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30 January 1998

**UNICE'S "OZONE" SHADOW GROUP****RESPONSE TO SPECIFIC POINTS OF 29 OCTOBER 1997 LETTER OF  
MR ENTHOVEN (DIRECTOR GENERAL, DG XI)  
ON OZONE AIR QUALITY STANDARDS.****Point 1** (\*)***1<sup>st</sup> paragraph.***

*WHO in common with other organisations/experts identified additional hospital admissions as being a clear example of a consequence of elevated ozone concentrations. We believe that the effects which lead to such admissions should be considered as "serious".*

The key issue here is the relationship between exposure to ozone and hospital admissions. The available environmental epidemiological studies that link hospital admissions to "ozone" levels are of two types. Firstly, there are the "summer camp" studies, in which the quantification of personal exposure to ozone is typically very poor. Furthermore, exposure to ozone is confounded by co-exposure to other air pollutants, pollens, moulds etc. Secondly, there are the US and more recent APHEA studies which again are subject to confounding with unspecified co-pollutants and lack adequate quantification of ozone exposure. US EPA estimates of the relationship between exposure and admission rates (included in the 1997 Guideline) have recently been significantly revised downwards by WHO-EUR following analysis of data from the APHEA series, and these values appear in the latest draft of the Ozone Health Risk Assessment. This change, however, underlines the inherent uncertainty in these estimates (especially given that the APHEA studies themselves may be criticised on several counts). In summary the use of these studies to set ozone air quality objectives is highly questionable for the reasons outlined above.

Even if such studies are used then the number of admissions is small in relation to the population exposed. The most recent analysis by WHO-EUR estimates that the total number of hospital admissions across the EU-15 attributable to exposure to ozone at concentrations greater than 55 ppb ( $110 \mu\text{g}/\text{m}^3$ ) is 706 per annum. A total of some 3000 hospital admissions per annum are estimated to be attributable to exposure to ozone at concentrations of 30 ppb ( $60 \mu\text{g}/\text{m}^3$ ) and above.

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(\*) The italic text represents the annex to Mr Enthoven's letter of 29 October 1997 to Mr Tyszkiewicz

The number of hospitalisations that might be prevented at the WHO 60 ppb level compared with the US 80 ppb level would total some 400 cases, per year, across the whole of the European Union.

## **2<sup>nd</sup> paragraph**

*...There is considerable evidence that people show a wide range of sensitivity to ozone. Especially those already suffering from respiratory diseases as well as asthmatics are regarded to be at enhanced risk from ozone exposure.*

It is true that there is wide sensitivity in response to ozone. A key factor in determining the magnitude of response has been shown to be the level of exercise; intensive exercise leading to higher personal exposure leads to more significant adverse effects. However, there is no clear evidence that individuals with pre-existing respiratory disease are actually more susceptible to ozone than healthy individuals.

*...The existence of a no-effect level is questionable and in any case should such a threshold exist it is considerably below 120ppb.*

UNICE believes a No-Observed Adverse Effect Level (NOAEL) has not yet been defined because of uncertainties in the current database; this is also true for certain other air pollutants (e.g. PM<sub>10</sub>). This does not mean that there is no NOAEL - only that at present, the level has not been defined. It is also important to distinguish whether any effect is significant in technical terms.

*...It would not be credible for the Community to base its ozone abatement strategy on the attainment of levels which are widely regarded as provoking severe adverse health effects.*

UNICE believes that assertions regarding the risk of "severe adverse health effects" at exposures greater than 60 ppb (120 µg/m<sup>3</sup>) overstate what is known about the risks from ozone. For example, WHO (1997) indicate that exposure of "the most sensitive 10% of young adults and children" at a concentration of 80 ppb for 8 hours, with moderate exercise throughout, would result in only a 10% reduction in Forced Expiry Volume (FEV). This change is acknowledged to be the very lowest response that can be considered to be of any clinical concern.

## **Point 2**

*...Recent papers presented at the "1. Workshop on Photochemical Pollution in Southern Europe" held in March 1997 in Valencia showed striking examples of short-term visible damage especially on crops. There was a close correlation established between short-term peak ozone concentrations and damage immediately appearing within a couple of days. So, referring also to a recently published report by the "International Co-operative Programme - Crops Co-ordination Centre" there is actually rather clear evidence for visible damage attributable to ozone pollution.*

Where crops are concerned, UNICE believes that it is important to establish the economic consequences, not simply visual effects. Under conditions of high solar irradiance and sufficient water, crops will do well anyway (this is the danger of taking laboratory exposure results at more

than face value). In a proper cost-benefit analysis, provision of irrigation is likely to be much more effective at preventing economic loss than ozone reduction.

