MSC/M/46/2016

Minutes

of the 46th Meeting of the Member State Committee (MSC-46)

2-4 February 2016

I. Summary Record of the Proceedings

Item 1 - Welcome and apologies

The Chairman of the Committee, Mr Watze de Wolf, opened the meeting and welcomed the participants to the 46th meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Section II of the minutes).

Item 2 - Adoption of the agenda

The agenda was adopted as provided for the meeting by the MSC Secretariat without further changes (adopted agenda is attached as Section III of these minutes).

Item 3 - Declarations of conflicts of interest to the items on the agenda

No potential conflicts of interests were declared by any members, experts or advisers with any item on the agenda of MSC-46.

Item 4 - Administrative issues

- **Outlook for MSC-47**

The Chairman presented an outlook on the potential length of the next meeting using best available estimates on key parameters from dossier and substance evaluation. Over time these estimates will become more certain, but in using different ranges to address the existing uncertainties this meeting may take from four to six days.

- **Minority positions/opinions in context of MSC work**

ECHA Secretariat (SECR) presented to MSC an overview of the main principles followed and gave further clarification on the procedural and practical aspects related to the preparation of majority and minority opinions of the MSC members on different REACH processes where MSC involvement has been triggered.

MSC had a brief discussion on the need to express all grounds of minority and majority views of the MSC members during the MSC discussion. Members agreed that often when a minority position is formed by several members based on same grounds there might be insufficient time to properly consult the minority position wording among these members (in particular when members who had given their proxy votes need to be consulted) if the position needs to be written by and presented at the time of the vote on a case.

Recognising the importance of presenting the grounds for a minority position at the time of the vote and the need to keep flexibility on the deadlines for editorial check and the final submission of MSC opinion(s), MSC concluded that all grounds for MSC members' votes should be presented and discussed during the meeting.

Where relevant, draft minority positions of MSC members including all the grounds for their minority views should already be presented at the time of the MSC vote on a case, however, possibilities should be given for editorial refinements and proxy checks on the minority position(s) but with no new grounds/arguments added. Further editorial formulation, consultation and submission of the final minority position(s) should be done in accordance with the deadline specified in the MSC plenary's Main conclusions and action points document. MSC decided on a standard deadline of five days for final editorial check and submission to the MSC-S of minority positions. Pending on specific case conditions, a reduced or extended deadline may be specified in the relevant plenary's Main conclusions and action points.

It was noted that there is no requirement to combine the grounds presented in minority votes into only one minority position and no need to set up rules for minority position forming. Finally, MSC decided to keep unchanged the current working practice regarding

the preparation and presentation of minority positions of MSC members and requested the MSC Secretariat to consider the newly set deadlines regarding the minority position finalisation and submission, where relevant in future.

- **Outcome of 2015 Satisfaction survey**

SECR introduced to MSC the outcome of the 2015 MSC Satisfaction survey and the actions undertaken on the main issues raised.

- **Online editing of voting files**

SECR informed MSC of the possibility of online editing of the voting files when introducing their votes in the written procedures.

- **Survey on after plenary activities**

SECR invited MSC to provide their feedback on the after plenary activities via a simple online survey that is to be launched shortly.

Item 5 – Minutes of the MSC-45

The minutes of MSC-45 were adopted as modified at the meeting.

Item 6 - Substance evaluation

6.1 Community Rolling Action Plan (CoRAP) & MSC opinion development

a) Discussion on the MSC opinion on the draft Community Rolling Action Plan (CoRAP) update

The Rapporteur presented the draft opinion and its annex and explained that since the December MSC-45 meeting 39 justification documents were updated on the request of the Working Group members. Overall, the changes made since the referral of the draft CoRAP update 2016-2018 included 1) withdrawal of two substances, one because of change to intermediate use and the other one because the substance is mostly used for polymer production at low tonnage; 2) changes in years of evaluation and Member State conducting the evaluation; 3) changes in initial grounds of concern; 4) notification and inclusion of a new substance and 5) changing of EC number and name of two substances following a substance identification compliance check.

b) Adoption of the MSC opinion

MSC adopted the opinion on the draft annual CoRAP update 2016-2018 and its annex by consensus. MSC also gave the mandate requested by the Rapporteur for any necessary editorial changes before publication. It was concluded that the MSC opinion together with the final update to CoRAP will be published on the ECHA website on 22 March 2016.

6.2 Decision making process

a) Written procedure report on seeking agreement on draft decisions on substance evaluation

SECR introduced the report on the outcome of the written procedure (WP) for agreement seeking on one substance evaluation case (see Section V for more detailed identification of the case). WP was launched on 8 January 2016 and closed on 18 January 2016. By the closing date, unanimous agreement was reached on the draft decision (DD) with no abstentions received.

b) Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CA's/ECHA reactions *(Session 1, open session)*

c) Seeking agreement on draft decisions when amendments were proposed by MS-CA's/ECHA *(Session 2, closed)*

SEV-UK-039/2014 – phenol, 4-nonyl-, branched (EC No. 284-325-5)

Session 1 (*open*)

Two representatives of the Registrants participated in the initial discussion. In absence of specific confidentiality concerns in the draft decision (DD), an open session was held.

The evaluating Member State Competent Authority (eMSCA) from the United Kingdom (UK-CA) presented the outcome of substance evaluation (SEv) of the above-mentioned substance which was performed on the basis of the initial grounds for concern relating to Environment/Suspected PBT; Exposure/Wide dispersive use, consumer use, aggregated tonnage. In the course of the evaluation, the eMSCA identified additional concerns for the environment as follows - the level of protection against endocrine effects provided by the aquatic PNEC, the interpretation of environmental half-life data, aquatic risks from degradation of nonylphenol ethoxylate (NPEO), and apparent deficiencies in the data sets available for assessing wastewater treatment plant (WWTP) partitioning, bioaccumulation, sediment organism toxicity, soil organism toxicity and secondary poisoning. Additional concerns for human health were the DNEL derivation and exposure modelling. MSC was guided through the information on the substance (including PfAs, Registrant(s) comments, and the eMSCA's responses to them).

