessed since data on socio-economic value is not part of the assessment under Regulation (EC) No 1107/2009.

[redacted] (2020) presents a review of existing socio-economic analyses and studies that relate to the social, economic and environmental impacts of a withdrawal of glyphosate to EU agriculture. The objective was to bring together existing information, aggregating information to the EU-28 level (Member States in

December 2019) and also to present information at the national level for the following Member States: France, Hungary, the Netherlands, Sweden, Germany, Italy, Poland and the UK. In total, 32 studies were assessed, which either had conducted a socio-economic impact assessment for the EU as a whole, or on one of the 8 identified countries.

The report presents consequences of a withdrawal of glyphosate at the EU level as estimated reduction in yield and production and associated cost, focussing on some major crops but discussing also impact on minor crops. Further, the report presents expected negative environmental impact of a potential withdrawal due to increased tillage practices, e.g. increased fuel consumption. Chemical and non-chemical alternatives and impact of a withdrawal on current production systems, practices and rotations are discussed.

Assessment and conclusion by RMS:
Evaluation of socio-economic value is not part of the assessment of applications for (renewal of) approval of active substances under Regulation (EC) No 1107/2009. The report ([redacted], 2020) is therefore only briefly presented here and not further considered.

The following error was noted in the report: In the Executive summary of the report it is stated that "The analysis specifically included studies from France, Hungary, the Netherlands and Sweden (the four member states who will be voting for re-approval of glyphosate in 2022) […]". This is not correct. A correct description of the four Member State's role is that we have formed the Assessment Group on Glyphosate (AGG) to act jointly as RMS in the evaluation of the application for renewal of the approval of glyphosate.

Data point	EU data requirement No. 3.1/003
Report author	[redacted]
Report year	2020
Report title	A review to assess the efficacy or socio-economic benefit of non-chemical alternatives to glyphosate for weed control in Agriculture
Report No.	Not available
Document No.	Not available
Guidelines followed in study	Not applicable
Deviations from current test guideline	Not applicable
Previous evaluation	Not previously submitted
GLP/Officially recognised testing facilities	Not applicable
Acceptability/Reliability	Not assessed since data on the efficacy or socio-economic benefit of alternatives is not part of the assessment under Regulation (EC) No 1107/2009.

A literature search was conducted by Bayer Agriculture BVBA to identify scientific literature on the efficacy or socio-economic benefit of non-chemical alternatives to glyphosate for weed control in agriculture. Total number of hits was 264. After a rapid screening for relevance, a list of 67 references was submitted to the author of the report for a detailed assessment. After scrutiny of the papers, 47 were identified as having high enough scientific quality and fulfilling the objective to deal with agriculture at large. Additional 9 papers were selected by the author, hence the review presents 56 papers.

The review summarises the articles identified, discusses the findings and takes note of difficulties in investigating alternatives to glyphosate. The review covers laboratory and greenhouse experiments on efficacy of alternatives; in field comparisons between agricultural practices and herbicides in cultivations of maize, soybean and cotton; in field comparison of different strategies for weed control in other crops; Integrated Weed Management (IWM); and finally, weed control, socio-economic and user attitude aspects.

Assessment and conclusion by RMS:
Evaluation of the efficacy or socio-economic benefit of non-chemical alternatives is not part of the assessment of applications under Regulation (EC) No 1107/2009. The report ([redacted] 2020) is therefore only briefly presented here, and not further considered.

B.3.2. FUNCTION

Herbicide.

B.3.3. EFFECTS ON HARMFUL ORGANISMS

Glyphosate is a post-emergence herbicide, taken up by green tissue of the leaves and stems of treated plants. It is transported systemically (via apoplastic and symplastic pathways) throughout the plant including the roots, rhizomes and stolons but especially to areas of metabolic activity within the plant (sinks), where it inhibits the shikimic acid pathway. Glyphosate is non-selective, hence used for the control of a broad range of annual, biennial and perennial monocotyledonous and dicotyledonous weeds. Treated plants show a gradual loss of green colour followed by death between one and four weeks later. The process is temperature related.

B.3.4. FIELD OF USE ENVISAGED

Commercial glyphosate products have registered uses in agriculture, horticulture, forestry, viticulture, amenity, weed control of non-cultivated areas, home and garden uses and aquatic weed control.

The renewal submission involves a selection of representative crop related uses. The uses in the representative GAP cover uses as pre-sowing and pre-planting in vegetables and sugar beet, post-harvest, pre-sowing and pre-planting in vegetables and sugar beet, post-emergence of weeds in orchards, vines, vegetables, railroad tracks against emerged annual, biennial and perennial weeds as well as cereal volunteers (for post-harvest, pre-sowing, pre-planting). Moreover, uses as spot treatment against invasive species and in vegetables and sugar beet against couch grass are included.

For details of the representative uses, see section 1.5.1 of Vol 1 of the RAR and the List of endpoints.

Studies submitted

Data point	EU data requirement No. 3.4/001
Report author	ECAF (European Conservation Agriculture Federation)
Report year	2020
Report title	Making Sustainable Agriculture Real in Europe with Conservation Agriculture: Judicious Use of Glyphosate in Integrated Weed Management
Report No.	Not available
Document No.	Not available
Guidelines followed in study	Not applicable
Deviations from current test guideline	Not applicable
Previous evaluation	Not previously submitted
GLP/Officially recognised testing facilities	Not applicable
Acceptability/Reliability	Not assessed since detailed data related to efficacy is not necessary for the assessment for renewal of approval of active substances under Regulation (EC) No 1107/2009 (SANCO/2012/11251 rev. 5, 22 March 2019).

Conservation Agriculture was (in accordance with FAO) described as an ecosystem approach to regenerative sustainable agriculture and land management based on the practical application of context-specific and locally-adapted three interlinked principles: (i) Continuous no or minimum mechanical soil disturbance, (ii) Permanent maintenance of a vegetative mulch cover on the soil surface, and (iii) Diversification of species in cropping system.