While visible crop damage may indeed be caused by exposure to high concentrations of ozone, the shape of the exposure-response curve is uncertain. The sensitivity of different crop species is known to vary considerably, whilst very few species have been studied in any detail. Confounding with other factors that can cause adverse effects, such as exposure to other pollutants, insects and diseases, makes isolation of the specific effects of ozone difficult. In addition, the effective yield may not be affected (especially if the marketed part of the plant is undamaged).

### **Point 3**

*It was clear from the Commission's discussion paper1 presented end of June and the following discussion, that neither the Commission nor any of the other participants in the ad-hoc working group proposed that WHO levels were to be taken as legally binding limit values for ozone.*

This is a clear admission of the unachievability of the WHO levels and the transboundary nature of ozone formation.. It is of concern to UNICE that although the WHO values are not to be legally binding, measures required to achieve the interim target will be. It would be more reasonable to base legally binding measures on an achievable target which bring tangible health and environmental benefits without disproportionate economic damage.

### ***2<sup>nd</sup> paragraph***

*...However, following the commitment of the 5<sup>th</sup> Environment Action Programme, values reflecting the WHO "critical levels" will be introduced in the daughter directive proposal as a long-term objective serving as basis for...*

WHO have clearly stated that their Guidelines are intended to provide background information and guidance to governments in making Risk Management decisions.

The use of the term "critical levels" is inaccurate in this context since it suggests the existence of firm thresholds between 'harmful' and 'harmless' exposures. This is misleading because of the uncertainties identified in relation to the exposure-response relationships, and further, the relationship of exceedance to AOT and adverse effects.

*...the assessment and monitoring requirements laid down in the Air Quality framework directive.*

The need to monitor environmental quality is independent of the level at which a standard/target is set and is not a justification for any particular value.

*...maintaining the current levels of the protection thresholds to be found in the present ozone directive and*

The present directive should not be taken as a good basis from which to continue since: firstly, it does not currently provide the claimed health protection since these levels are exceeded regularly. Secondly, it never included risk assessment, and did not include a cost-benefit study. Additionally, the question of appropriate risk management was not addressed. While ozone levels are falling in Europe it is important not to confuse wishes on paper with current reality. A future 90 ppb (180  $\mu\text{g}/\text{m}^3$ ) level, actually delivered, may offer better protection than a lower level which remains theoretical.

*...providing a strategic reference point for future policy.*

Although acceptable as a basis for discussion, the WHO level should not be taken as a reference point for long-term future policy since it might be subject to change by the WHO without reference to the EU. In short the EU would be abdicating policy-setting to WHO.

### ***3<sup>rd</sup> paragraph.***

*...Since the results of the analysis are not yet available the possible level for the target values have not yet been discussed in any of the working groups or expert groups.*

Regarding the interim target value and the extent to which it has been discussed, it can only be claimed that different degrees of compliance with AOT 60 (and 40) have been considered; as discussed later, there is no evidence in the discussion documents circulated so far of any work being done against 90 ppb (180  $\mu\text{g}/\text{m}^3$ ). It is quite clear that 60 ppb (120  $\mu\text{g}/\text{m}^3$ ) is being discussed as if it were the inevitable health standard.

We are concerned that the combination of a higher numerical limit value with higher percentile compliance, combined with public information, may be the most effective combination to protect human health, yet this approach is currently being overlooked. UNICE has raised this issue with experts from WHO-EUR, who indicated their interest in this possibility.

*...With regard to the use of WHO guidelines the Commission will continue to use these guidelines as a basis for all proposals on air quality.*

UNICE accepts that the WHO guidelines should be used as the basis for proposals to be debated with all parties, but to neglect the risk management step and not to consider other outcomes or new information is not a workable approach.

*...It is assumed that UNICE is not suggesting that the Community should follow WHO until 2000 and thereafter move to a lower level of protection as the basis for establishing levels of public health protection in the Community.*

UNICE is certainly not proposing a reduction in the level of protection after 2000. It must be emphasised that in the EU we do not meet the WHO number by a considerable margin at the moment, so reality must not be confused with theory. Due consideration must also be given to the reality of continually improving ozone levels in the EU region because of measures already in place, and those the EU is already committed to in the coming years.