The DD that was notified to the MSCAs and ECHA for consultation consisted of a total of 23 requests distributed in six sections. Twelve proposals for amendments (PfAs) were received in total. PfAs were received on all the six sections. Three requests out of 23 did not receive any PfA. Following the analysis of the PfAs, the eMSCA accepted six PfAs and dropped five requests resulting in a DD for discussion at MSC with 5 sections and a total of 18 requests. After confirmation by MSC that there was no further need for a discussion of all PfAs submitted or how they had been addressed by the eMSCA, only the following PfAs were discussed during the meeting.

A general PfA stated that the DD is not sufficiently explicit in what additional risk management the eMSCA foresees as a possible outcome of the substance evaluation requests and to what extent the information requested is necessary to achieve this objective. It proposed to update Section III by addressing the future use of the requested information, type of risk management measures envisaged to be needed in the future to ensure a safe use of the substance (either regulatory risk management or risk management measures by manufacturers and importers) and the appropriateness and necessity of the requests to achieve the objectives.

With regards to five requests on *information for environmental exposure assessment*, a PfA proposed to limit the scope of the requests to the area of responsibility of the Registrants of NP. The PfA submitter is of the opinion (following the European Court of Justice Judgement (Case C-558/07) concerning the requirements laid down in REACH for polymer manufacturers and importers), that the Registrants are responsible to cover in their CSR the whole life cycle of the monomer NP, of the residual unreacted monomer, and the degradation from the polymers to the monomer. However, the Registrants of NP are not responsible to cover hazards and risks arising from derivatives and ethoxylates which have a separate registration. As an alternative to requesting the information from the Registrants, the PfA invited the eMSCA to consider doing the assessment themselves using reasonable worst case scenarios.

With regards to the request on a *monitoring programme to determine a (total) average annual regional concentration of the registered substance in receiving surface fresh and marine waters for the purpose of updating the PECregional used in the registration dossiers,* a PfA proposed to delete this request on the grounds that it appeared to be not justified, also in terms of proportionality, and to go beyond the responsibility of the Registrants of NP.

With regards to three requests on *information for environmental fate*, one PfA proposed to delete these information requests as they did not seem to be necessary to clarify the concern, and did not aim at generating new information, but at reassessing and improving the information already included in the dossier.

In addition, with regards to the request on the *derivation of reasonable worst case values for fish bioconcentration factor (BCF), biomagnification factor (BMF) and trophic magnification factor (TMF)*, (which is part of the three request on information for environmental fate), a PfA provided an analyses of data available on bioaccumulation and highlighted the uncertainties in the bioconcentration potential of the substance. The PfA suggested to request a bioconcentration study with dietary exposure (OECD TG 305) for the assessment of this endpoint, in case P was confirmed, and if no dietary exposure literature search was found on NP. With regards to seven requests on *information for environmental PNECs*, a PfA proposed to delete these requests since it considered that in SEv, after assessing the available information, eMSCA is responsible for deriving an appropriate chronic NOEC or request for the generation of new information when derivation is not possible. Furthermore, there appeared to be no reasons indicated for the requests in terms of possible regulatory outcome.

With regards to the request for an *environmental risk assessment for all exposure scenarios involving nonylphenol ethoxylates (NPEO)*, one PfA proposed to limit the scope of the request to the sphere of responsibility of the Registrant, as argued in their PfA for the requests on information for environmental exposure assessment.

The Registrant(s) provided two separate sets of written comments on the PfAs. Since in their written comments, the Registrant(s) when disagreeing with a PfA wrote for the PfA to be corrected or retracted, the Chairman explained that the decision making process does not allow for retraction of any of the PfAs submitted. He further explained that the discussion at MSC-46 meeting would give the possibility to the Registrant(s) representatives to express their views on the PfAs submitted.

The Registrant(s)' representatives explained that they understand the motivation of the requests, the goals of DD and what it wants to achieve. However they noted concerns and requested more clarity on the scope of the evaluation, the proportionality of the requests and the technical merit of the requests. They explained that they are fully committed to generate data on NP to make sure that it is safely managed. However, they do not agree that they have the responsibility of all the uses for the downstream derivatives e.g. polymers containing impurities of NP and polymer degradation products. They do not agree with the interpretation of the European Court of Justice Judgement presented in the PfA. For the Registrant(s) this interpretation that the CSR should cover the whole life-cycle of the monomer, including the stage(s) of the polymer regarding exposure to residual unreacted monomer and possible degradation of the polymer to the monomer, has implications far beyond the registration of NP. The Registrants could understand that the eMSCA wanted to address uncertainty in the risk assessment, but disagreed that SEv should provide a catch-all mechanism. They clarified that the Registrants cannot be responsible for any and all broad concerns relating to substance; that would not be proportionate.

Registrants questioned the extent to which the information requested could influence the risk management measures (RMM) for the substance and explained that RMMs are already in place for NP and NP derivatives and both NP and NP ethoxylates are already highly regulated. They believe that wide dispersive uses of NP are limited by the existing restriction under REACH and, if such type of uses occur at all, they are limited to NP derivatives. They also remarked that competition law needs to be considered when requesting for collection of information from downstream users. With regards to PNEC derivation, the Registrant(s) representatives stated that in their view the echinoderms and molluscs studies requested are not validated methods yet, so there is no good and unambiguous framework for evaluating the results of these studies. They considered further that for NP there is a very strong database available, PNECs are very well derived and they questioned whether the additional information will change the PNEC. They expressed that they are willing to update their dossier including an updated literature search, but questioned the validity of the request for further tests.

In response to the contributions from the Registrant(s)' representatives, the expert from the eMSCA stated that they consider their requests as proportionate since NP is a high

tonnage SVHC (due to its endocrine disruption properties) and RAC expressed in their opinion[1] that a residual risk remained despite the textile restriction. Hence, the eMSCA aims to understand what additional RMMs are needed. Furthermore, the eMSCA expert stressed the importance of defining an NP background concentration for being able to demonstrate the safe use of the substance. Additionally, demonstration of safe use in NP ethoxylates authorisation applications would rely on PNECs derived for NP. In relation to technical viability, they had agreed already that it was difficult to test winter flounder and removed the test request and ask for a literature search instead. The expert stated that, although testing echinoderms and molluscs is unusual, yet it is technically feasible. Furthermore, as a species, they appear to be very sensitive to NP. Since the RAC's opinion on the NP restriction proposal PNEC established a PNEC relying predominantly on fish, having data from such more sensitive taxa could lead to a lower NOEC value for use in the species sensitivity distribution.