The report describes challenges to agriculture, the principles of Conservation Agriculture (CA), its environmental and economic benefits, the importance of Integrated Weed Management (IWM) in CA, and the

use of glyphosate and alternatives to glyphosate. To understand more reliably the use of herbicides, and specifically the use of glyphosate, in agriculture in Europe, the European Conservation Agriculture Federation (ECAF) conducted a survey in 2020. In total, 1,677 farmers from 21 countries responded. Of these, 26% use production systems that are able to meet the three principles of CA while the most common soil management system used was minimum tillage (55%). Percentage of farmers using glyphosate was similar regardless of soil management system. Pre-emergence and pre-sowing applications were reported as the most prevalent uses of glyphosate, accounting for 81%. According to the report, an increase of herbicide use is not taking place in CA, when compared to conventional tillage-based systems, but rather a change in timing of herbicide application: to pre-seeding control instead of post-emergence control, and glyphosate is the herbicidal active ingredient that is most frequently preferred for pre-seeding weed control. The main alternative to glyphosate would be intensified tillage, not in line with CA.

Assessment and conclusion by RMS:
Detailed evaluation of agricultural practices is not part of the assessment of applications for renewal of approval of active substances under Regulation (EC) No 1107/2009. The report (ECAF, 2020) is therefore only briefly presented here. However, the report also provides a relevant description of a situation in which glyphosate is used.

It is noted that the applicant referred to the report as [redacted] (2020) but the report's recommended reference was ECAF (2020).

Data point	EU data requirement No. 3.4/002
Report author	[redacted]
Report year	2019
Report title	Value of Glyphosate in the Railway Industry in Europe, Focus on France
Report No.	Not available
Document No.	Not available
Guidelines followed in study	Not applicable
Deviations from current test guideline	Not applicable
Previous evaluation	Not previously submitted
GLP/Officially recognised testing facilities	Not applicable
Acceptability/Reliability	Not assessed since data related to the value of active substances are not considered under Regulation (EC) No 1107/2009. Furthermore, data related to efficacy mainly referred to Nolte et al (2018), see below.

[redacted] (2019) is a review of existing reports on current methods of weed management using herbicides, and outlines the availability and effectiveness of potential alternatives to herbicides on European railways. The report considers the implications that a withdrawal of glyphosate would have on the European railway system, with a particular focus on France. Consideration is given to the cost of maintaining weed control at the levels currently achieved using glyphosate, and the implications of failing to achieve this level of control on railway safety, operational efficiency and environmental impact.

Assessment and conclusion by RMS:
For the review of methods, effectivity and alternatives, [redacted] (2019) mainly refers to the report by Nolte et al (2018). See below for a short presentation of Nolte *et al* (2018). Assessments of the value of active substances is not considered under Regulation (EC) No 1107/2009. The report ([redacted] 2019) is therefore only briefly presented here, and not further considered.

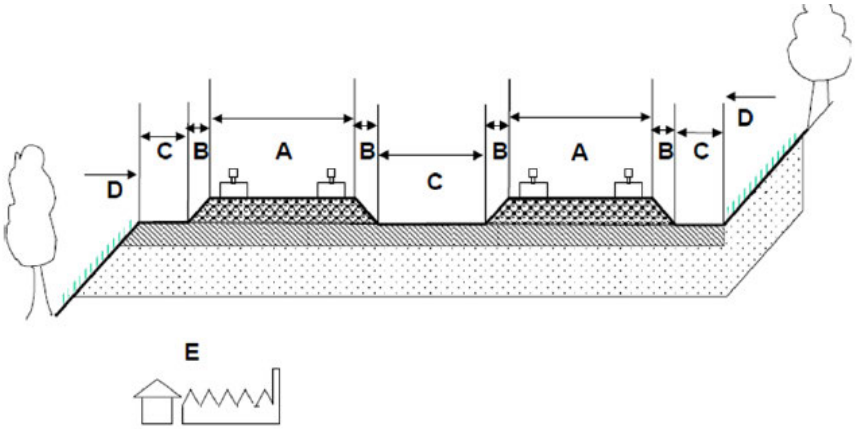
Data point	EU data requirement No. 3.4/003
Report author	Nolte R. *et al*
Report year	2018
Report title	Guidelines, State of the Art and Integrated Assessment of Weed Control and Management for Railways "HERBIE"
Report No.	Not available
Document No.	Not available
Guidelines followed in study	Not applicable
Deviations from current test guideline	Not applicable
Previous evaluation	Not previously submitted
GLP/Officially recognised testing facilities	Not applicable
Acceptability/Reliability	Not assessed since detailed data related to efficacy is not necessary for the assessment for renewal of approval of active substances under Regulation (EC) No 1107/2009 (SANCO/2012/11251 rev. 5, 22 March 2019).

The report is divided in parts A, B and C:

Part A - UIC[1] Guideline for Integrated Vegetation Management
Vegetation control on the premises of railway companies is governed by legislation and regulation from local to European level. The legislations and regulations are derived from four obligations for railway companies:
1. Safe and reliable railway operation
2. Prevent the endangerment of customers and personnel
3. Protecting the environment
4. Preventing negative impacts on neighbouring property.

For vegetation management on unsealed surfaces (embankments, unsealed paths, forest land, meadows, unsealed areas around stations etc.) and sealed surfaces (areas not directly linked to the track like paths, driveways, parking lots, station platforms etc.), the main methods applied are mechanical (such as mowing and mulching) or thermal. The only exceptions were described as certain pests and invasive species. For the railway tracks (ballast bed, slopes of the ballast bed, areas between tracks, and paths for maintenance/inspection etc.), the impact of vegetation was described in terms of risks to operational safety and reliability, reduced operational and technical performance, and reduced economic performance. A topic of increasing importance for railways is the control of invasive alien species. In the below figure, A, B and C represent the railway track area.

[1] UIC International Union of Railways, Paris, France



Zone	Name	Description
A	Ballast bed	Part of the track bed made of ballast or gravel including embedded sleepers or rails
B	Ballast shoulder	Part of the track bed covering the slopes on both sides of the ballast bed
A&B	Slab track	Concrete track bed construction
C	Transition area	Part of the track abutting the slope on both sides of the ballast bed, includes walking path for maintenance reasons/ Inspection walk way and areas between two tracks (double and more lines). Drainage ditches are also built in Area C in some cases.
D	Embankment	The slopes alongside the track away from the track adjoining Area C
E	Outside the track area	All other areas not directly linked with the track such as paths, areas around power supply stations, loading areas, station platforms, parking sites

Figure 3.4-1: Schematic representation of application areas for vegetation control methods. From [redacted] 2019. Similar figures were presented also in Nolte *et al*, 2018.