#### **Point 4**

*...It should be noted that within the Auto-Oil Programme as an ozone standard not only 180  $\mu\text{g}/\text{m}^3$  (1h) but also 110  $\mu\text{g}/\text{m}^3$  as an 8h average was used. The latter is the protection threshold for human health used in the current ozone directive and is the same as the former WHO guideline value. Furthermore, the new 8h WHO guideline and the recent development in US show a shift from 1h to 8h based values when establishing standards for human health protection.*

The text of the report deals exclusively with the 180  $\mu\text{g}/\text{m}^3$  -1 hr standard and indicates that the WHO 120  $\mu\text{g}/\text{m}^3$  - 8 hr guideline was regarded as a sensitivity case because of the "recalcitrance" of the problem.

Clearly, the Auto/Oil partners have considered various standards as laid down in the Directive 92/72/EEC and the WHO-Europe guideline of 120  $\mu\text{g}/\text{m}^3$  (see table 4, page 14, of Auto/Oil report). However, most of the modelling work was done against the 180  $\mu\text{g}/\text{m}^3$  -1 hr standard and the 120  $\mu\text{g}/\text{m}^3$  -8 hr guideline (and not 110 as indicated above) (see table 5, page 16, of Auto/Oil report<sup>1</sup>). The Auto/Oil partners pragmatically focused on the 70 % ozone precursor emissions reduction scenario for the cost-effectiveness study (i.e. consistent with a 180  $\mu\text{g}/\text{m}^3$  -1 hr standard at 99 % compliance). If a 70 % reduction of ozone precursors vs. 1990 base case is selected, then EMEP modelling indicates that 180  $\mu\text{g}/\text{m}^3$  -1 hr standard will be met in 99 % of EU land area while the WHO 120  $\mu\text{g}/\text{m}^3$  - 8 hr guideline will be met only in 37 % of EU land area.

#### ***2<sup>nd</sup> paragraph***

*...Finally it should be stressed, that in countries like e.g. the UK (50ppb, 8h), Sweden (40 ppb -1hr), Switzerland, Japan (60ppb -1h) the standards used are obviously more stringent than 120  $\mu\text{g}/\text{m}^3$  currently proposed for the long-term objective.*

UNICE agrees that a few countries have selected more severe standards than the WHO-Europe guideline within the special frameworks of their own national approaches; this means compliance criteria vary hugely. Considering Japan with a standard of 60 ppb- 1 h , current level of compliance is around 1 (one) %. The UK has adopted a 97<sup>th</sup> percentile for compliance. UNICE hopes the Commission will demonstrate realism with respect to achievability and affordability of the future European standard.

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<sup>1</sup>Ref. : The European Auto/Oil programme, A Report by the European Commission's Directorate General for Industry, Energy and Environment, Civil Protection and Nuclear Safety of the, Green Cover; 66 pages; undated.

Furthermore, some individual countries are better placed than the EU to set tight limits owing to geographic and population density considerations. It is wrong to expect heavily populated hot regions to achieve the same ozone concentrations as less populated, northern regions.

### **Point 5**

*...With respect to the application of the precautionary principle and the objective in the 5<sup>th</sup> Action Programme we cannot agree with the notion that 180 µg/m<sup>3</sup> (1h) would provide an adequate public health protection level.*

UNICE believes that the weight of evidence shows that 180 µg/m<sup>3</sup> (90 ppb) for 1 hour or 160 µg/m<sup>3</sup> (80 ppb) for 8 hours is protective of human health, based on the available scientific information. Considering the substantial amount of knowledge available on the type of effects caused by ozone and the level at which these effects occur, it would be inappropriate to use the precautionary principle to justify a "zero" risk approach. In any event, the precautionary principle should not be applied in isolation, without due consideration of the other principles included in the Rio Declaration.

It is misleading to imply that an air quality target set at the level of 180 µg/m<sup>3</sup> means the public is exposed to 180 µg/m<sup>3</sup> more than a tiny fraction of the time. If we meet 180 µg/m<sup>3</sup> then most of the time ambient levels are well below 180 µg/m<sup>3</sup>. Furthermore, personal exposure is not the same as the ambient air concentration - indoor levels for example are much lower than outdoors.