MSC members asked the Registrant(s)' representatives to clarify questions amongst which why in the view of the Registrant(s)' representatives there are no wide dispersive uses of NP since there seem to be indications to the contrary (e.g. measurements in the environment). The Registrant(s)' representatives explained that the statement was related to the use of NP itself, since they believe that there is no other use than intermediate. If at all, dispersive uses are related to the ethoxylates and the resins and these uses would be restricted or are already restricted.

Furthermore, the Registrant(s)' representatives were requested to share what they know of the current contribution from NP manufactured in EU to the overall concentration observed, and the contributions from other sources specifying the sources that are in their control and how these contribute. The Registrant(s) representatives explained that they do not have exact figures on the relative contribution of the individual uses. They considered that one of the complications was the inherent difficulty around gathering data from the individual downstream uses and another was other sources, like textile articles being imported in EU, which are not covered by the NP registration and which could lead to some releases in environment.

During the discussion an MSC member highlighted that both the Registrant(s) and MSC should consider the safe use of chemicals in the real world and not in theoretical cases. This Member stated that for NP there is a concern in the real world and the Registrant(s) has the duty of not doing only hypothetical risk assessment, but judge all the sources that are contributing to the risk and not only his own. The Registrant(s) representatives responded that they recognise their responsibility and they are not trying to avoid it. What they questioned was the proportionality of being asked to take care of NP exposure levels coming mainly from other sources such as nonylphenol ethoxylate in textiles and the associated request to determine all background levels in the EU. Hence, they questioned the request for a monitoring program considering the preparatory work and level of effort needed to create something useful and valuable especially since the eMSCA had indicated that the monitoring data from the Water Framework Directive was not aimed to provide an environmental background concentration and therefore not considered directly applicable in this respect.

Session 2 *(closed)*

The discussion focused on three main topics: 1) limiting the scope of use and exposure requests to the area of responsibility of the Registrants namely the monomer Nonyl Phenol (NP), including exposure to residual unreacted monomer and degradation of the polymer to the monomer; 2) the (dis)proportionality of the requested environmental monitoring programme, as well as its scientific/technical merits; 3) the Registrant's burden of proof to provide information or the eMSCA's duty to assess all available information. All of these discussions took into consideration that the substance is already heavily regulated, and thus that it should be very clearly argued why and how the substance evaluation requests would contribute to further risk management measures.

[1] RAC opinion on an Annex XV dossier proposing restrictions on nonylphenol and nonylphenol ethoxylates (ECHA/RAC/RES-O-0000005317-74-01/F) adopted on 3 June 2014.

As for the first main topic, the eMSCA and MSC unanimously agreed to ECHA's opinion (following the European Court of Justice Judgement (Case C-558/07) concerning the requirements laid down in REACH for polymer manufacturers and importers), that the Registrants are responsible to cover in their CSR the whole life cycle of the monomer NP, of the residual unreacted monomer, and the degradation from the polymers but not from derivatives and ethoxylates as far as those derivatives either have a separate registration or may be/need to be registered as separate substances under REACH.

With regards to the second main topic the discussion focused on the PfA to delete the request for a monitoring programme to determine a (total) average annual regional concentration of the registered substance in receiving surface fresh and marine waters for the purpose of updating the PECregional used in the registration dossiers, on the grounds that it appeared to be not sufficiently justified, also in terms of proportionality, and went beyond the responsibility of the Registrants of NP. Some MSC members supported this view, other Members supported eMSCA's view to keep it amongst the requests in the DD. In general, MSC agreed that environmental monitoring requests can be supported in Substance Evaluation. However, for the specific case it was argued that there are potentially many (registered) sources of NP in the environment and hence it may not be proportional to request only the NP registrants to perform such a programme. Several members supported a monitoring request, but raised some questions on the technical merits (e.g. level of detail of the monitoring program and its representativeness) and thus the possibility to come to meaningful results. Taking these arguments together MSC decided not to request a monitoring programme for now, and to await the results of the other requests in the decision first.

With regards to the third main topic, the eMSCA decided not to drop the information requests related to data that could affect the aquatic PNEC, since they considered these potentially relevant also to future authorisation applications for nonylphenol ethoxylates. Deletion of these requests was discussed since it had to be considered whether in SEv, after assessing the available ecotoxicity information, eMSCA is responsible for deriving an appropriate chronic NOEC or alternatively is able to request that the registrant refines these NOECs based on concerns highlighted in the available information. Furthermore, MSC discussed the inclusion in the DD of reasons for the requests in terms of possible regulatory outcome. The eMSCA also clarified that these requests could be waived if the Registrant(s) concludes that the registered substance meets the PBT criteria. The Registrants in their comments to the original DD had selectively quoted parts of the RAC opinion on the restriction proposal of use of NP in textile applications to argue that additional fully valid and conclusive chronic tests would not reveal significantly lower adverse effect concentrations for the traditional, apical endpoints than those in the existing aquatic toxicity data set. Since the eMSCA had not fully addressed this comment in the DD, MSC felt the DD should further elaborate on the context of the RAC opinion (i.e. use of NP in textile applications) and address why a PNEC-refinement is still to be considered appropriate in the context of substance evaluation. MSC agreed to request for further testing on molluscs and echinoderms indicating a possibility to adapt the information request if the registrants can justify derivation of reliable long-term reproduction and growth NOEC/EC10 values based on an updated review of the scientific literature. For the request on avian reproductive toxicity testing it was agreed not to request a test itself but instead require the registrants to determine whether a new bird test is required using the Integrated Testing Strategy (ITS) provided in the REACH Guidance. If so, then the registrants should not perform the test, but records his consideration on the need for testing in the registration dossier. eMSCA will evaluate the need for testing in the follow up evaluation stage.

Considering the previous five requests that were dropped from the DD before the MSC discussion and the monitoring program request that was dropped during the MSC discussion, the deadline for submission of the information was changed from 24 months to 18 months from the date of the final decision.