Preventive measures focus on avoidance or restriction of colonization from neighbouring unsealed and sealed surfaces by regular mowing and mulching of weeds and shrubs and cutting of trees and tree-like shrubs in these areas in combination with continuous monitoring of the status of vegetation growth and the assessment of its impact. At certain threshold values of vegetation cover, control measures are activated. The report stated that non-chemical vegetation control measures should be the first priority for the track area but that currently there is no cost efficient alternative to chemical measures. The most efficient and therefore most common method for the application of herbicides for the track area is the use of spraying trains. Drift of herbicides into adjacent areas is minimized by special design of the injectors producing big and heavy enough droplets, by limiting the operational speed of the trains (usually to 50 km/h), addition of wetting agents and by avoiding the application if strong cross winds are present. The dosage has to be limited to the absolutely necessary level. Adjustment of dose is currently either done manually (on view) – or automatically based on plant detection. The frequency is restricted to one or – for problem zones – to maximum two treatments per year.

Part B - State of the Art of Vegetation Control

Herbicides on railways are used for the sole purpose of providing safe and efficient operation by keeping tracks and other operational areas free of weeds, and accounts for <1% of the total amount of herbicides sold annually in Europe. Within the framework of a project ("Herbie") a survey on the state of the art of vegetation control and management of European Railways was performed in 2017, in which 15 European railway companies responded covering 83.3% of EU 27 total track. The survey identified application of herbicides as the most important single method – more than 90% of the railway tracks (A-C) covered by the survey are treated with herbicides. Only 4% of the tracks are treated mechanically and only 1% have very low needs for treatment because of constructive measures. Use of herbicides is restricted/forbidden for certain areas, e.g., water protection areas or nature reserves. Automatic plant detection with closure of nozzles if there is no or only marginal plant growth detected was reported as a current state of the art method to reduce the amounts of herbicides needed for the track area. Hence, the reported "treated track km" in the survey does not mean that the every km is actually treated. Glyphosate was described as the most important and universally used active substance. According to the report,

the use of herbicides on sealed (E) and unsealed surfaces (D, E) is restricted and expected to be further restricted and diminished.

Part C - Assessment and recommendations
A multidimensional socio-economic and ecological assessment of different vegetation control methods (with and without herbicides) was carried out in order to:
- Identify the sustainability and performance of different methods
- Rank methods according to their performance
- Identify the methods with the highest performance and development potentials.

The assessment focused on methods for weed control for the track area. Methods with a potential for future development were identified but at the current state of development and automation levels, it was concluded that alternative measures cannot compete economically and performance-wise with herbicides.

Assessment and conclusion by RMS:
Detailed evaluation of efficacy and alternatives is not necessary for the assessment of applications for renewal of approval of active substances under Regulation (EC) No 1107/2009). Socio-economic analyses (Part C of the report) are not considered under the Regulation. Those aspects are therefore not presented above and Nolte *et al* (2018) is only briefly presented. However, the report also provide a relevant description of the use of glyphosate in railway areas.

Data point	EU data requirement No. 3.4/004
Report author	[redacted]
Report year	2019
Report title	Integrated weed management of railways and the role of glyphosate in IWM
Report No.	Not available
Document No.	Not available
Guidelines followed in study	Not applicable
Deviations from current test guideline	Not applicable
Previous evaluation	Not previously submitted
GLP/Officially recognised testing facilities	Not applicable
Acceptability/Reliability	Not assessed since detailed data related to efficacy is not necessary for the assessment for renewal of approval of active substances under Regulation (EC) No 1107/2009 (SANCO/2012/11251 rev. 5, 22 March 2019).

This report described railway construction, vegetation and the need for control, current methods for vegetation control and potential methods for vegetation control having high or moderate potential for development. These sections mainly referred to Nolte *et al* (2018), see above.

The report also described the principles of Integrated Weed Management (IWM) and presented a framework for IWM. Different IWM protocols were developed, adapted from Nolte *et al* (2018) for different parts of the railway area: Railway track areas (A-C in Fig 3.4-1), Unsealed surfaces (D and E) and Sealed surfaces (E). For each, the specific needs and requirements were described, and the following steps described:
- Monitor, identify and assess
- Prevention
- Set an action threshold
- Control
- Re-evaluation.

For the railway track areas, the report stated that in the absence of currently viable alternatives the main focus at present is on targeting traditional herbicides so they are only applied where needed. The key equipment used for this process, automatic plant detection systems mounted on the spray train, was described. The need to keep herbicide modes of action was mentioned, since resistant populations can quickly spread along railway networks.

Assessment and conclusion by RMS:
Detailed evaluation of management practices is not necessary for the assessment of applications for renewal of approval of active substances under Regulation (EC) No 1107/2009. The report ([redacted] 2019) is therefore only briefly presented herein. However, the report also provides a relevant description of a situation in which glyphosate is used.

Data point	EU data requirement No. 3.4
Report author	Document M-CA Section 3; summaries of developments in technology
Acceptability/Reliability	Not assessed since data on technology for weed detection and precision of spraying is not necessary for the assessment for renewal of approval of active substances under Regulation (EC) No 1107/2009.

Test of functioning of Smart Weeding System weed detection in Railway with automatic steering of spray nozzles - evaluation of weed detection accuracy from algorithm
Two trials with the objective to assess and validate the performance of weed detection by the Smart Weeding System spray train were reported. In the first trial the focus was on the accuracy of plant identification by the algorithm and evaluation of the spraying event with automatic steering of spray nozzles. The second trial validated the performance of the weed detection system from the smart weeding system train as a whole and measured the accuracy of the automatic steering of spray nozzles following implementation of improvements.

Smart weed spray concept
Smart spraying techniques in agriculture was addressed. One of the objectives of the smart weed spray concept is to find advanced technological opportunities for localized treatment applications to achieve highly efficient, highly efficacious and sustainable herbicide use. The following was highlighted: the development of weed maps as a customer service to identify the areas and even individual plants to treat, the cost savings of locally targeted weed spraying, and ecological aspects of reduced herbicide use.

Detection Systems (Drones and/or Satellites for Imagery, WeedSeeker®) and Application Systems (Drone Sprayer, conventional Sprayer with single Nozzle Control or Section Control)
Techniques for weed detection and for adjustment of spraying (site and volume) in agriculture were addressed. The main idea is to spray weed patches only and/or adjust herbicide applications according to weed density or weed species composition. The process includes three steps:
- weed detection through specific sensors to provide real-time information for the weeding process or to generate weed maps for later intervention,
- decision-making processes to decide on an action for weeding based on the previously detected information and farmer experience and allow the correct intervention at the correct time,
- execution of the weeding decision via an actuator (variable rate application of herbicide) to apply just the amount needed to just the right spot.