UNICE considers that a lot is known about the health effects, if the effects are evident at all; they are mild below 180 µg/m<sup>3</sup> and certainly not a threat to health. Meeting a peak level of 180 for say 99% of the time in 99% of grid squares means that real life exposure even to 180 µg/m<sup>3</sup> is very limited indeed.

*...This threshold is used for informing the public according to the current ozone directive, in particular giving advice to sensitive groups of the population in order to reduce their own ozone exposure.*

Whilst this value is used for public information, the alert value of 240 µg/m<sup>3</sup> is surely the appropriate value which the wider general public should use to take action to avoid exposure.

### **Point 6**

*...The legislation mentioned here is either already adopted or projected. Consequently costs associated from its implementation are not directly related to the achievement of an ozone target value or an interim objective. The emission reductions achieved by current legislation or reduction plans will therefore not be part of the optimisation carried out in the cost-effectiveness analysis.*

UNICE believes that although the legislation mentioned is already adopted or projected, and is out of scope of the RAINS optimisation, the point remains that extremely high costs are foreseen for

these measures. Therefore, they must be given due weight in any consideration of cost effectiveness. Otherwise, the cost attributed to addressing ozone will be determined by the order of initiatives at the Commission and give a false impression of the overall economic impact.

UNICE wants to take part in a constructive dialogue aimed at making best use of society's economic resources for addressing air quality (but also a whole range of other environmental and social issues) - in this context it seems to be really very distorting to seek to ignore the costs of the projected measures. The currently projected cost burden inevitably affects society's ability to pay even more to make a further incremental improvement on this particular issue. We need to consider the projected costs of all the measures if the debate is to reach rational and balanced conclusions.

*...The first results of the analysis will be presented soon for discussion in the working group.*

The preliminary analysis which has already been circulated by DGXI in the draft chapter on Risk Assessment is based only on a target value of 60 (and 40) ppb. UNICE would welcome any sign of flexibility on this issue in such technical discussion documents to consider practically achievable target values e.g. 90 ppb. It is also very pertinent to note that the arguments in the risk assessment document are seriously flawed because they choose ways of calculating and assessing results which effectively hide the true cost of meeting a particular air quality target. They do this in the following ways:

RAINS optimises on an AOT60 statistic, and derives a cost for a series of reductions of AOT60 ignoring the worst years of meteorology and the hardest grid squares. This of course means that even if measures were taken which RAINS predicted would provide "compliance" there would be grid squares every year which failed. Furthermore, there would be years where many grid squares failed because meteorology was more extreme than the RAINS 'average' weather. These particular problems aside, the interim target is being discussed only in terms of exceedance-days. The non-linearity of the relationship between AOT60 and exceedance-days is not addressed at all. An AOT60 value of 1ppb.h (which everyone must surely accept is negligible) automatically gives rise to 1 days exceedance. A mere 2 ppb could give 2 exceedances-days and so on. This non-linearity exaggerates the problems of low AOT60 values; not only does it get rapidly more expensive to reduce AOT by a given amount, the same reduction in AOT yields a rapidly diminishing return in reduced exceedance-days.

Consequently, a given reduction in AOT60 will not give a proportionate benefit in the measure proposed in the draft chapter. If a 60% gap closure in terms of exceedance days is required then AOT60 will have to be reduced by considerably more, probably by 80-95%, bringing in many more expensive marginal measures.

### **Point 7**

*...Ozone levels on a large spatial scale due to natural sources are estimated to be not more than 20ppb. Pre-industrial levels which indicate the ozone production potential from natural sources were established at even lower levels. Furthermore presently*

*recorded background ozone concentrations due to factors outside Europe are between 30-35ppb and thus well below 60ppb. The stratospheric source for ground-level zone is estimated to be 15ppb with an annual minimum in summer and autumn parallel to the annual variation of stratospheric ozone. Because the vertical exchange between lower troposphere and higher troposphere/lower stratosphere is suppressed during anticyclonic weather conditions favourable for ozone production, the contribution of stratospheric ozone transport during ozone episodes is rather limited. Ozone intrusions from stratosphere occur mainly together with frontal weather systems (i.e. under cyclonic conditions) and commonly effect only elevated spots over a short time period.*

UNICE questions that, if average background ozone levels in Europe vary between 30 and 35 ppb according to the latest Eurotrac Report (vol. 10), why then does the EMEP Ozone model (and therefore RAINS) assume an average value for ozone of 45 ppb as the boundary condition at the lower troposphere and atmospheric boundary layer - a value which is assumed to be constant from 1990-2010. The suppression of all man-made emissions means that RAINS will predict 45 ppb in each grid square as a baseline, which is too close to 60 ppb to make any emissions reduction strategy based on it meaningful. If we accept 30-35 ppb background, EMEP and RAINS must assume this value as boundary condition at the atmospheric boundary layer and lower troposphere.