MSC discussed the limited editorial mandate to SECR and eMSCA to finalize the DD after MSC's deliberations, and specifically agreed to broaden it considering that MSC unanimously agreed on the information requests as detailed in Section II. MSC mandated

SECR and eMSCA to implement within two weeks after the meeting further editorial changes in Section III of the decision including: 1) Reflection of the MSC's considerations so as to allow the registrant to clearly understand why the information requested in Section II is needed; 2) Restructuring the section so that it clearly follows the order in Section II using the reasoning agreed by the MSC; 3) Clarification of the text on follow-up actions as discussed.

d. General topics

- **Appeals update (partly closed session)**

SECR gave a general review of litigation relevant to MSC work from the years 2008-2015, highlighting statistics and rulings of 2015.

In addition, in a closed session SECR provided an update on two substance evaluation decisions of the Board of Appeal. MSC took note of the information received.

- **Efficiency improvement proposals for SEv**

In view of the high impact on the workload of MSC from substance evaluation draft decisions SECR wished to share some proposals on how this step of the process could be made more efficient. The template for SEv draft decision in use for the evaluation of 2015 CoRAP substances was used as the starting point, together with the suggestions on the draft decision drafting from the 2015 substance evaluation workshop. Specifically, MSC was invited to consider potential implementation actions for improving efficiency at MSC stage and some initial suggestions were shared for discussion. Several participants raised questions about the new decision template and among other things wanted to learn more about the experience in using it. One observer also indicated that the recipients of the draft decisions (registrants) should receive sufficient communication on the relevance of the appendices in the new decision structure, and flagged that reasons or possibilities for alternatives for animal testing should easily be found in the decision.

MSC thoroughly discussed the different possibilities that could lead to reduction of discussion time needed at the plenary. It was recognised that defining actions and boundaries in advance could be a challenge and hence it was agreed to move cautiously forward. One member noted that in accordance with the legal text the decisions are taken by MSC and it must be clear to everyone what the outcome of the discussion was. MSC supported the idea that for some suitable cases an extended but well-specified mandate is defined by MSC to ensure completeness and correctness of the full decision text after comprehensive agreement of the information requirements and in-depth discussion of their justifications at the plenary. In closing this item the Chairman invited MSC to consider further the suggestions made and to bring forward additional ideas where they see potential for efficiency improvements.

- **Possible criteria for use of written procedures**

SECR had prepared a document describing possible criteria to be used when deciding for which substance evaluation draft decisions a written procedure could be used for MSC agreement seeking. They were prepared based on criteria previously shared with MSC which were further developed based on existing practise and suggestions received. These criteria could be used to guide case-specific discussions in which also the eMSCA expert will take part. In absence of any immediate comments from MSC the Chairman concluded the item by describing these as evolving criteria to be applied as appropriate and inviting MSC for any further feedback.

Item 7 – Dossier evaluation

a. Written procedure report on seeking agreement on draft decisions on dossier evaluation

SECR introduced the report on the outcome of the written procedure (WP) for agreement seeking on six dossier evaluation cases (see Section VI for more detailed identification of the cases agreed in WP). WP was launched on 8 January 2016 and closed on 18 January 2016. By the closing date, unanimous agreement was reached on five draft decisions (DD). One member abstained from voting on one case. For one DD, MSC Chairman terminated the WP on the basis of Article 20.6 of the MSC Rules of Procedure as at least one MSC member requested meeting discussion of the case at the MSC-46 meeting.

Following a comment from one MSC Member on the Fish Embryo Toxicity (FET) test, the Chairman informed MSC that the contractor's report commissioned by ECHA will be finalized and published shortly, and that the ECHA project team will prepare by summer a position paper concerning the FET's potential use in the context of three regulations (REACH, CLP, Biocides), and will continue monitoring other projects and activities on FET.

b. Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals after MS-CA reactions *(Session 1, open session)*

c. Seeking agreement on draft decisions on testing proposal examinations and compliance checks when amendments were proposed by MS-CA's *(Session 2, closed)*

d. General topics

Session 1 (open)

<u>Testing proposal examinations (TPE)</u>

Summary for the two cases

SECR explained that the two proposals for amendment (PfA) to ECHA's DDs on two cases (TPE-154/2015 and TPE-158/2015) were submitted on *in vivo* mammalian alkaline comet (single cell electrophoresis) assay (OECD TG 489) and had similar contents for both cases. Therefore, the two cases were discussed together. However, the agreement was sought individually for each case.

MSC was satisfied with ECHA's response to the other PfA whilst MSC discussed the below-mentioned PfA at the meeting.

TPE-154/2015 – (3E)-2-chloro-3-(hydroxymethylene)cyclohexene-1-carbaldehyde (List No. 801-656-8)

TPE-158/2015 – 1,3-diphenylpropane-1,3-dione (EC No. 204-398-9)

No representative of the Registrant for either case participated in the initial discussion. In absence of specific confidentiality concerns in the DD, an open session was held.

The PfA on the comet assay considered it proportionate to request, besides liver as the main metabolizing organ, the analysis of both glandular stomach and duodenum/jejunum as initial site of contact, whereas the initial request was providing the choice between glandular stomach and duodenum/jejunum. It argued that there was insufficient scientific basis for choosing one tissue over the other, and considered two sites of contact tissues should be requested where there is a concern for genotoxicity at the initial site of contact after oral exposure.

SECR had not modified the DD based on the PfAs in advance of the meeting.

Further information on the comet assay

SECR gave a general presentation on the choice of site of contact tissue for *in vivo* comet assay via oral route. It summarised several issues brought forward in the course of past meetings when requesting the comet assay.

The Dutch MSC member's expert introduced the background document they submitted to the meeting ("Tissues to be chosen in comet assay"). It concluded that, in view of the precautionary principle and with some additional extra costs, and in view of protecting human health, requesting both stomach and intestinal tissue currently seemed the most reasonable approach. Furthermore, it considered that by default both these tissues should be requested, with the possibility of waiving a tissue when properly justified, and for practical reasons glandular stomach could be chosen over forestomach. The document also reasoned why testing on an empty stomach should be requested.