Trials with different crops conditions, target weeds and equipment were summarised with savings of herbicide amount or reduction of area treated reported. The summary noted that further development and combination of various sensing techniques have the potential to increase the possibility of differentiation between grasses and broad-leaved weeds, or even different weed species. This would further improve automated, targeted weed spraying. Increasing accuracy of both the imagery created and the application technique contains a high potential to reduce herbicide amount in the future.

Assessment and conclusion by RMS:
Assessments of technology for weed detection and precision of spraying are not considered under Regulation (EC) No 1107/2009. These data are therefore only briefly presented here, and not further considered.

B.3.5. HARMFUL ORGANISMS CONTROLLED AND CROPS OR PRODUCTS PROTECTED OR TREATED

The major existing and registered uses of glyphosate products are listed in the table below. Not all of these uses are part of the representative use GAP in this renewal dossier (see first paragraphs of section 3.4).

Table 3.5-1: General overview of the major existing and registered uses of glyphosate products. From document M-CA Section 3.

Crop	Existing uses	Target organisms
All crops[1]	Pre-planting of crop	Emerged annual perennial and biennial weeds
All crops[1]	Post- planting pre-emergence of the crop	Emerged annual perennial and biennial weeds
Cereals, peas and beans, oilseed rape/flax/mustard and linseed	Pre-harvest	Emerged annual perennial and biennial weeds
Orchard crops, vines, including olives, citrus and tree nuts	Directed spray applications under foliage around the base of the trunk and inter-row	Emerged annual perennial and biennial weeds
Forestry and ornamentals	Pre-planting (preparation of nurseries and post planting around the trunk (after woody stem development) and/or inter-row with shielded spray over the top applications of selected conifer species when dormant	Emerged annual perennial and biennial weeds
Industrial and amenity	Road, railways, industrial sites	Emerged annual perennial and biennial weeds
Lawn and garden	Landscape renovation, selective treatment in gardens and backyards, terraces and yard paths	Emerged annual perennial and biennial weeds
Aquatic uses	Application during active weed-growth period	Floating and emergent weeds
Tree stumps	Brush-application (of stump surface) + tree injection	Prevent shoots from re-emerging

1 All seeded or transplanted crops, including but not restricted to root and tuber vegetables, bulb- and stem vegetables, field vegetables (fruiting vegetables, brassica vegetables, leaf vegetables and fresh herbs, legume vegetables), pulses oil seeds, cereals, sugar- and fodder beet.

Details of harmful organisms against which protection is afforded

Glyphosate controls the most important annual dicot species like *Chenopodium album*, biennial species such as *Cirsium* spp., and perennial broadleaved weeds such as *Rubus* spp. In addition, glyphosate controls annual monocot species such as *Alopecurus myosuroides* and perennial grass weeds including *Sorghum halepense* and *Elymus repens* in stubble, cereals, peas, bean, oilseed rape, flax, mustard, orchards, pasture, forestry and industrial weed control. Glyphosate is also used to control invasive plants that have been introduced in Europe such as *Fallopia japonica* and *Heracleum mantegazzianum*.

The applicant submitted reports on biology and treatments of some of these plants, presented below.

Studies submitted

Japanese knotweed (*Fallopia japonica*)

Data point	EU data requirement No. 3.5/001, 3.5/002, 3.5/003
Report author	[redacted]
Report year	2019
Report title	Three separate reports: Japanese knotweed - Literature Review – Part A Japanese knotweed - Treatment Sustainability Index – Part B Japanese knotweed - Europe and North America – Part C
Report No.	Not available
Document No.	Not available
Guidelines followed in study	Not applicable
Deviations from current test guideline	Not applicable
Previous evaluation	Not previously submitted
GLP/Officially recognised testing facilities	Not applicable
Acceptability/Reliability	Not assessed since detailed data related to efficacy is not necessary for the assessment for renewal of approval of active substances under Regulation (EC) No 1107/2009 (SANCO/2012/11251 rev. 5, 22 March 2019).

Introduction: Today, the invasive alien plant (IAP) Japanese knotweed (introduced in Europe in the 19th century) is widely spread across numerous countries in Europe with a significant population in UK. In contrast to weed control in agricultural systems, control of IAPs is commonly undertaken in less intensively managed systems or unmanaged areas, such as abandoned agricultural land, riparian areas and brownfield sites. Consequently, IAP establishes and subsequent development progresses unhindered. Japanese knotweed produces an extensive network of rhizomes that may extend underground for ≤20 m from the main stand and commonly penetrate deeply into the soil. Japanese knotweed rhizomes rapidly accumulate and store large quantities of carbohydrates and may remain alive for decades. Therefore, IAP control methods which frequently are directed against large, well-established plants may permit recovery from a sublethal herbicide application. Consequently, many weed control methods used in agronomic settings, including those based on herbicides, cannot be directly transferred for the effective control of IAPs. The species can regenerate directly from tiny pieces of rhizome and also from cut stems and leaves. As a result, it is very easy to inadvertently spread knotweed, particularly when moving knotweed contaminated soil. Japanese knotweed is not on the EU list of Invasive Alien Species of Union Concern, regulated under Regulation EU) No 1143/2014. This is due to the legislation focusing on prevention and early detection, whereas Japanese knotweed is already well established and is already widespread in many member states.

Part A: This is a literature review covering nomenclature, taxonomy and ecology of Japanese knotweed, "best practice" guidances from the UK, followed by a review of the grey literature and academic research on chemical and physical treatments, a review of the principal pieces of legislation and relevant common laws cases in the UK concerning Japanese knotweed control, treatment and enforcement, brief summary of the main international agreements on preventing the spread of invasive alien plants, and, finally, a summary of a large peer-reviewed field-trial on the herbicide control of Japanese knotweed, highlighting the key findings of the paper, focussing on the efficacy of late season, glyphosate-based herbicide treatments.

Part B: Describes and evaluates different methods to control Japanese knotweed using a simple evaluative tool that considers a range of technical, cost, and ecological criteria in a sustainability index. The report concludes that effective chemical control of Japanese knotweed relies entirely on the use of glyphosate-based treatment protocols. Finally, the effects of a potential withdrawal of glyphosate (e.g. for the amenity sector and property market) are discussed.

Part C: Uses the UK as a general, worst-case example and presents the invasion curve as a general model of invasive plant species spread as well as a series of national case studies of Japanese knotweed invasion in Europe

and the US. It also summarises the overall stage of invasion, pertinent dates and vectors of introduction, range and distribution and highlights key recommendations in national guidance.