Furthermore, it is highly misleading to focus solely on averages, especially when all the health issues revolve around peaks; exceedances are not about average values, they are about the above average. The point is that the natural variability of ozone periodically causes 60 ppb -8hr to be exceeded sometimes. The fact that this can occur for, instance by a stratospheric intrusion, without human intervention also means that no measures can be taken to prevent it, so AOT 60 = 0 is *not humanly achievable*. Setting a more realistic target also has the added benefit of focusing much more on anthropogenic events. As described earlier, such a target could be 90 ppb -1hr, but if the Commission desired to retain 8-hour averaging then employing the US standard (based on 80 ppb - 8hr) would have broadly similar cost implications.

### **Point 8**

*...Referring to the intensive work done within the frame of UN-ECE it is justified to introduce a separate parameter (AOT40) for the protection of vegetation. It should be noted that it is also used in connection with the negotiations for a new multipollutant protocol within UN-ECE.*

UNICE understands that, within the above UN-ECE process, Member States views on the uncertainty of predicted adverse effects can be taken into account during the negotiations. The process for establishing an EU AQS must also take account of this uncertainty. It is acknowledged that the AOT 40 parameter represents only a "first order" approximation for predicting adverse environmental impacts (a single "Level 1" parameter that can be included in RAINS modelling). There are many reasons to believe that consideration of Europe-wide application of fixed exceedance of AOT 40 is not an efficient or cost-effective way to protect vegetation:

- the definition of exceedance is complicated by the need to include consideration of soil moisture, daylight and season;

- there are few plant species for which an adequate exposure-response relationship has been defined. The best database is available for wheat, which is acknowledged to be a very sensitive species;
- even for the better studied crop species, there is uncertainty about the degree and significance of confounding with air pollutants;
- tree protection is based on very limited data, with uncertain extrapolation to forest ecosystems;
- there is evidence that high background levels of ozone leads to the development of some "tolerance".

### **Point 9**

*...As pointed out under 3., the long term objective currently under discussion is associated neither with a strict attainment obligation nor with a relevant time period. It can already be anticipated that compliance with the long-term objective may not be possible everywhere in Europe within a time-period during which reliable emission projections can be made. Therefore a target value will be defined, serving as an interim objective which accounts for feasibility and cost factors.*

UNICE believes it is highly questionable to put forward a long-term strategic objective which cannot be achieved within any foreseeable time period. What is the value of such an approach, other than to create a straitjacket for future policy-making? It would appear to be far more pragmatic to set a realistic objective, based on sound scientific data which can be achieved within a given time period. Once this objective is achieved, further objectives can then be proposed as appropriate.

### **Conclusions**

*The new US standards and the new WHO guidelines indicate, that a human health standard should be expressed as an 8hr average. With regard to the 5<sup>th</sup> action programme 120 µg/m<sup>3</sup> (8h) seems the most appropriate choice for the long-term objective. An interim objective or target value, respectively, should be expressed as a certain percentile of the long-term objective, e.g. allowing a certain number of exceedances. It will be derived from the results of the integrated assessment analysis which takes fully into account the feasibility, costs and expected benefits.*

Whilst a 1 hour standard was used in the Auto-Oil programme, UNICE accepts that an 8 hour standard can also be used. 90 ppb, 1 hour is approximately equivalent to 80 ppb, 8 hours. The 5th Environmental Action Programme refers to WHO values; however WHO-EUR have clearly stated that their guidelines are intended to provide background information to governments in making risk-management decisions. Clearly, automatic adoption of WHO-EUR guidelines as air quality standards is not proposed by WHO-EUR.

UNICE believes that realistic objectives based on sound risk management and cost-benefit should be chosen, and then compliance should be expressed as a certain percentile of the objectives.

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