Discussion

In relation to the case TPE-158/2015, a stakeholder observed inquired whether any of the potentially requested repeat dose tests (subchronic toxicity study 90-day and comet assay) could be performed as a combined test. A MSC member confirmed that ECHA guidance on genotoxicity suggests combining, and SECR replied that also the testing guidelines mention such a possibility.

One MSC member argued it was proportional to request two site of contact tissues, due to the current uncertainty whether the substances would reach different tissues, the relatively modest increase in costs, and the absence of a need for additional animals. The MSC member further concluded that glandular stomach was a proper choice over forestomach as the former has been validated, and queried whether different grades of chemical reactivity could be further investigated to develop better guidance on choosing tissues of concern. Another MSC member was of the opinion that dossier evaluation was not a process to address the scientific uncertainties which in his view should be explored through research projects. However, the member agreed that a request for more tissues was a reasonable way forward to avoid possible further testing later. One MSC member considered that if there was no scientific reason to decide on testing either tissue, then both should be analysed. An observer indicated that the scientific uncertainties brought to the attention of MSC were also relevant to the OECD Test Guidelines expert group, and invited members to submit these considerations. The observer also highlighted that MSC should consider the OECD-agreed principle of Mutual Acceptance of Data when deciding on the most appropriate use of the comet assay test guideline in a REACH context.

SECR noted that it indeed it is necessary to stay within the limits of the test guideline, that the decision should be clear which tissues the Registrant is requested to investigate, that the price increase due to additional tissues could be around 20–30%, and that duodenum/jejunum might not be considered as site of contact. One MSC member agreed to ask three tissues (liver and two site of contact tissues) and suggested to leave it for the registrant to justify if any of those would not be necessary, which they could also relate to the reactivity of the tested substance.

One MSC member indicated no preference on testing on empty stomach, and supported asking three tissues to address uncertainty, referring to testing guidelines which ask for relevant sites of contact. Another MSC member mentioned the possibility of freezing sampled tissues to be analysed later if the first two tissues would not be positive, but considered that the freezing and thawing may introduce other uncertainties and therefore did not advocate this approach.

Session 2 (closed)

Several MSC members indicated their support to request two site of contact tissues (glandular stomach and duodenum/jejunum). However, one MSC member maintained that the higher costs were not proportional, and that other tools should be used to address scientific questions.

SECR noted that the testing guidelines were open to some interpretation and that when a registration dossier includes sufficient justification for the choice of site of contact tissues the chosen approach for testing proposals could also apply to compliance checks. One MSC member supported the view that only duodenum (and not duodenum/jejunum) should be referred to, since requesting jejunum would open up the possibility to Registrants for sampling of a distal part of the intestine and a highly reactive or quickly dissipating test substance may not reach jejunum. However, it was explained that the wording

"duodenum/jejunum" is to allow for the practical issue that when sampling duodenum also some jejunum material might be included.

One MSC member was of the view that there were no data to define groups of substances, which could be used to target the site of contact tissues to be analysed, and other scientific *a priori* reasons did not exist to select between glandular stomach and duodenum. One MSC member argued that fasting was not part of the testing guidelines and would also be of concern to the animal welfare. Another MSC member suggested to refer the fasting issue to the appropriate working group of OECD.

Based on the discussion, the Chairman concluded that by default two site of contact tissues would be requested for all types of substances *i.e.* glandular stomach and duodenum/jejunum, and agreed to have jejunum included, noting that sampling preferably should occur close to the stomach. MSC members also agreed to prefer glandular stomach over forestomach. The Registrant would need to provide arguments whether a site of contact tissues is needed, as waiving or adaptation for any site of contact tissue is considered possible. SECR reminded additionally that the Registrant should present the justification in his testing proposal examination, and in case of a compliance check could still present adaptation arguments in his comments to the draft decision. Finally, the feeding issue was not considered within the scope of the comet assay but should be further referred to the OECD.

Some members acknowledged that ECHA was revising its approach due to the uncertainties and precautionary principle, and suggested to inform the Registrants on this approach.

Agreement seeking for the two cases

MSC agreed unanimously to both DDs as amended at the meeting, by refining the approach on requesting comet assay by oral route, in particular to (a) request examination of site of contact tissue(s) by default for all types of substances, (b) prefer glandular stomach over forestomach; (c) default analysis of two site of contact tissues (glandular stomach and duodenum/jejunum), in addition to liver; and (d) consider justifications of the Registrant to justify waiving or adapting analysis of any site of contact tissue. MSC agreed not to include a request for fasting the animals before dosing, also noting that this has not been addressed before in any of the proposals for amendment or the ECHA decisions and does not follow the comet assay testing guideline.

TPE-162/2015 – 2-imidazolidone (EC No. 204-436-4)

Session 2 (closed)

SECR explained that agreement was initially sought in written procedure. The written procedure was terminated by the Chairman of MSC on request of one MSC member suggesting MSC discussion.

SECR introduced the PfA that was received to ECHA's DD. The PfA on the sub-chronic toxicity study (90-day repeated inhalation exposure) in rats, oral route, supported the original proposal from the Registrant for a standard 90-day study. It also supported the request for a more detailed investigation of the testis, given the testicular effects observed in a 28-day drinking water study. However, the PfA considered the need of requesting for a mechanistic investigation of thyroid hypertrophy/hyperplasia not adequately justified and suggested removing it.

SECR had modified the DD based on the PfA.

The expert of the MSC member who requested stopping the written procedure explained that there was limited substance specific information to support the requested mechanistic investigations and therefore the use of satellite groups appeared unjustified. The expert agreed, however, that the generation of such mechanistic data necessitating the use of satellite groups may be justified on a case-by-case basis.

SECR explained that the aim of suggested additions in this case is the exclusion of a specific MoA in generation of thyroid tumors in rodents.

During the discussion MSC members supported the scientific reasons necessary to substantiate or to exclude a certain MoA and the complex character of multiple possible MoAs. The level of details and the key events to be taken into consideration for the interpretation of new data on rodents were also discussed in order to consider their relevance for humans.

MSC agreed unanimously to the DD as circulated for the written procedure.

d. General topics

- **Appeals update (partly closed session)**

See under 6.2.d.