Assessment and conclusion by RMS:
Detailed evaluation of management practices and comparison of different methods etc. is not necessary for the assessment of applications for renewal of approval of active substances under Regulation (EC) No 1107/2009. The report ([redacted] 2019) is therefore only briefly presented herein. However, the report also provides a relevant description of one of the harmful organisms controlled.

Giant hogweed (*Heracleum mantegazzianum*)

Data point	EU data requirement No. 3.5/004
Report author	[redacted]
Report year	2020
Report title	Key Aspects on the Biology, Impacts and Control Methods of Giant Hogweed (*Heracleum mantegazzianum*) in Europe
Report No.	Not available
Document No.	Not available
Guidelines followed in study	Not applicable
Deviations from current test guideline	Not applicable
Previous evaluation	Not previously submitted
GLP/Officially recognised testing facilities	Not applicable
Acceptability/Reliability	Not assessed since detailed data related to efficacy is not necessary for the assessment for renewal of approval of active substances under Regulation (EC) No 1107/2009 (SANCO/2012/11251 rev. 5, 22 March 2019).

The report describes the biology of Giant hogweed (*Heracleum mantegazzianum*), its health hazards, impact and methods for control. The species was introduced into Britain at the end of the 19th century. It is easily spread via its seeds and now widespread throughout Europe. Giant hogweed and its relatives can be found primarily on riverbanks and in drainage ditches, forests, orchards, vineyards, and non-agricultural areas but are rarely found on arable crop land due to frequent cultivation. Giant hogweed found in pasture can become a hinderance for grazing animals. The sap of the plant can cause severe phytophotodermatitis on human skin, and this problem of poisoning appears to be increasing. Due to its size (it can grow up to 5 m tall with dark green, deeply lobed leaves up to 1 m across) the plant overshadows and suppress other vegetation. Giant hogweed and its close relatives are on the EU list of Invasive Alien Species of Union Concern, which are regulated under Regulation EU) No 1143/2014. According to the report, spraying with glyphosate is the most efficient method to achieve good control compared to manual and mechanical control methods.

Assessment and conclusion by RMS:
Detailed evaluation of management practices and comparison of different methods etc. is not necessary for the assessment of applications for renewal of approval of active substances under Regulation (EC) No 1107/2009. The report [redacted], 2020) is therefore only briefly presented herein. However, the report provides a relevant description of one of the harmful organisms controlled.

Johnsongrass (*Sorghum halepense*)

Data point	EU data requirement No. 3.5/005
Report author	Travlos I.S. *et al*
Report year	2019
Report title	Key Aspects on the Biology, Ecology and Impacts of Johnsongrass [*Sorghum halepense* (L.) Pers] and the Role of Glyphosate and Non-Chemical Alternative Practices for the Management of this Weed in Europe
Report No.	Not available
Document No.	Not available
Guidelines followed in study	Not applicable
Deviations from current test guideline	Not applicable
Previous evaluation	Not previously submitted
GLP/Officially recognised testing facilities	Not applicable
Acceptability/Reliability	Not assessed since detailed data related to efficacy is not necessary for the assessment for renewal of approval of active substances under Regulation (EC) No 1107/2009 (SANCO/2012/11251 rev. 5, 22 March 2019).

This article describes the distribution, biology, ecology and impacts of Johnsongrass and different methods for control. The species is one of the most common and troublesome weeds in a wide range of field crops but also in several perennial crops. Johnsongrass can reproduce via seed through self- or cross-pollination and vegetatively via an extensive rhizome network. It is highly competitive, due to, e.g., the ability to photosynthesize efficiently at high temperatures and drought-resistance of plants originating from rhizomes. A high level of allelopathic activity has been found in the root exudates of *S. halepense* and the presence of the plant in the field can cause allelopathic effects on several subsequent crops like soybean and maize.

Management of Johnsongrass requires effective control of both the plants emerged from seeds and those plants emerged from rhizomes. Integrated weed management systems combining several weed control methods including chemical, non-chemical, and agronomic tools are discussed. The author stated that preventive, cultural, mechanical, and chemical methods should be used together in a consistent, integrated program - but that adequate control of *S. halepense* is very difficult without the use of herbicides. Johnsongrass has developed resistance to several herbicides, with the majority of the cases being selective herbicides. The role of glyphosate, being non-selective and systemic (controlling both seedlings and rhizomes) was highlighted and illustrated with studies from Hungary, Spain, Serbia and Greece. Non-chemical methods were also discussed. The author recommended the adoption of integrated weed management (IWM) techniques such as glyphosate use coupled with crop rotation and deep tillage.

Assessment and conclusion by RMS:
Detailed evaluation of management practices and comparison of different methods etc. is not necessary for the assessment of applications for renewal of approval of active substances under Regulation (EC) No 1107/2009. The report (Travlos *et al*, 2019) is therefore only briefly presented herein. However, the report provides a relevant description of one of the harmful organisms controlled.

Couch grass (*Elymus repens*)

Data point	EU data requirement No. 3.5/006
Report author	[redacted]
Report year	2020
Report title	Non-chemical management of couch grass (Elymus repens) in European agriculture
Report No.	Not available
Document No.	Not available
Guidelines followed in study	Not applicable
Deviations from current test guideline	Not applicable
Previous evaluation	Not previously submitted
GLP/Officially recognised testing facilities	Not applicable
Acceptability/Reliability	Not assessed since detailed data related to efficacy is not necessary for the assessment for renewal of approval of active substances under Regulation (EC) No 1107/2009 (SANCO/2012/11251 rev. 5, 22 March 2019).

Couch grass (*Elymus repens* (L.) Gould) is a highly competitive, allelopathic, perennial grass with a rapidly expanding rhizome network. It is present in most of the temperate regions of the and is a common and aggressive grass species Northern Europe. This literature review aimed to determine what non-chemical tools and strategies are available or currently being developed for managing couch grass in different cropping systems in European agriculture. The main point of comparison was the most common chemical control method, i.e. glyphosate. Different treatment regimes with glyphosate were also discussed. The main control treatments against *E. repens* are glyphosate or intensive tillage in the intercrop period, or selective herbicides in dicot crops. The author stressed that a systematic approach and a diverse set of weed control tools with different modes of action (both chemical and non-chemical) are needed to achieve resource efficient control of not just *E. repens*, but other perennial weeds and the weed flora as a whole.