Item 8 – ECHA's recommendations of priority substances to be included in Annex XIV

• Presentation of the preliminary prioritisation results in preparation for ECHA's 8th draft recommendation

SECR presented preliminary prioritisation results in preparation of ECHA's 8th draft recommendation of priority substances to be included in Annex XIV and shared its first observations on the results with MSC. The focus was on results for the substances newly added to the Candidate List (between December 2014 and December 2015, 13 substances in total) to provide an early view on how the newly assessed substances rank among other Candidate List substances, and SECR shared several of its observations. General prioritisation approach had been applied for the assessment but it was emphasised that any registration updates made by 1 August 2016 will be take into account in the assessment for priority for the 8th draft recommendation in the second half of the year. These prioritisation results will then be discussed at MSC in December.

In the discussion two industry stakeholder observers welcomed the clear messages, in particular as regards the need for updating the registration dossiers, and for the early warning of what to expect. They also indicated that they would be happy to share the preliminary results with their membership as an input to having updated registration information available by 1 August for the actual prioritisation purposes.

Given the fact that the next MSC discussion in preparation of the 8th draft recommendation is planned only for end of the year the Chairman invited the participants to flag any open topics for discussion also in advance in case they would be for any general principal issues.

Item 9 – Any other business

• Status update on EOGRT cases

SECR gave a presentation on the activities related to extended one-generation reproductive toxicity study (EOGRTS), first describing the work of the advisory expert working group, which has refined internal ECHA guidance on e.g. search strategy for triggers, certain complex triggers, sequential testing, and related standard texts. It also explained several CCH cases that were sent to registrants in 2015 and highlighted the distribution of various study designs. Finally, SECR summarised the EOGRTS cases referred to the Commission for decision making.

A stakeholder observed inquired whether the ECHA internal guidance was public, and SECR informed that the section on search strategy will be published. The representative of the Commission informed that the cases to them, excluding those where a cease of manufacture has occurred, are being prepared to send drafts to the registrants for commenting in the upcoming months, and subsequent for approval by the REACH Committee.

- **Report from PBT and Endocrine Disrupter Expert Group activities**

SECR reminded to MSC the role and the mandates of the PBT and ED Expert Groups (EG) and gave a brief report on their ongoing activities. In this regard, MSC was requested to provide suggestions on the long-term approach development priorities of the PBT EG based on the listed topics as provided in MSC S-CIRCABC.

- **Report on the outcome of the Topical Scientific Workshop on Soil Risk assessment**

MSC took note of the overview given by SECR on the aim, scope, format, themes and outcome of the workshop.

Item 10– Adoption of conclusions and action points

The conclusions and action points of the meeting were adopted at the meeting (see Section IV).

II. List of attendees

Members/Alternate members
ALMEIDA, Inês (PT)
ANDRIJEWSKI, Michal (PL)
ATTIAS, Leonello (IT)
BUSUTTIL, Ingrid (MT)
COCKSHOTT, Amanda (UK)
COSGRAVE, Majella (IE)
DEIM, Szilvia (HU)
DIMCHEVA, Tsvetanka (BG)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
GAIDUKOVS, Sergejs (LV)
HUMAR-JURIC, Tatjana (SI)
KREKOVIĆ, Dubravka Marija (HR)
KULHANKOVA, Pavlína(CZ)
LONDESBOROUGH, Susan (FI)
LUNDBERGH, Ivar (SE)
MANSUY, Patrick (FR)
MARTÍN, Esther (ES)
MIHALCEA UDREA, Mariana (RO)
PALEOMILITOU, Maria (CY)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
WAGENER, Alex (LU)
WIJMENGA, Jan (NL)
Representatives of the Commission
SCHUTTE, Katrin (DG ENV)
Observers
ANNYS, Erwin (Cefic)
DE KNECHT, Joop (OECD)
DROHMANN, Dieter (ORO)
HÖK, Frida (ChemSec)
KERÄNEN, Hannu (CONCAWE)
MUSU, Tony (ETUC)
STODDART, Gilly (PISC)
TAYLOR, Katy (ECEAE)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
ANASTASI, Audrey Anne
ANDERSSON, Niklas
BELL, David
BERCARU, Ofelia
BROERE, William
CARLON, Claudio
DELOFF-BIALEK, Anna
DE WOLF, Watze
DREVE, Simina
FEEHAN, Margaret
HERBATSCHEK, Nicolas
HUUSKONEN, Hannele
JOHANSSON, Matti
KAPANEN, Anu
KARHU, Elina
KASARUHO, Anisa
LEPPER, Peter
LE CURIEUX, Frank
MÜLLER, Birgit
NAUR, Liina
PELLIZZATO, Francesca
PELTOLA-THIES, Johanna
RODRÍGUEZ-IGLESIAS, Pilar
RÖNTY, Kaisu
SUMREIN, Abdel
TAI, Kaihsu
VAHTERISTO, Liisa
VASILEVA, Katya

Proxies

- MARTÍN, Esther (ES) also acting as proxy of KOUTSODIMOU, Aglaia (EL)
- TYLE, Henrik also acting as proxy of DUNAUSKIENE, Lina (LT) in the morning of 4 February

Experts and advisers to MSC members

BOUWMAN, Tialda (NL) (expert to WIJMENGA, Jan)
BUDASOVA, Jana (EE) (expert to VESKIMÄE, Enda)
CATONE, Tiziana (IT) (expert to ATTIAS, Leonello)
DOBRAK-VAN BRELO, Agnieszka (BE) (expert to VANDERSTEEN, Kelly)
GRACZYK, Anna (PL) (expert to ANDRIJEWSKI, Michal)
GREGOROVIĆ, Gordana (HR) (expert to KREKOVIĆ, Dubravka Marija)
GRINCEVICIUTE, Otilija (LT) (expert to DUNAUSKIENE, Lina)

INDANS, Ian (UK) (expert to COCKSHOTT, Amanda)
HERINGA, Minne (NL) (adviser to WIJMENGA, Jan)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBERGH, Ivar)
NYGREEN, Beryl C. (NO) (expert to REIERSON, Linda)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)
PRIHA, Maarit (FI) (adviser to LONDESBOROUGH, Susan)
RISSANEN, Eeva (FI) (adviser to LONDESBOROUGH, Susan)
TERENDIJ, Carline (FR) (expert to MANSUY, Patrick)

MSCA Experts for SEV cases
DOYLE, Ian (UK)

By WEBEX/phone connection:
During the agenda item 5: Helen KLINT (SE) and Margareta WARHOLM (SE)
During the agenda item 7d: Nathalie PRINTEMPS (FR)
During the whole meeting from DG GROW: Enrique GARCÍA-JOHN, Jacek RODZWADOWSKI, Maila PUOLAMAA and Georg STRECK
During the whole meeting from DG ENV: Andrej KOBE

Case owners:
Representatives of the Registrants were attending under the agenda item 6.2b for SEV-UK-039/2014.

Apologies:
KOUTSODIMOU, Aglaia (EL)
PISTOLESE, Pietro (IT)

III. Final Agenda

ECHA/MSC-46/2016/A/46

Agenda
46th meeting of the Member State Committee

2-4 February 2016
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland
2 February: starts at 9 am
4 February: ends at 1 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/046/2016
For adoption

Item 3 – Declarations of conflicts of interest to items on the Agenda

Item 4 – Administrative and procedural issues

- Outlook for MSC-47

For information

- Minority positions/opinions in context of MSC work

ECHA/MSC-46/2016/013
For discussion

- Outcome of 2015 Satisfaction survey

For information

Item 5 – Minutes of the MSC-45

- Draft minutes of MSC-45

MSC/M/45/2015
For adoption

Item 6 – Substance evaluation

Closed session for 6.2c, partly closed for 6.2d
Indicative time plan for 6.2b is Day 1

6.1 Community Rolling Action Plan (CoRAP) & MSC opinion development

c) Discussion on the MSC opinion on the draft Community Rolling Action Plan (CoRAP) update

ECHA/MSC-46/2016/011

d) Adoption of the MSC opinion

For discussion and adoption

6.2 Decision making process

d) Written procedure report on seeking agreement on draft decisions on substance evaluation

ECHA/MSC-46/2016/001
For information

e) Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CA's/ECHA reactions *(Session 1, open session)*
For discussion followed by agreement seeking under 6.2c:

ECHA/MSC-46/2016/002

MSC code	Substance name	EC number	Document
SEV-UK-039/2014	phenol, 4-nonyl-, branched	284-325-5	ECHA/MSC-46 /2016/003-004

For discussion

f) Seeking agreement on draft decisions when amendments were proposed by MS-CA's/ECHA *(Session 2, closed)*

Case as listed above under **6.2 b**

For agreement

g) General topics

- Appeals update[2]

For information

- Efficiency improvement proposals for SEv

For information and discussion

- Possible criteria for use of written procedures

ECHA/MSC-46/2016/014
For discussion

Item 7 – Dossier evaluation

Closed session for 7c
Indicative time plan for 7b is Day 1

a) Written procedure report on seeking agreement on draft decisions on dossier evaluation

ECHA/MSC-46/2016/005

[2] A combination of Appeal updates for Substance and Dossier Evaluation may be introduced, if appropriate.

For information

b) Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals after MS-CA reactions *(Session 1, open session)*

For discussion followed by agreement seeking under 7c:

ECHA/MSC-46/2016/006

Testing proposal examinations

MSC code	Substance name	EC / List No. / Document
TPE-154/2015	(3E)-2-chloro-3-(hydroxymethylene)-cyclohexene-1-carbaldehyde	801-656-8 ECHA/MSC-46/2016/007-008
TPE-158/2015	1,3-diphenylpropane-1,3-dione	204-398-9 ECHA/MSC-46/2016/009-010

For discussion

c) Seeking agreement on draft decisions on testing proposal examinations and compliance checks when amendments were proposed by MS-CA's *(Session 2, closed)*

Cases as listed above under **7b** and a case returned from written procedure for agreement seeking in the meeting:

TPE-162/2015[3]	2-imidazolidone	EC No. 204-436-4

For agreement

d) General topics

1) Choice of site of contact tissue for *in vivo* comet assay via oral route (presentation by ECHA)

ECHA/MSC-46/2016/015

For discussion

2) Appeals update[1]

For information

Item 8 – ECHA's recommendations of priority substances to be included in Annex XIV

- Presentation of the preliminary prioritisation results in preparation for ECHA's 8th draft recommendation

ECHA/MSC-46/2016/012

For information

Item 9 – Any other business

- Status update on EOGRT cases
- Report from PBT and Endocrine Disrupter Expert Group activities
- Report on the outcome of the Topical Scientific Workshop on Soil Risk assessment

For information

[3] Documents are available in MSC CIRCABC under substance specific folder (05. Dossier evaluation).

Item 10 – Adoption of main conclusions and action points

- Table with main conclusions and action points from MSC-46

For adoption

Information documents:

Information documents are not allocated a specific agenda time but the documents are available on MSC CIRCABC before the meeting. Based on the listed documents and the meeting agenda, if any MSC member considers that information documents may merit a discussion under any agenda point, they should inform MSC Secretariat

- *Substance evaluation status report (presentation slides)*
- *Dossier evaluation status report (presentation slides)*
- *Report from MSC work in 2015 (presentation slides)*
- *Preparing for authorisation applications – an industry association recommendation on LADs*

Outside plenary activities (tentatively after closure of Day 2 plenary):

- Presentation by ECHA entitled: *Nanomaterial identification and characterization under REACH.*