Assessment and conclusion by RMS:
Detailed evaluation of management practices and comparison of different methods etc. is not necessary for the assessment of applications for renewal of approval of active substances under Regulation (EC) No 1107/2009. The report ([redacted], 2020) is therefore only briefly presented herein. However, the report provides a relevant description of one of the harmful organisms controlled.

B.3.6. MODE OF ACTION

In plants glyphosate inhibits the shikimic acid pathway. Glyphosate binds to and blocks the activity of its target enzyme EPSPS (5-enolpyruvylshikimate-3-phosphate synthase), an enzyme of the aromatic amino acid biosynthetic pathway. The inhibition of the enzyme prevents the plant from synthesizing essential aromatic amino acids (phenylalanine, tryptophan and tyrosine) needed for the production of proteins, auxin, phytoalexins, folic acid, lignin, plastoquinones and many other secondary products. EPSPS is present in all plants and some bacteria and fungi but does not exist in animals including humans.

B.3.7. INFORMATION ON THE OCCURRENCE OR POSSIBLE OF THE DEVELOPMENT OF RESISTANCE AND APPROPRIATE MANAGEMENT STRATEGIES

According to EPPO guideline PP 1/213 “Resistance risk analysis”, resistance is the naturally occurring, inheritable adjustment in the ability of individuals in a population to survive a plant protection product treatment that would normally give effective control.

The applicant gave examples of their management strategies to minimize the development of resistance; e.g. to continually evaluate their recommendations for weed control and to support research.

Mode of Action
Glyphosate is classified by HRAC (Herbicide Resistance Action Committee) within group G (Inhibition of EPSP synthase, see section B.3.6) and classified by the new HRAC (2019) in group 9.

The mode of action of glyphosate is unique, which provides an alternative solution to control weeds and plays a role to manage the development of resistance of weeds to other chemical herbicide with a different mechanism of action.

Resistance mechanism
For many European *Lolium* spp. and *Conyza* spp. biotypes, the mechanism of resistance is either unknown or has not been entered in the global herbicide resistance database (weedscience.org/Home.aspx). *Lolium* spp. and *Conyza* spp. resistant to glyphosate are found in many other world regions and the mechanisms of resistance studied are concluding to a similar outcome. A few European studies of this nature have been conducted and conclusions are coherent with outcomes of studies in other world areas. Studies on the mechanism of resistance of the HRAC Group G or 9 (according to the new classification) resistant Italian Ryegrass and Rigid Ryegrass from Spain indicate that resistance might be attributed to altered translocation. Studies on the mechanism of resistance of the HRAC Group G or 9 resistant Rigid Ryegrass from Italy indicate that resistance might be attributed to an altered target site, sequestration or not known. Studies on *Conyza* spp. in Greece provided indications of changes in translocation. A recent publication shows that enhanced metabolism of glyphosate in *Echinochloa colona* is the mechanism of resistance to glyphosate in this weed (in Australia). Scientific work from other world regions on *Lolium* spp. and *Conyza* spp. indicate that the reduced efficacy can be a combination of the different mentioned mechanisms of resistance. The applicant listed 18 references on mechanisms of resistance. The references were not submitted, nor requested by the RMS, as the information from the global herbicide resistance database is considered as sufficient.

Evidence of weed resistance cases
Europe
The first case of reported resistance to glyphosate in Europe was recorded in 2004 for *Conyza bonariensis* in orchards in Spain. In Europe there are confirmed glyphosate resistance cases reported for *Conyza* spp. and *Lolium* spp., and recently a resistance case for *H. murinum* subsp. *leporinum* was reported from Spain[2]. This was the first reported case of glyphosate resistance in this subspecies in the world. Only two confirmed cases (*Lolium* spp.) have been reported in European arable crops (wheat). The below table summarises the confirmed cases of glyphosate resistance in weeds in Europe. In March 2021, the applicant informed about new cases of resistance in three additional species[3]: *Bromus madritensis* and *Bromus rubens* in Spain, and *Eleusine indica* in Italy. The case in *Bromus madritensis* in Spain was the only case of resistance in this species reported at weedscience.org/Home.aspx.

The applicant stated “Root cause analyses indicates that all cases of commercial evolved resistance can be brought back to over-usage of glyphosate in combination with not respecting the label recommendation (weed stage, repeated reduced rates of application). Attractive cost, application flexibility and high efficacy performance did result in overreliance on glyphosate and not in the appropriate implementation of integrated weed management practices. As the above was most applicable to the perennial crop situations in Europe, it does lead to the fact that all (but two) reported and confirmed cases of *Lolium* spp. and *Conyza* spp. resistance are found in European perennial crop situations or railways.”

[2] weedscience.org/Home.aspx and
Vázquez-García et al (2020) Agronomy 2020, 10, 992; doi:10.3390/agronomy10070992
[3] weedscience.org/Home.aspx and (Italian case) article at https://www.mdpi.com/2073-4395/10/11/1692

Table 3.7-1: Weeds resistant to EPSP synthase inhibitors (HRAC Group G or 9) in Europe. From document M-CA, Section 3, modified by RMS.

No.	Species	Years, Countries, Situations	First Year
1	*Conyza bonariensis* Hairy Fleabane	2004 - Spain, 1 case in orchards 2010 - Greece, 1 case in orchards 2010 - Portugal, 1 case in orchards	2004
2	*Conyza canadensis* Horseweed	2006 - 2009 Spain, 2 cases in orchards 2007 - Czech Republic, 1 case on railways 2010 - Poland, 1 case on railways 2011 - Italy, 1 case in orchards 2011 - Portugal, 1 case in olives 2012 - Greece, 2 cases in grapes and orchards 2016 - Hungary, in vineyards 2019 - France, in vineyards[3]	2006
3	*Conyza sumatrensis* Sumatran Fleabane	2009 - Spain, 1 case in orchards 2010 - France, 1 case in vineyards 2012 - Greece, cases in vineyards and orchards 2016 - France Multiple – 2 SOA's, in grapes[1]	2009
4	*Lolium perenne* Perennial Ryegrass	2013 - Portugal in vineyards	2013
5	*Lolium perenne* ssp. *multiflorum* Italian Ryegrass	2006 - Spain, in orchards 2008 - Italy Multiple - 2 SOA's, arable crop[1] 2011 - Switzerland in orchards 2012 - Italy Multiple - 2 SOA's, arable crop[1] 2020 - Germany in orchard [2]	2006
6	*Lolium rigidum* Rigid Ryegrass	2005 - France, 1 case in grapes and orchards 2006 - Spain, 1 case in orchards 2007 - Italy, 1 case in grapes and orchards 2016 - Spain Multiple – 2 SOA's, 1 case in olives[1] 2016 - Greece, 1 case in orchards	2005
7	*Hordeum murinum* subsp. *leporinum* False barley or Wall barley	2018 - Spain, in orchards and olives[4]	2018
8	*Bromus madritensis* Compact Brome	2018 - Spain in grapes and olives[5]	2018
9	*Bromus rubens* Red Brome	2018 - Spain in orchards, almonds and olives[5]	2018
10	*Eleusine indica* Goosegrass	2019- Italy, in nurseries[5]	2019