Main conclusions and action points
MSC-46, 2-4 February 2016
(adopted at MSC-46)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 – Administrative and procedural issues	
• Minority positions/opinions in context of MSC work MSC took note on the overview presented by the MSC-S on the established working practice for preparation and presentation of minority positions in the context of the MSC agreement seeking/opinion adoption. Members agreed that, where relevant, draft minority positions of MSC members including all the grounds for their minority views should be presented at the time of the MSC vote on a case, while the further editorial formulation, consultation and submission of the final minority position should be done in accordance with the deadline specified in the MSC plenary's Main conclusions & Action points document. Further, MSC decided on a standard deadline of 5 days for final editorial check and submission to the MSC-S of minority positions, where relevant. Pending on specific case conditions, an extended deadline may be specified in the relevant plenary's Main conclusions & Action points. MSC decided to keep unchanged the current working practice regarding the preparation and presentation of minority positions of MSC members.	**MSC-S** to take note of the newly set-up deadlines regarding the minority position finalisation and submission and to follow the established practice in this regard, as relevant.
Item 5 – Minutes of the MSC-45	
MSC adopted the draft minutes as modified at the meeting.	**MSC-S** to upload final version of the minutes on MSC S-CIRCABC by 4 February 2016 and on ECHA website without undue delay.
Item 6 – Substance evaluation ***6.1 Community Rolling Action Plan (CoRAP) & MSC opinion development*** **e) Discussion on the MSC opinion on the draft Community Rolling Action Plan (CoRAP) update** **f) *Adoption of the MSC opinion***	
MSC adopted by consensus the draft opinion and its Annex on the draft CoRAP update 2016-2018. MSC mandated MSC-S and the rapporteur to include further editorial changes in the opinion and its Annex as necessary and as already indicated during the	**MSC-S and Rapporteur** to review the agreed opinion and include further editorial changes by 10 February 2016. **MSC-S** to upload the MSC CoRAP Opinion including its Annex on MSC S-CIRCABC by 11 February 2016.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
presentation.	**SECR** to publish the opinion on the ECHA website together with the annual CoRAP update on 22 March 2016.
Item 6.2 - Substance evaluation - Decision making process **a) Written procedure report on seeking agreement on draft decisions on substance evaluation**	
MSC took note of the written procedure report.	**MSC-S** to upload on MSC S-CIRCABC the final ECHA decision agreed in written procedure.
b) Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CA's/ECHA reactions *(Session 1, open session)* **c) Seeking agreement on draft decisions when amendments were proposed by MS-CA's/ECHA *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decisions as modified in the meeting: **SEV-UK-039/2014** Phenol, 4-nonyl-, branched (EC No. 284-325-5) MSC mandated SECR and eMSCA to perform editorial changes in Section III of the decision including: 1. Reflection of the MSC's considerations so as to allow the registrant to clearly understand why the information requested in section 2 is needed 2. Restructuring the section so that it clearly follows the order in Section II using the reasoning agreed by the MSC. 3. Clarification of the text on follow-up actions discussed.	**SECR and eMSCA** to complete the decision as per the mandate given by MSC within 2 weeks. **MSC-S** to upload on MSC S-CIRCABC the final ECHA decision of the agreed case.
Item 6 - Substance evaluation **6.2 Decision making process** **d) General topics** • Efficiency improvement proposals for SEv • Possible criteria for use of written procedures	
MSC took note of the efficiency improvement proposals under MSC's control and suggested to try those with some suitable cases.	**MSC members** to provide feedback on the items and structure of the decision template to MSC FMB. **MSC members** and **StOs** to provide any additional suggestions on the criteria for the use on written procedure to FMB.
Item 7 – Dossier evaluation **a. Written procedure report on seeking agreement on draft decisions on dossier evaluation**	
MSC took note of the report.	**MSC-S** to upload on MSC S-CIRCABC the final ECHA decisions agreed in written procedure.
Item 7 – Dossier evaluation **b. Introduction to and preliminary discussion on draft decisions on testing proposals and compliance checks after MS-CA reactions *(Session 1, open session)***	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
c. Seeking agreement on draft decisions on a testing proposal examination and a compliance check when amendments were proposed by MS-CA's (Session 2, closed)	
MSC reached unanimous agreement on the following ECHA draft decisions (as modified in the meeting): **TPE-154/2015** (3E)-2-chloro-3-(hydroxymethylene)-cyclohexene-1-carbaldehyde (EC No. 801-656-8) **TPE-158/2015** 1,3-diphenylpropane-1,3-dione (EC No. 204-398-9) **TPE-162/2015** 2-imidazolidone (EC No. 204-436-4)	**MSC-S** to upload on MSC S-CIRCABC the final ECHA decisions of the agreed cases.
Item 7 – Dossier evaluation **d) General topics** Choice of site of contact tissue for *in vivo* comet assay via oral route (presentation by ECHA)	
MSC concluded to refine the approach on requesting comet assay, in particular to (i) prefer glandular stomach over forestomach; (ii) default analysis of two site-of-contact tissues (glandular stomach and duodenum/jejunum), in addition to liver; (iii) consider justifications of the Registrant to justify waiving or adapting analysis of any site-of-contact tissue; (iv) not include a request for fasting the animals before dosing.	**SECR** to discuss how to publicise the refined approach most effectively to registrants. **SECR** to apply this approach in Dossier evaluation**.**
Item 8 – ECHA's recommendations of priority substances to be included in Annex XIV	
Presentation of the preliminary prioritisation results in preparation for ECHA's 8th draft recommendation	
MSC took note of the results and the first observations presented.	**SECR** and **StOs** to consider how best to share the preliminary results externally so as to inform industry and to have updated registration information available by 1 August 2016 for the prioritisation purposes. **MSC** and **StOs** to flag any open topics related to prioritisation work if those should be discussed at MSC prior to the scheduled discussion in December 2016.
Item 9 – Any other business	
• Report from PBT and Endocrine Disrupter Expert Group activities	**MSC members** to provide comments on the list of long-term approach development issues of the PBT EG by 26 February 2016.
Item 10– Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-46 at the meeting.	**MSC-S** to submit draft minutes of MSC-46 for commenting by 2 March 2016. **MSC-S** to upload the main conclusions and action points on MSC S-CIRCABC by 5 February 2016.

V. Substance evaluation cases agreed in written procedure (WP):

MSC ID number	Substance name used in draft decision
SEV-DE-010/2014	Dimethyl disulphide

VI. Dossier evaluation cases agreed for MSC agreement seeking in written procedure (WP)

Draft decisions unanimously agreed by MSC in WP:

Compliance checks (CCH)

MSC ID number	Substance name used in draft decision	EC number
CCH-115/2015	Alcohols, C7-9-iso-, C8-rich	271-231-4

Testing proposal examinations (TPE)

MSC ID number	Substance name used in draft decision	EC number
TPE-160/2015	Ethylene bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]	251-073-2
TPE-161/2015	3-methylbutanone	209-264-3
TPE-171/2015	Tellurium dioxide	231-193-1
TPE-172/2015	Tert-butyl α,α-dimethylbenzyl peroxide	222-389-8

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