1 SOA - Site of Action, see Table below.
2 Resistance recently confirmed by [redacted] but not yet published.
3 Added by RMS. Reported by the applicant in July, 2020. See also weedscience.org/Home.aspx.
4 Added by RMS. Reported by the applicant in July, 2020, and in Vázquez-García et al (2020) Agronomy 2020, 10, 992; doi:10.3390/agronomy10070992. See also weedscience.org/Home.aspx.
5 Added by RMS. Reported by the applicant in March, 2021 and (Italian case) at https://www.mdpi.com/2073-4395/10/11/1692. See also weedscience.org/Home.aspx.

Globally
To date (October, 2020), 50 different species/sub-species have been confirmed as having weed populations resistant to glyphosate (weedscience.org/Home.aspx summary sheet "Glyphosate Resistant Weeds"), but all cases may not necessarily have an agronomic impact. The first glyphosate resistant population was identified in 1996 in Australia.

Cross-resistance and multiple resistance
There are no reported cases of confirmed cross-resistance to glyphosate globally (weedscience.org/Home.aspx).

There are cases of resistance to multiple sites of herbicide action reported for glyphosate resistant *Lolium* spp. and *Conyza* spp. in Europe, see below table.

Table 3.7-2: Cases of multiple resistance reported for glyphosate resistant *Lolium* spp. and *Conyza* spp. in Europe. From document M-CA Section 3. Slightly modified by the RMS.

Country	Species	Year	Details
Italy	*Lolium perenne* ssp. *multiflorum* Italian Ryegrass	2008	Multiple Resistance: 2 Sites of Action ACCase inhibitors (Group A/1) EPSP synthase inhibitors (Group G/9)
		2012	Multiple Resistance: 2 Sites of Action ALS inhibitors (Group B/2) EPSP synthase inhibitors (Group G/9)
France	*Conyza sumatrensis* Sumatran Fleabane	2016	Multiple Resistance: 2 Sites of Action ALS inhibitors (Group B/2) EPSP synthase inhibitors (Group G/9)
Spain	*Lolium rigidum* Rigid Ryegrass	2016	Multiple Resistance: 2 Sites of Action PPO inhibitors (E/14) EPSP synthase inhibitors (G/9)

Sensitivity data
The applicant stated: "Glyphosate has been applied to large areas of farmer's fields for more than 40 years suggesting that shifts in sensitivity both between and within populations have already occurred. Baseline data from which to detect shifts in sensitivity are consequently not applicable. Sensitivity data have been generated as reference to confirm specific cases of resistance of *Conyza sumatrensis*, *C. bonariensis*, *C. canadensis* and *Lolium rigidum* in southern Europe." The applicant further mentioned their work to follow up cases of lack of expected performance or reduced sensitivity. New confirmed cases of resistance are reported to authorities in accordance with Article 56 of the Regulation EC/1107/2011.

Monitoring of resistance based on analysis of field efficacy failure should be requested at national level.

Use pattern
In the absence of resistance, strict adherence to the labelled rates and application conditions should be followed for optimum effect for each registered/approved use.

Resistance risk assessment of unrestricted use pattern
After 40 years of use across Europe, only few species have confirmed cases of glyphosate resistance and occurred mostly in perennial crops or railways. According to the applicant, most, if not all, of these cases can be attributed to not following label recommendations.

Management strategy
There are limited cases of reported resistance to glyphosate in the EU. The promotion of diverse weed control systems via integrated weed management approaches by combining agronomic practices (including crop rotation, mechanical operations, non-synthetic chemistry) and herbicides available in the EU reduce the specific selection pressure on glyphosate. According to the applicant, the risk of resistance development to glyphosate can be considered low when adhering to best management practices for using glyphosate in integrated weed/crop management systems.

Appropriate strategies and measures should be implemented in agricultural situations, such as perennial crops, where limited economically attractive alternatives are available as weeding options. Further, the applicant pointed to the fact that glyphosate is a broad spectrum herbicide and therefore will in most situations remain a critical tool in integrated weed management.

The product label provides general advice to minimize the potential for the development of herbicide resistant weeds according to the proposed HRAC stewardship guidelines on best management practices (www hracglobal.com/prevention-management/best-management-practices) (not repeated here).

Implementation of the management strategy
Where weed resistance occurs, a reactive resistance strategy should be developed by the applicant and presented to the local (or country) authorities. The applicant proposed to base reactive resistance strategies on the HRAC guidelines (not repeated here).

Applicant's proposal for a General resistance statement for glyphosate product labels in EME
"Any weed population may contain plants naturally more tolerant or resistant to certain herbicides, which may in some cases lead to poor control using those products. Glyphosate is a Group G herbicide based on the mode of action classification of the Herbicide Resistance Action Committee (HRAC).

A strategy for delaying development and managing herbicide resistance should be adopted based on local needs and a diversified integrated weed management program. This includes the proper use of herbicides, integrating different mechanisms of action and/or using complimentary agronomic, cultural or mechanical practices.

Recommended Integrated Weed Management Practices:

- follow label recommendations, particularly to ensure the treatment is made at the correct weed growth stage, under suitable climatic conditions and at the correct dosage.
- optimize the use of the range of tools which are part of normal crop or landscape management programs to manage weed growth, including agronomic, cultural or mechanical practices.
- minimize the risk of spreading weed infestations by ensuring that farm equipment is clean of soil and vegetation when moving between fields.
- always follow good spraying practice to attain effective weed control:
    - spray equipment should be checked periodically (e.g. by authorized people).
    - dose and spray accurately – calibrate the sprayer and make the correct amount of spray mix for the area to be treated.
    - use the correct nozzles to maximize coverage of the weeds with minimum spray drift.
    - apply only under appropriate weather conditions.
    - monitor the weed control after application to look out for potential control problems; report any unexpected results to [your local Bayer representative / others?]
    - control escaped target weeds mechanically or with registered effective herbicides different from glyphosate before they produce seeds.
- work towards driving down the weed seed bank.

Further information can be obtained from HRAC (www.hracglobal.com), your distributor, your official extension service or your local Glyphosate Renewal Group representative."

Applicant's proposal for a Specific resistance statement for glyphosate products
In document M-CA Section 3 the applicant also presented a specific resistance statement in addition to the above general statement, for countries with confirmed glyphosate resistant weed types, to be modified depending on country. This part of the proposal for labelling is not repeated here.

Monitoring, reporting and reaction to changes in performance
The applicant has developed the below flow chart of monitoring, reporting and reaction to changes in performance of glyphosate.

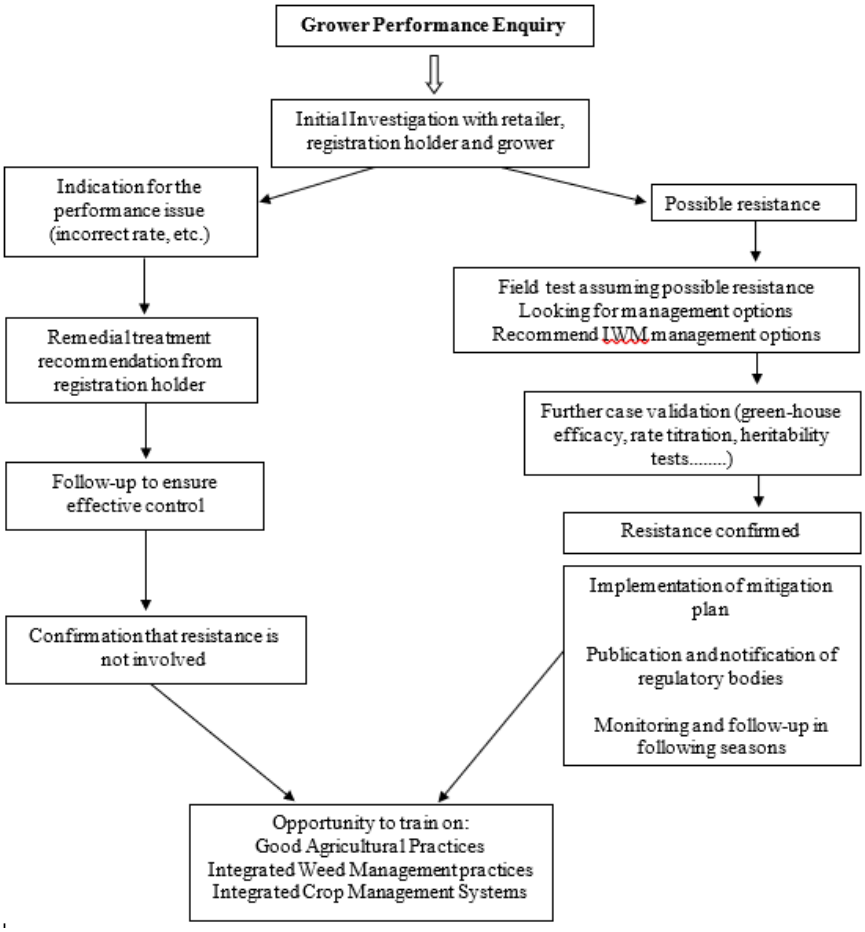


Figure 3.7-1: Applicant's proposed flow-chart for monitoring, reporting and reaction to changes in performance. From document M-CA Section 3.

B.3.8. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?
KCA 3.1-001	[redacted]	2010	The agronomic benefits of glyphosate in Europe Report No.: - Document No.: - - GLP/GEP: N Published: N	N	N	-	GTF	N
KCA 3.4-001	ECAF	2020	Making Sustainable Agriculture Real in Europe with Conservation Agriculture: Judicious Use of Glyphosate in Integrated Weed Management Report No.: - Document No.: - ECAF GLP/GEP: N Published: N	N	N	-	GRG	N
KCA 3.4-003	Nolte, R. et al.	2018	Herbie - Guidelines, State of the Art and Integrated Assessment of Weed control and Management for Railways Report No.: ISBN: 978-2-7461-2775-3 Document No.: - UIC-ETF GLP/GEP: N Published: Y	N	N	-	LIT	N
KCA 3.4-004	[redacted]	2019	Integrated weed management of railways and the role of glyphosate in IWM Report No.: 1030130 Document No.: - ADAS GLP/GEP: N Published: N	N	N	-	GRG	N
KCA 3.5-001	[redacted]	2019	Japanese knotweed: Part A - Literature Review Report No.: 10080998 Document No.: - Advanced Invasives Limited GLP/GEP: N Published: N	N	N	-	GRG	N

KCA 3.5-002	[redacted]	2019	Japanese knotweed: Part B - Treatment Sustainability Index Report No.: 10080998 Document No.: - Advanced Invasives Limited GLP/GEP: N Published: N	N	N	-	GRG	N
KCA 3.5-003	[redacted]	2019	Japanese knotweed: Part C - Europe and North America Report No.: 10080998 Document No.: - Advanced Invasives Limited GLP/GEP: N Published: N	N	N	-	GRG	N
KCA 3.5-004	[redacted]	2020	Key Aspects on the Biology, Impacts and Control Methods of Giant Hogweed (*Heracleum mantegazzianum*) in Europe Report No.: - Document No.: - Bayer GLP/GEP: N Published: N	N	N	-	GRG	N
KCA 3.5-005	Travlos, I.S. *et al.*	2019	Key Aspects on the Biology, Ecology and Impacts of Johnsongrass [*Sorghum halepense* (L.) Pers] and the Role of Glyphosate and on-Chemical Alternative Practices for the Management of This Weed in Europe Report No.: DOI: 10.3390 Document No.: - MDPI, Agronomy 2019, 9, 716 GLP/GEP: N Published: Y	N	N	-	LIT	N
KCA 3.5-006	[redacted]	2020	Non-chemical management of couch grass (*Elymus repens*) in European agriculture Report No.: - Document No.: - Division of Biotechnology and Plant Health, Norwegian Institute of Bioeconomy Research (NIBIO) GLP/GEP: N Published: N	N	N	-	GRG	N

[1] In order to facilitate the compilation of the final list of the tests and studies relied upon and the corresponding data protection, indicate whether the study was used in the previous DAR/RAR or, when the information is available, whether the study was already submitted in the framework of national authorisations.
[2] See Art.3 of Annex of Regulation No 283/2013 and 284/2013.